DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 410

[Docket No. 95–051P]

RIN 0583–AC72

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 130

[Docket No. 1995N–0294]

RIN 0910–AC54

Food Standards; General Principles and Food Standards Modernization

AGENCIES: Food Safety and Inspection Service, USDA; Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) (we, our, the agencies) are proposing to establish a set of general principles for food standards. The adherence to these principles will result in standards that will better promote honesty and fair dealing in the interest of consumers and protect the public, allow for technological advances in food production, be consistent with international food standards to the extent feasible, and be clear, simple, and easy to use for both manufacturers and the agencies that enforce compliance with the standards. The proposed general principles will establish the criteria that the agencies

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will use in considering whether a petition to establish, revise, or eliminate a food standard will be the basis for a proposed rule. In addition, each agency may propose to establish, revise, or eliminate a food standard on its own initiative or may propose revisions to a food standard in addition to those a petitioner has requested. These proposed general principles are the agencies' first step in instituting a process to modernize their standards of identity (and any accompanying standards of quality and fill of container) and standards of composition.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: *You may submit comments to FSIS, identified by Docket No. 95–051P, by any of the following methods:*

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions):

Send an original and two copies of comments to: FSIS Docket Clerk, Docket No. 95–051P, rm. 102, Cotton Annex Bldg., 300 12th St. SW., Washington, DC 20250–3700.

Instructions: All submissions received must include the agency name and Docket No. 95–051P or regulatory information number (RIN) 0583–AC72.

Other Information: All comments submitted in response to this proposal, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm.*

You may submit comments to FDA, identified by Docket No. 1995N–0294 and/or RIN 0910–AC54, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments.* Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov.* Include Docket No. 1995N–0294 and/or RIN 0910–AC54 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions): Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. 1995N–0294 or RIN 0910–AC54. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FSIS: Robert C. Post, Labeling and Consumer Protection Staff, rm. 602, Cotton Annex Bldg., 1400 Independence Ave. SW., Washington, DC 20250–3700, 202–205–0279.

FDA: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

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I. Background

FSIS and FDA share responsibility for ensuring that food labels are truthful and not misleading. FSIS has the authority to regulate the labeling of meat and poultry products, and FDA has the authority to regulate the labeling of all other foods. Some foods, such as eggs, are regulated by both agencies. Food standards are used to ensure that products sold under particular names have the characteristics expected by consumers.

A. FSIS Food Standards

Meat and poultry product standards of identity or composition are codified in title 9 of the Code of Federal Regulations (CFR). FSIS has established by regulation approximately 80 meat and poultry product standards of identity or composition (9 CFR parts 319 and 381, subpart P, for meat and poultry products, respectively) under its authorities in the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 607(c) and 457(b)). These sections provide:

The Secretary [of Agriculture], whenever he determines such action is necessary for the protection of the public, may prescribe * * * definitions and standards of identity or composition for articles subject to [the FMIA and PPIA] and standards of fill of container for such articles not inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act [act] (21 U.S.C. 301 *et seq.*) and there shall be consultation between the Secretary [of Agriculture] and the Secretary of Health and Human Services prior to the issuance of such standards under [the FMIA, PPIA, or act] relating to articles subject to this chapter to avoid inconsistency in such standards and possible impairment of the coordinated effective administration of [the FMIA, PPIA and the act]. There shall also be consultation

between the Secretary [of Agriculture] and an appropriate advisory committee provided for in [21 U.S.C. 454 and 661] prior to the issuance of such standards * * * to avoid, insofar as feasible, inconsistency between Federal and State standards.

Consistent with the statutes, FSIS has consulted with FDA regarding the proposed general principles. In addition, FSIS consulted with the National Advisory Committee on Meat and Poultry Inspection about this proposed rule in November 2001, and incorporated their comments in this document. FSIS's food standards regulations cover many different foods. The contents of individual food standards or groups of food standards are extremely varied, depending on the complexity of the food and the level of detail necessary to define the characterizing features of the food. Some food standards are relatively simple, consisting of only a sentence or two (e.g., beef stew, 9 CFR 319.304), or a paragraph or two (e.g., deviled ham, 9 CFR 319.760). Other food standards are extremely detailed and prescriptive. For example, the standard for frankfurter, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst and similar products describes the form of the product, the expected ingredients, and the allowable meat and nonmeat ingredients and poultry products that can be used in these products (9 CFR 319.180). There are more standards for meat products than for poultry products because processed meat products have been in existence longer and have been consumed more widely than processed poultry products. Although the FMIA and PPIA authorized standards of fill, FSIS has not established any standards of fill in regulations.

FSIS standards of identity generally require the presence of certain expected ingredients in a food product or mandate how a product is to be formulated or prepared. For example, a poultry product labeled "(kind) a la

Kiev" is required to be stuffed with butter, which may be seasoned (9 CFR 381.161). In the poultry products inspection regulations, the term "kind" refers to the type of poultry used. In this standard of identity, butter is an expected ingredient, and the standard also requires that the product be prepared by stuffing the butter in the poultry. The standard of identity for barbecued meats requires that barbecued meats be cooked by the direct action of dry heat resulting from the burning of hard wood or the hot coals therefrom for a sufficient period to assume the usual characteristics of a barbecued article, which include the formation of a brown crust on the surface and the rendering of surface fat (9 CFR 319.80). This standard of identity specifies exactly how the product must be prepared and also includes a description of the defining characteristics of products that meet the standard.

Standards of composition specify the minimum or maximum amount of ingredients in a product. Many of these standards for meat products establish a minimum amount of meat or a maximum amount of fat in the product. For example, the standards of composition for ground beef, chopped beef, hamburger, and fabricated steaks require that the product contain no more than 30 percent fat (9 CFR 319.15). Several of the poultry standards of composition specify minimum poultry levels and maximum added liquid levels. For example, canned boned poultry, labeled, "boned (kind)" must contain at least 90 percent cooked, deboned poultry meat of the kind indicated on the label, with skin, fat and seasoning, and may contain no more than 10 percent added liquid (9 CFR 381.157). The standards of composition for mechanically separated (species) (9 CFR 319.5) and mechanically separated (kind) (9 CFR 381.173) limit the amount and size of bone particles that the product may contain.

Some FSIS standards require that product be labeled with a specific name, such as "hamburger" (9 CFR 319.15(b)) or "(kind) patties" (9 CFR 381.160), while other standards provide examples of terms that can be used to label the products but do not prescribe the exact terms or phrases that must be used to label the product. For example, numerous phrases may be used in labeling fabricated steaks, including "beef steak, chopped, shaped, frozen," "minute steak, formed, wafer sliced, frozen," or "veal steaks, beef added, choppedmolded- cubed-frozen, hydrolyzed plant protein, and flavoring" (9 CFR 319.15(d)). Fabricated steaks also may be labeled with other terms not specified in the regulations.

In addition, some FSIS standards require specific label information. For example, Italian sausage products that are cooked must be labeled with the word "cooked" in the product name (9 CFR 319.145(c)), and cooked sausages, such as frankfurters, franks, furters, or hotdogs, that are prepared with meat from a single species of cattle, sheep, swine, or goats must be labeled with the term designating the particular species in conjunction with the generic name of the sausage (9 CFR 319.180(c)). The standard for poultry rolls requires that when binding agents are added in excess of 3 percent for cooked rolls and 2 percent for raw rolls, the common name of the agent or the term "binders added" must be included in the name of the product (9 CFR 381.159(a)).

Under FSIS's food standards regulations, products that do not conform to a standard may not represent themselves as the standardized food. However, such products still may be sold under another name. For example, a beef stew that contains less than 25 percent beef can be marketed as "gravy, vegetables, and beef" or "chunky beef soup," but can not be identified as "beef stew" because the food standard for meat stew requires that the product contain not

less than 25 percent of meat of the species named on the label (9 CFR 319.304). A product that does not meet the sausage standard (9 CFR 319.140) because it contains more than 10 percent of added water in the finished product may be marketed under another name, such as "pork, water, and soy protein concentrate link."

Finally, in addition to its food standards regulations, FSIS has established numerous informal or "policy" food standards for meat and poultry products in the FSIS "Food Standards and Labeling Policy Book" (Policy Book).

B. FDA Food Standards

FDA has established over 280 food standards of identity, some of which include standards of quality and fill of container, under the authority set forth in section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341). This section provides in part:

> Whenever in the judgment of the Secretary [of Health and Human Services] 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, or reasonable standards of fill of container.

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The standards of identity, quality, and fill of container for foods regulated by FDA are codified in title 21, parts 130 to 169 (21 CFR parts 131 to 169). FDA food 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). FDA food standards may specify minimum levels of the valuable constituents and maximum levels for fillers and water. They also may describe the manufacturing process when that process has a bearing on the identity of

the finished food. Finally, FDA food 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 FDA 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. For example, the standard of identity for fruit preserves and jams (§ 150.160 (21 CFR 150.160)) lists the minimum amount of fruit and sugar that these foods must contain. Other food standards focus on compositional characteristics of the food, rather than on the specific ingredients. For example, the standards of identity for milk products (part 131) list the minimum levels of milkfat and milk solids (excluding fat) that must be contained in these foods. Still other foods owe their distinctive characteristics to the manner in which they are produced, and the standards for these foods reflect this fact. For example, the standards of identity for cheese products (part 133) specify the manufacturing process, in addition to compositional characteristics, to distinguish one cheese from another. Some other foods are defined by their physical characteristics. For example, particle size is an important factor in distinguishing cracked wheat from crushed wheat, and the standards of identity for these foods (§ 137.190 and 137.195, respectively) include methods of analysis for the determination of the particle size of these foods. Depending on the level of detail necessary to define the characteristics of the food, some food standards

of identity consist of only a few paragraphs (e.g., sap sago cheese in § 133.186), while others are longer. For example, the canned tuna standard (§ 161.190) covers approximately eight pages in the CFR and prescribes the vegetables that must be used if the tuna is seasoned with vegetable broth.

FDA's food standards of quality set minimum specifications for such factors as tenderness, color, and freedom from defects for canned fruits and vegetables. 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 a can). FDA food 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.

In a manner similar to the FSIS food standard regulations, FDA's food standard regulations do not permit products that do not conform to a standard to be represented as the standardized food; such products, however, may be sold under other nonstandardized names. For example, a fruit product that does not meet the standard of identity for fruit preserves and jams (§ 150.160), because its fruit content is lower than the standard requires, may be marketed under another name, such as "fruit topping."

C. Advance Notices of Proposed Rulemaking

In 1995, FSIS and FDA began reviewing our regulatory procedures and requirements for food standards to determine whether food standards were still needed, and if so, whether they should be modified or streamlined. To initiate this review, we published advance notices of proposed rulemaking (ANPRMs) on food standards (60 FR 67492, December 29, 1995 (FDA), and 61 FR 47453, September 9, 1996 (FSIS)). These ANPRMs discussed regulations and policy

governing food standards, the history of food standards, and the possible need to revise the food standards.

In the ANPRMs, we identified problems with existing food standards. Specifically, we stated that some food standards might impede technological innovation in the food industry. FSIS stated that the existing food standards also may prevent the food industry from producing products that have lower amounts of constituents associated with negative health implications, such as fat, saturated fat, cholesterol, and sodium (61 FR 47453). FDA stated that manufacturers of nonstandardized foods are developing new ingredients and plant varieties to enhance a food's organoleptic or functional properties, alter its nutritional profile, or extend shelf life. Incorporation of these advances into standardized foods may be difficult without the laborious amendment of the relevant standard (60 FR 67492).

In the ANPRMs, FDA and FSIS presented alternatives to the existing food standards. The alternatives presented by FSIS included permitting the use of a lesser amount of meat or poultry in standardized products provided the product's label contained a declaration of the percentage of the meat or poultry content in the product; establishing a general standard of identity for standardized products that would provide for deviations from current ingredient allowances and restrictions (deviations would be highlighted in the ingredient statement on the product label); establishing categories of meat or poultry products and corresponding recommendations for expected meat and poultry contents; amending the statutes to allow private organizations to certify that food products meet consumer expectations; and revoking existing food standards and regulating all foods as nonstandardized foods (61 FR 47453).

The alternatives presented by FDA included revoking existing food standards and regulating all foods as nonstandardized foods; requiring that products declare the percentage of all major ingredients on the label; requiring that products declare the percentage of characterizing ingredients in the food name; identifying "parent" products with minimum compositional requirements (for example, creating a standard for jam or jelly that specifies minimum fruit content requirements) to avoid misleading use of percentage declaration on the food label; establishing generic food standards (such as the standards of identity for hard cheeses (§ 133.150) and spiced, flavored standardized cheeses (§ 133.193)); amending the statute to allow private organizations to certify that food products meet consumer expectations; and requiring appropriate labeling of foods that deviate from government quality standards (60 FR 67492).

In the ANPRMs, the agencies asked for comments on the benefits or lack of benefits of the food standards regulations in facilitating domestic and international commerce and on the benefits of the food standards regulations to consumers. We asked how the food standards could be revised to grant the flexibility necessary for timely development and marketing of products that meet consumer needs, while at the same time providing consumer protection. We also asked for comments on the alternatives to the food standards presented in the ANPRMs and whether to coordinate efforts to revise the food standards regulations.

D. Comments to the ANPRMs

FSIS received 28 letters, each containing one or more comments, from industry, consumers, a consumer group, and the U.S. Department of Agriculture (USDA) Food and Consumer Service (FCS) (now known as Food,

Nutrition, and Consumer Services) in response to its ANPRM. FDA received 95 letters, each containing 1 or more comments, from industry, consumers, consumer groups, and the USDA FCS in response to its ANPRM. Most comments to both ANPRMs strongly supported the concept of food standards, while a few requested that standards be eliminated. However, very few comments to both ANPRMs supported the existing food standards as currently written. The types of concerns expressed in the comments to the ANPRMs follow.

Many of the comments that supported retaining food standards stated that they protect consumers from fraudulent and substandard products by establishing the basis upon which similar products are formulated. Others argued that food standards ensure that products meet consumers' nutritional expectations and needs. Several comments from industry, a consumer, and two consumer groups stated that nutrition labeling and ingredient declarations cannot substitute for food standards, as reliance on nutrition labeling and ingredient declarations would be a burden to consumers.

Several industry comments that supported food standards also stated that the Federal food standards ensure a level playing field for industry because they provide direction to industry members producing standardized products. Several industry comments and one comment from the USDA FCS also stated that, in the absence of Federal food standards, the States would be able to establish their own food standards and manufacturers would be confronted with the challenge of meeting different States' requirements. In addition, many industry comments stated that the food standards provide a basis for negotiations related to the international harmonization of standards and facilitate international trade. One comment stated that, without a U.S. food

standards system, food standards development could shift to international bodies, which may not be sensitive to the American consumer or industry. Another comment stated that the absence of food standards could pose a barrier to exports and international markets.

Although most comments supported retaining food standards in some form, they requested that food standards be simplified, be made more flexible, or be clarified. For example, one industry comment stated that food standards should not include manufacturing methods, prohibitions regarding classes of ingredients, or product-specific labeling (other than the acceptable product name). This comment also stated that standardized and nonstandardized food product labeling should be the same. Similarly, other industry comments requested that the food standards be made more flexible to allow for alternative safe and suitable ingredients and alternative technologies that do not change the basic nature or basic characteristics of the food. Several industry comments recommended limiting food standards to the name of the product and the essential characterizing properties of the product. Several industry comments to FSIS's ANPRM recommended that food standards be limited to meat and poultry content requirements. Conversely, other industry comments to FSIS's ANPRM recommended that industry be given the flexibility to reduce the percentage of meat in standardized products.

Several industry comments and a consumer comment to FDA's ANPRM recommended that FDA revise certain specific food standards (e.g., jams, jellies, preserves, milk chocolate, and sweetened condensed milk) to provide more flexibility in food technology and ingredient options.

In response to FSIS's and FDA's requests for suggestions as to how they should revise food standards, several comments from industry and from a

consumer group recommended rescinding or modifying them on a case-by-case basis. Some comments from industry recommended instituting advisory committees, contracting with independent groups, or forming nongovernment groups to revise the food standards. Further, several industry comments recommended establishing general or "guiding" principles or a fundamental philosophy for reviewing food standards and revising them. Other industry comments and a consumer group suggested that revisions to standards should be initiated by petitions and supported by adequate data. Finally, several comments to both ANPRMs stated that FSIS and FDA food standards should be consistent, and that we should attempt to harmonize our efforts to revise the food standards.

Comments to FSIS's alternatives: Few comments supported the alternatives to food standards that FSIS presented in its ANPRM. A consumer organization was opposed to all of the alternatives presented in the ANPRM. Several trade groups specifically stated their opposition to percentage labeling. One of these groups stated that products would be cheapened if this alternative were allowed. The USDA FCS comment stated that percentage labeling had merit, but that this alternative does not address all the factors that might make a product inferior in quality. The USDA FCS comment-and several industry comments that generally opposed the other alternatives presented in the ANPRM-expressed support for the general standard alternative that would provide for deviations from current ingredient allowances and restrictions. These comments stated that this approach would allow consumers to discern differences between the standardized product and the modified version. One of these comments stated that this approach may not allow enough ingredient deviations in standardized products. Another of these comments stated that

a general standard's approach should expressly permit reduction of meat and poultry content in standardized products. Many of the industry comments opposed private certification that food products meet consumer expectations.

Comments to FDA's alternatives: Several comments opposed the alternatives presented in FDA's ANPRM. One trade association stated that percentage labeling was not an adequate substitute for standards. One industry comment stated that percentage labeling might be acceptable if it provided for the marketing of "heavily breaded shrimp" without requiring "imitation" labeling but that any other use of percentage labeling would be too cumbersome and could give away proprietary information. The USDA FCS comment stated that percentage labeling has merit but does not address all of the factors that could make a product inferior in quality. Another alternative that was presented in conjunction with percentage characterizing ingredient labeling was to identify a "parent" product, for example, a standardized jam or jelly that complies with minimum compositional requirements, to avoid misleading use of the percentage declaration on a food label. In response, one industry comment stated that this approach might be useful, but would not be adequate to replace all standards. Another industry comment stated that minimal compositional standards are necessary to provide a benchmark to ensure product integrity and to satisfy consumer expectations. Comments also opposed the alternative of extending the generic food standard concept (such as the existing standard of identity for hard cheeses (§ 133.150) or the generic standard for nutritionally modified versions of traditional standardized foods in § 130.10 (21 CFR 130.10)) to other classes of food standards. Two industry comments stated that generic food standards should not be used to create standards for nonstandardized foods, while another industry comment stated

that the current generic standards in § 130.10 were adequate. On the other hand, an industry comment stated that generic standards in addition to those covered in § 130.10 could be beneficial to maintain product characteristics. Similarly, the USDA FCS stated that the generic standards approach has merit. With regard to the alternative of requiring that foods that deviate from government quality standards be labeled appropriately, one comment stated that foods that deviate from standards should be named so that they are readily distinguishable from the standardized food. Another comment stated that current labeling requirements provide sufficient information concerning deviation from standards. While two industry comments supported private certification of foods that meet consumer expectations, most comments opposed this alternative.

E. Options in the Food Standards Modernization Process

As noted previously, several comments recommended that FDA and FSIS establish general principles or a fundamental philosophy for reviewing food standards and revising them. The agencies agree with these comments supporting the development of general principles for reviewing and revising food standards regulations and also agree with the comments that stated that the agencies should work in concert to develop consistent food standards regulations.

On September 12, 1996, FDA convened an internal agency task force to discuss the current and future role of food standards and to draft a set of principles for reviewing and revising FDA's food standards regulations. The task force agreed that the food standards should protect consumers without unduly inhibiting technological advances in food production and marketing.

To ensure that FSIS and FDA were consistent as the food standards reform process continued, in January 1997, a joint FDA and FSIS Food Standards Work Group (the Work Group) was convened, chaired by the Director of the FDA's former Office of Food Labeling (now incorporated into the Office of Nutritional Products, Labeling, and Dietary Supplements) and the Director of the FSIS Labeling and Compounds Review Division (now the Labeling and Consumer Protection Staff). The Work Group revised the principles that the FDA task force had developed to reflect the goals and needs of both agencies.

In addition to developing these general principles, the Work Group considered five options, as the next step in the process of food standards reform, and analyzed the advantages and disadvantages of each option. The first option the Work Group considered was not proceeding any further with the review of the food standards regulations. The advantage of this option is that, in the short run, it would require little or no increase in the agencies' use of resources.

A major disadvantage of this option is that there is very little industry or consumer support for it. As noted previously, the majority of comments supported revising the existing system of food standards to simplify them and to make them more flexible. In addition, even if this first option were adopted, we would need to continue to expend resources interpreting and enforcing food standards that may be outdated. Additionally, a system of food standards that does not allow technological advancement in food production may not be in the long-term interest of consumers. If we do not revise the food standards, FDA would need to continue to devote resources to temporary marketing permit (TMP) applications, which allow companies to sell products that deviate from established food standards while testing the marketplace for

consumer acceptance of the new product (§ 130.17), and both agencies would need to devote resources to keeping their respective standards systems functioning. In the long run, demands on each agency's resources would likely increase as technological and marketing advances conflict with the requirements in the existing food standards regulations. However, if food standards were revised to provide flexibility in manufacturing, the number of TMP applications would be reduced and agencies' resources conserved. Finally, not reviewing or revising food standards to ensure that they are current with international food standards, as appropriate, could create difficulties in international negotiations and trade.

The second option the Work Group considered was removing all food standards from the regulations and treating all foods as nonstandardized foods. One advantage of this option is that, in most cases, fewer agency resources would be required to eliminate food standards than to review and revise them. Also, under this option, we no longer would devote resources to responding to petitions requesting an amendment to an existing standard or the establishment of a new food standard.

As with the first option, however, very few comments on the ANPRMs supported eliminating food standards completely. We agree with the comments that stated that States might establish their own food standards in the absence of Federal food standards. For meat and poultry products, if there were no Federal standards, States with their own meat and poultry inspection programs could have State standards for meat and poultry products and these would only apply to products produced at establishments within the State that are distributed within the State. Such food standards for meat and poultry products could differ from State to State. For FDA-regulated food products,

if there were no Federal food standards, States would be free to create their own standards which might differ from each other, making compliance by manufacturers more difficult. Without Federal food standards, there would be no reference point for ensuring consistency of products for national commodity programs or feeding programs, such as the National School Lunch Program. In addition, as comments stated, without Federal food standards, the United States would have no reference point for negotiating international food standards, or facilitating international trade.

Another disadvantage of this option is the loss of enforcement efficiency. Without food standards, we would have to rely solely on the general adulteration and misbranding provisions of our statutes rather than upon the specified requirements of a food standard to determine if a product were economically adulterated (i.e., adulterated under § 402(b)(1)) or misbranded. This would likely require more enforcement resources than a food standards system would require.

The third option the Work Group considered was using our resources to review and revise food standards to make them internally consistent, more flexible for manufacturers and consumers, and easier to administer. The majority of comments supported this option and several provided specific suggestions concerning regulatory revisions. If we were to revise the food standards, we would ensure that the revisions reduced the burden on industry and ensured adequate protection of consumers. The disadvantage of this option is competing priorities would make it unlikely we could do this in a timely manner.

The fourth option the Work Group considered was to request external industry groups to review, revise, and administer the food standards (private

certification). This option would require little or no use of the agencies' resources. In addition, the revised food standards would provide the level of flexibility that industry desires. However, for private organizations to review, revise, and administer the food standards, the act, FMIA, and PPIA would have to be amended, so that these standards would have the force of law.

Although a few industry comments supported private certification of food standards, most comments to the ANPRMs opposed private certification. In addition, the Work Group determined that this option might not provide a mechanism for consumer input, unless required by legislation. Therefore, consumers' interests would not necessarily be reflected in the revised food standards, which might result in the standards failing to promote honesty and fair dealing in the interest of consumers or to protect the public. Also, food standards for which industry was unwilling to commit resources would not be revised. Under this option, there might be no mechanism for resolving conflict, should it arise, among industry segments, unless legislative changes provided such a mechanism. Furthermore, we determined that food standards established and maintained by industry would be voluntary, not mandatory, unless legislative changes authorized industry to establish and maintain the standards.

The fifth option the Work Group considered was to rely on external groups-consumer, industry, commodity, or other groups-to draft recommended revisions to existing Federal food standards but retain the agencies' authority to establish the final food standards. Under this option, we would continue to codify the food standards in our respective regulations. The external groups would use the general principles put forward by us to draft new food standards and would submit these in petitions. Similarly, external groups would use the

general principles to draft revised food standards or to propose eliminating existing food standards. We would review any petitions submitted to ensure that they were consistent with the general principles. Under this option, if we determined that a petition to establish, revise, or eliminate a standard was consistent with the general principles, and provided adequate data and support for the suggested change, we would more quickly propose and, when appropriate, finalize a new or revised and simplified standard or the elimination of a standard.

One major advantage of this option is that it would require the use of fewer of our agencies' resources than would be required if we were to review and propose amendments to the food standards without the benefit of petitions. In addition, this option allows for the participation of consumer groups and an opportunity for them to express interest through the petition process and through the submission of comments in response to proposed rules on new or revised food standards. Because we would have ultimate authority and jurisdiction over the final food standard established or eliminated, we would ensure that consumer interests were protected. Another advantage of this option is that it would rely largely on information from those groups that have the most interest in, and knowledge of, the particular food standards being considered for revision. These groups could draw on technical experts with knowledge of current production practices and marketing trends who could suggest which aspects of a specific standard are necessary to define the essential characteristics of a particular food. This approach would also likely result in consistent food standards because the general principles would govern all changes that are made to the standards.

The disadvantage to this fifth option is that, if a consumer, industry, or commodity group does not feel strongly about revising a particular group of food standards, we might not receive a petition and would then need to commit resources to reviewing the food standards without the benefit of a petition. However, comments to the ANPRMs and informal communications with external groups following publication of the ANPRMs indicate the willingness of consumer, industry, and commodity groups to submit for our consideration complete and thorough revisions for many food standards. In the event we do not receive a petition requesting that we revise, revoke, or establish a food standard, we, on our own initiative, may, when appropriate, propose to revise, revoke, or establish a standard.

For the reasons discussed previously, we have tentatively determined that the fifth option is the most appropriate course of action. The Work Group preliminarily determined that we could rely on external groups to suggest new food standards, revisions to existing food standards, or elimination of certain food standards that are consistent with the proposed general principles. The general principles approach would allow us to chart the basic course of food standards review and modernization. Moreover, it would allow consumer and industry groups to participate in the development of new and revised food standards and to identify food standards that should be eliminated. In addition, it would provide an opportunity for consumer and industry groups to submit data to support any claims made in petitions relating to consumer expectations or beliefs, and hence, protect consumer interests.

F. Consumer Research

To gain a preliminary understanding of current consumer attitudes toward Federal food standards of identity and the usefulness of food standards to

consumers, we funded a series of focus group discussions (FGDs) that were conducted by the Research Triangle Institute, North Carolina. A total of 64 household grocery shoppers were recruited to participate in 8 FGDs held, 2 each in 4 cities: Raleigh, NC; San Diego, CA; Philadelphia, PA; and St. Louis, MO. Male and female participants were selected to represent diversity in age, level of education, and race. The purpose of this research was to collect the following information on consumers: (1) Attitudes toward arguments for and against standards of identity regulations; (2) preferences for standards of identity regulations for different types of food products; (3) preferences for various types of requirements in standards of identity regulations; (4) preferences for possible alternatives to standards of identity regulations; and (5) attitudes towards the standards setting process and suggestions for improving it.

The FGDs revealed that the opinion of participants on standards of identity varied widely ranging from those who felt that such standards are always necessary to those who felt that such standards are never necessary. However, the FGDs did not generate sufficient data to explain the basis for these differences. The majority of participants at these FGDs supported the need for food standards to ensure product quality and protect consumers, and opined that food standards should not be eliminated. Some participants stated that standards were necessary to ensure that products are named and labeled appropriately, and that food standards would allow consumers to base purchase decisions simply on the name of the product. Some participants also stated that standards should be based on consumers' beliefs about minimum acceptable levels of product characteristics and were concerned that a lack of standards would lead to increased shopping time and costs associated with

trying different brands of a particular food to find one that meets their expectations. A majority of participants also indicated that food standards help ensure a certain degree of product uniformity.

However, some participants did not support the use of food standards. A few participants in the FGDs questioned the need for standards. With respect to quality provisions in standards, some participants stated that they prefer variety over a set standard quality of a food product; they also felt that some consumers might value the ability to choose a product of lower quality at a reduced price. These participants believed that standards were not necessary because consumer expectations of essential product characteristics and product quality can vary, and normal market forces, including the ability of a product to meet consumers' expectations, will determine whether it stays on the market. Therefore, they maintained that government oversight over product quality and uniformity was not needed. Some of these participants asserted that food standards do not serve consumers because they do not reflect the diversity of consumer expectations and beliefs, and restrict product choice and innovation.

In addition to being asked whether they support or oppose the need for food standards, participants were asked which food products or characteristics of food products it was most important to standardize and monitor. In response, participants stated that they considered food standards to be most necessary for foods with multiple, unrecognizable ingredients (e.g., cheeses or hot dogs) and least necessary for foods with a single, recognizable ingredient (e.g., milk or canned corn). Many participants identified requirements for the types and amounts of ingredients and the quality of a product as the most

important ones of a food standard, while the physical characteristics of a food were stated as least important.

Additionally, several participants suggested that we review food standards periodically and revise them as needed on a case-by-case basis to accommodate changes in consumer preferences and reflect advances in processing and ingredient technologies. Finally, participants expressed the need for FSIS and FDA to obtain input from consumers during the process of establishing and revising food standards so consumers' preferences and beliefs are accurately reflected in food standards (Refs. 1 and 2).

Overall, although the opinion of participants on standards of identity varied widely, some tentative conclusions can be drawn. Many participants found standards of identity to be valuable. Participants stated that having uniform product names for products with certain defined characteristics makes shopping easier. Many participants also felt that standards of identity help ensure a product has its expected characteristics. Most participants did not agree that standards hinder the variety of products available on the market. In general, participants felt that it was more important for standards to address characteristics that participants could not readily observe (such as ingredients in products with multiple, unrecognizable ingredients) rather than characteristics they could observe (such as appearance, size, or number). Participants also stated that standards of identity should be based on consumer beliefs and expectations about the product that are implied by a product's name and its minimum acceptable characteristics. In addition, participants believed that standards should be periodically revised to accommodate changes in consumer beliefs and technological advances. Most participants also expressed the desire for consumers to play a role in the development or

revision of standards and did not feel that the government should rely solely on input from industry. Although tentative, and drawn from the limited focus group research data that is available, these conclusions provide support for the general principles discussed in section II of this document.

II. The Proposed General Principles

We are proposing general principles for establishing new food standards and for revising or eliminating existing food standards. In the list of proposed general principles for both of our agencies, the first four state the purpose or function of a food standard, and the remaining principles state how the requirements of a food standard should be written and what should be incorporated, in general, in the standard. Although the general principles have been developed to be consistent between our two agencies, they are not identical. Because FSIS and FDA regulate different products, principles that are specific to a particular agency were developed to reflect that agency's regulatory needs and perspectives.

FSIS is proposing to establish 9 CFR 410.1(a) and FDA is proposing to amend 21 CFR 130.5(b) to include these new general principles. Under this proposed rule, the agencies will deny a petition to establish a food standard if the proposed food standard is not consistent with all of the general principles that apply to the proposed standard. The agencies recognize that not all of the general principles will be applicable to every food standard. The agencies will deny a petition to revise an existing standard if the proposed revision is inconsistent with any of the general principles that apply to the proposed revision. Under this proposed rule, when proposing a revision to a standard, petitioners will not be required to propose all the revisions that might be needed to modernize the entire existing standard. Rather, the

petitioner may propose only limited changes to existing standards, provided the proposed revisions are consistent with the general principles that apply to them.

The first four general principles state the purpose or function of a food standard. These principles are the most fundamental principles addressing consumer protection from an economic standpoint. Therefore, the agencies are proposing to deny a petition to eliminate a food standard if the petition does not demonstrate how the standard proposed to be eliminated is inconsistent with any one of the first four general principles. As stated in section I.B of this document, the act explicitly states that regulations establishing food standards of identity shall be issued when such action will "promote honesty and fair dealing in the interest of consumers" (21 U.S.C. 341). In addition, as stated in section I.A of this document, the FMIA and PPIA require that standards of identity or composition established under these acts be consistent with standards of identity, quality, or fill of container established under the act. Also, as stated previously, the FMIA and PPIA authorize the Secretary of Agriculture, after consultation with the Secretary of Health and Human Services, to prescribe definitions and standards of identity or composition for meat and poultry products whenever he or she determines that such action is necessary for the protection of the public. Therefore, all of the general principles set forth in this proposal have been designed to achieve the goals of promoting honesty and fair dealing in the interest of consumers and protecting the public. This is further explained as each individual or group of general principles is discussed below. Consistent with section 401 of the act, section 457(b) of the PPIA, and section 607(c) of the FMIA, the first four proposed general principles primarily address consumer protection from an

economic standpoint. These first four principles are consistent with the findings of the focus group studies where a majority of participants maintained that food standards are needed to ensure product quality and uniformity and to protect consumers from economic deception. The first general principle listed under proposed 9 CFR 410.1(a)(1) and 21 CFR 130.5(b)(1) makes it explicit that FSIS' purpose for a food standard is to protect the public and FDA's is to promote honesty and fair dealing in the interest of consumers. Food standards would provide a system by which consumer interests are protected and consumer expectations of a food are met. Historically, food standards have been beneficial because they provide assurance to consumers of product uniformity with respect to certain significant characteristics of standardized foods, resulting in the expectation and belief of consumers that all products bearing a particular name will possess the same essential characteristics, irrespective of where they are purchased, or by whom they are manufactured or distributed. Thus, to ensure that consumers are not misled by the name of the food, to meet consumers' expectations of product characteristics and uniformity, and, in turn, to promote honesty and fair dealing in the interest of consumers and to protect the public, a food standard should, as stated in proposed 9 CFR 410.1(a)(2) and 21 CFR 130.5(b)(2), describe the basic nature of the food. The basic nature of the food is directly related to consumer expectations and beliefs about the food.

Also, to promote honesty and fair dealing in the interest of consumers and to protect the public, proposed 9 CFR 410.1(a)(3) and 21 CFR 130.5(b)(3) would state that the food standard should reflect the essential characteristics of the food. While the basic nature of a food is directly related to consumer expectations and beliefs about the food, the essential characteristics are the

attributes of a food that make the food what it is even though they may not be readily apparent to the consumer. The essential characteristics of a food are those that define or distinguish a food or describe the distinctive properties of a food. Further, the essential characteristics of a food may contribute to achieving the basic nature of the food or may reflect relevant consumer expectations of a food product. Foods may be defined or distinguished by their ingredients, compositional characteristics, physical characteristics, levels of certain nutrients, or the manner in which they are produced—all of which are the essential characteristics of a food. For example, the essential characteristics of a hotdog include a certain fat and moisture content, and the use of water or ice to form an emulsion, whereas the basic nature of a hotdog is that it is a comminuted, semisolid sausage prepared from one or more kinds of raw skeletal muscle meat and/or cooked poultry meat. Similarly, the essential characteristics of a particular type of cheese may include the bacterial culture used, the processing method, and the fat and moisture content that contribute to the unique characteristics of that cheese and the basic nature of that cheese is that it is a milk-derived food of a certain form and consistency. Likewise, the essential characteristics of wheat flour include granulation requirements (the percentage of flour that has to pass through a certain sieve size), its moisture content, and its ash content, whereas the basic nature of wheat flour is that it is a ground product of cleaned wheat grain. Therefore, although the essential characteristics of a food may contribute to achieving the basic nature of that food or may be relevant to meeting certain consumer expectations about the food, they differ from the basic nature of the food in that consumers may not be aware of the essential characteristics that make the food what it is.

Preserving the basic nature and essential characteristics of a food would promote honesty and fair dealing in the interest of consumers and protect the public by ensuring that consumer expectations of the economic and nutritional value of a food are met. Historically, food standards have been adopted to protect consumers of traditional foods from deceptive, inferior quality products of lesser economic value. Current food standards ensure the economic value of a food. For example, the standards of identity for cheeses (part 133) specify milk solids or milkfat content requirements to prevent the substitution of less valuable ingredients for more valuable ingredients.

In addition to ensuring the economic value of a food, FDA food standards, on occasion, also may serve to ensure the nutritional quality of a food by imposing requirements in addition to the labeling requirements in part 101 (21 CFR part 101). For example, the requirements for mandatory addition of vitamin D to evaporated milk and of vitamin A to margarine are specified within the standards of identity for these foods (§§ 131.130 and 166.110, respectively). These nutritional requirements are an integral part of the standards of identity of these two foods and are not regulated under FDA's other nutritional quality provisions, such as its nutrient content claims regulations (part 101). The use of food standards as vehicles to improve the nutritional quality of the food supply has always been based on documented public health need and substantiated with sound science to ensure that, within the context of the total diet, the food is suitable for its intended use with reasonable assurance of effectiveness and safety in achieving the nutritional goals. FDA will continue to apply this standard for any future use of standardized foods or any other food as a vehicle to improve the nutritional quality of the food supply.

Numerous FSIS standards specify the minimum amounts of meat and poultry and maximum amounts of fat or other ingredients a product may contain. These provisions ensure both the economic value and nutritional quality of standard meat and poultry products.

Therefore, proposed 9 CFR 410.1(a)(4) and 21 CFR 130.5(b)(4) state that the food standard should ensure that the food does not appear to be better or of a greater value than it is. Additionally, the food standard may be used as a vehicle to improve the overall nutritional quality of the food supply.

In addition to protecting the consumer, the next three proposed general principles would promote clear and straightforward requirements for food manufacturers. They would also promote, to the extent feasible, flexibility in food technology.

Regulatory requirements written in plain and simple language facilitate the manufacture of foods that comply with the regulations and, thereby, help reduce manufacturers' costs of compliance and government costs of enforcement. Lowered costs of producing foods that meet the standards may potentially benefit consumers in the form of lowered prices of products in the marketplace. Therefore, proposed 9 CFR 410.1(a)(5) and 21 CFR 130.5(b)(5) state that the food standard should contain clear and easily understood requirements to facilitate compliance by food manufacturers.

Establishing regulations that do not stifle innovations in food technology and allow for technological alternatives and advancements in food processing would improve manufacturing efficiency and lessen costs which may be passed on to the consumer. Improved technologies may additionally benefit product quality and diversity. Increased diversity in, and potentially lower costs of, food products in the marketplace that continue to meet consumer

expectations would promote honesty and fair dealing in the interest of consumers and protect the public. Therefore, proposed 9 CFR 410.1(a)(6) and 21 CFR 130.5(b)(6) provide that the food standard should permit maximum flexibility in the food technology used to prepare the standardized food, so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality, or safety of the food. In addition, these provisions would state that the food standard should provide for any suitable, alternative manufacturing process that accomplishes the desired effect and should describe ingredients as broadly and generically as feasible.

We are proposing the provision concerning flexibility in food technology to ensure that any requirement of a standard accomplishes its purpose without impeding technological advances that are not in conflict with the intent of the requirement. For example, in FSIS's current regulations, the standard for barbecued meats requires that products such as "beef barbecue" or "barbecued pork" be cooked by the direct action of dry heat (9 CFR 319.80). However, there may be other cooking methods that result in the same product characteristics that the direct action of dry heat achieves, such as infrared heating. During FGDs, consumers expressed the need to revise food standards to reflect current advances in food manufacturing technology, and we believe that this general principle provides an avenue to keep food standards current with technological advances.

In addition to addressing flexibility in food technology, proposed 9 CFR 410.1(a)(6) and 21 CFR 130.5(b)(6) would also state that the food standard should provide for any suitable, alternative manufacturing process that accomplishes the desired effect and should describe ingredients as broadly and

generically as possible. Examples of standards that would permit flexibility in manufacturing processes would be those that provided for any suitable procedure for removing glucose from dried eggs, for instantizing flours, or for low-temperature rendering of meat. We proposed that any food standard that includes a specific manufacturing process should allow for alternative procedures. If the manufacturing process specified in a food standard is essential to the character of the food, the food standard should allow for the use of any alternative procedure that yields a product with the same physical, nutritional, and sensory characteristics as the food made according to the traditional procedure specified in existing food standards.

To allow for flexibility in ingredients used to formulate standardized products, the ingredients for frozen raw breaded shrimp, for example, might be described to be "batter and breading ingredients" (§ 161.175) and those in frankfurters, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products might be described to be "byproducts and variety meats" (9 CFR 319.180). If it is necessary to specify ingredients, the standard should specify these ingredients by functional use category, e.g., "stabilizers and thickeners" or "texturizers," rather than by listing specific ingredients. Also, where appropriate, in accordance with current regulations, the specific levels of ingredients that can be used may be modified if they reflect safe and suitable levels or those levels that reflect good manufacturing practices.

The general principles would also promote uniformity between Federal food standards and any international standards for the same food. With the rising trend in globalization and increased accessibility of U.S. goods to other nations' markets, efforts to harmonize U.S. food standards with international

food standards will facilitate international trade and foster competition. These efforts may also result in lowered costs and the increased diversity of the food supply, which in turn would benefit consumers. Therefore, we are proposing harmonization of U.S. standards with international food standards to the extent feasible, while preserving the integrity, quality, and economic value that U.S. consumers expect of the food. Proposed 9 CFR 410.1(a)(7) and 21 CFR 130.5(b)(7) state that the food standard should be harmonized with international food standards to the extent feasible. If a food standard presented in a petition is different from the requirements in a Codex standard for the same food, we are proposing that the petition should specify the reasons for these differences. This principle is consistent with FDA's existing regulation, 21 CFR 130.6, which states that food standards adopted by the Codex Alimentarius Commission will be reviewed by FDA, and either will be accepted (with or without change) or will not be accepted. This regulation also states that petitioners who petition FDA for a new or amended food standard based on the relevant Codex food standard shall specify any deviations in the requested standard from those in the Codex standard and the reasons for any such deviations.

The next six proposed general principles promote simplicity, brevity, and consistency in food standards. Providing regulatory requirements that are simply and concisely stated and are consistent among different foods would help improve efficiency and reduce the costs of compliance by industry, as well as reduce enforcement costs by regulatory agencies. Increased industry efficiency may also result in lowered costs of food products. Unnecessary details and requirements in a food standard not only burden enforcement and compliance efforts but also limit manufacturing options and create

inefficiencies. Therefore, proposed 9 CFR 410.1(a)(8) and 21 CFR 130.5(b)(8) state that the food standard provisions should be simple, easy to use, and consistent among all food standards. This proposed principle also states that food standards should include only those elements that are necessary to define the basic nature and essential characteristics of a particular food, and that any unnecessary details should be eliminated. As noted in section I.B of this document, the existing FDA food standards vary widely in their content and level of detail. In this principle, we are proposing to make it clear that simplicity in, and consistency among, food standards is essential. This proposed principle makes it clear that any unnecessary details, such as details related to manufacturing processes, ingredients, or variations of different forms of the same food that are not necessary to define the basic nature and essential characteristics of a food, should be eliminated from the standards regulations. For example, in the FSIS food standards, the list of curing ingredients in the corned beef hash standard (9 CFR 319.303(a)(3)) is an unnecessary detail because curing agents permitted in meat products are listed in 9 CFR chapter III, subchapter E or in 21 CFR chapter I, subchapter A or B. Also, in addition to the standard for corned beef hash, the FSIS regulations contain a standard for hash (9 CFR 319.302). It may not be necessary to have separate standards for different forms of hash. An example of unnecessary detail in FDA food standards may be the provision for nutritive carbohydrate sweeteners in the standard for "yogurt" (§ 131.200), "lowfat yogurt" (§ 131.203), and "nonfat yogurt" (§ 131.206), which lists several sweeteners, because nutritive sweeteners have been defined in § 170.3(o)(21) (21 CFR 170.3(o)(21)). This provision could be incorporated by simply using the functional category "nutritive carbohydrate sweeteners" without listing the different sweeteners.

This general principle is consistent with the findings of FGDs where participants expressed the belief that certain characteristics of a food, such as its type and amount of ingredients, are the more important elements of a food standard than certain other characteristics of a food.

Proposed sections 9 CFR 410.1(a)(9) and 21 CFR 130.5(b)(9) state that the food standard should allow for variations in the physical attributes of the food. Also, this proposed principle states that where it is necessary to provide for specific variations in the physical attributes of a food within the food standard, the variations should be consolidated into a single food standard. Thus, this provision would promote simplification of food standards. For example, it is necessary to provide for specific variations of cereal flours (e.g., flour, bromated flour, instantized flour, and phosphated flour (21 CFR part 137)). According to this proposed principle, the variations for these standards should be consolidated into a single food standard. Similarly, existing provisions in FSIS's food standards for different forms of ham (e.g., chopped, ground, flaked, chipped, and pressed for cured ham products ("ham patties," "chopped ham," "pressed ham," "spiced ham," and similar products (9 CFR 319.105) and "deviled ham" (9 CFR 319.760))) could be simplified or consolidated. In order to promote food standards that are simple and consistent, proposed 9 CFR 410.1(a)(10) and 21 CFR 130.5(b)(10) state that, whenever possible, general requirements that pertain to multiple food standards of a commodity group should be incorporated into general regulatory provisions that address the commodity group. For example, enrichment requirements for cereal flours and related products might be codified in a new subpart A of part 137 entitled "General Provisions." Further, the methods of analysis relevant to different foods within the same commodity group might be codified under the general

provisions for that commodity group. Additionally, the curing requirements common to cured beef products could be codified in a new section at the beginning of 9 CFR part 319, subpart D. When provisions are of a general nature and affect more than one commodity group, we would consider codifying these requirements all together in an appropriate CFR section. For example, some fill of container requirements are codified in 21 CFR part 100, subpart F ("Misbranding for Reasons Other Than Labeling") and apply to a wide array of products. Likewise, § 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term permits the modification of a standardized food to achieve a nutrition goal, such as a reduction in fat or calories. Such modified foods may be named by the use of a nutrient content claim, such as "reduced fat" and a standardized term, such as "cheddar cheese" (i.e., reduced fat cheddar cheese). To further promote consistency among food standards, proposed 9 CFR 410.1(a)(11) states that any proposed new or revised food standard should take into account whether there are FSIS labeling regulations or ingredient regulations that are affected by, or that cover, the new or revised food standard. FSIS is proposing this principle so that any requirements of the standards are consistent with other regulatory requirements. Similarly, proposed § 130.5(b)(11) states that any proposed new or revised FDA food standard should take into account any other relevant regulations. For example, a proposed new or revised food standard should be consistent with common or usual name regulations for related commodities or products. FDA is proposing this general principle to encourage the grouping of similar food products when changes to food standards are addressed, so that there is a consistent approach to establishing, revising, and eliminating food standards in the regulations.

Separately from FSIS, FDA is further proposing within this general principle (§ 130.5(b)(11)) that any specific requirements for foods intended for further manufacturing should be incorporated within the reference food standard rather than being established as a separate food standard. FDA believes that any specific and important requirements for foods that are to be manufactured further could be incorporated within the standard for its particular reference food, and, therefore, existing FDA standards for foods-for-further manufacturing should be considered for elimination and incorporation within the appropriate reference food standard. For example, important elements of the requirements stated in the FDA food standard for cocoa with dioctyl sodium sulfosuccinate for manufacturing (21 CFR 163.117) could be incorporated as a separate paragraph within the standard for its reference food (i.e., cocoa). Similarly, the requirements stated in the FDA food standard, cheddar cheese for manufacturing (§ 133.114), could be incorporated into the food standard for cheddar cheese. This proposed principle also applies to FDA food standards where the differences between a standardized food and the same food-for-further-manufacturing are minimized by processes used to make a finished food from the food-for-further-manufacturing. Because FSIS does not have standards for foods-for-further-manufacturing, there is no parallel provision in FSIS's proposed general principle, 9 CFR 410.1(a)(11). Proposed 9 CFR 410.1(a)(12) and 21 CFR 130.5(b)(12) state that food standards should provide the terms that can be used to name a food and should allow such terms to be used in any order that is not misleading to consumers.

Thus, under this proposed principle, the food standard should provide the terms that can be used to name a food and should provide that such terms can be used in any order that is not misleading, rather than list every possible

combination of terms that may be used to name a standardized food (e.g., the nomenclature in the current FDA standard of identity for wheat and soy macaroni product (21 CFR 139.140) and the FSIS standard for braunschweiger and liver sausage or liverwurst (9 CFR 319.182)).

Proposed 9 CFR 410.1(a)(13) and 21 CFR 130.5(b)(13) state that the names of ingredients and functional use categories in a food standard should be consistent with other food standards and relevant regulations and, when appropriate, incorporate current scientific nomenclature. Functional use categories include, but are not limited to, emulsifiers, sweeteners, antioxidants, stabilizers and thickeners, and texturizers. We are proposing these provisions because some discrepancies exist in the designated name of ingredients and the designated name of functional use categories in different food standards written at different times. For example, the standards for artificially sweetened canned fruits in 21 CFR part 145, for frozen concentrate for artificially sweetened lemonade in § 146.121 (21 CFR 146.121), and for artificially sweetened fruit jams, preserves, and jellies in part 150 are not consistent in the designated names of artificial sweeteners permitted. Another example is the use of the terms "thickening ingredient" in the standard for frozen concentrate for artificially sweetened lemonade in § 146.121 and "bulking agents" in the standards for cocoa or sweet and milk chocolates and vegetable fat coatings in 21 CFR part 163. Although these ingredients are designated using different terms, both of them fall into the functional category "stabilizers and thickeners" as described in § 170.3(o)(28). The food ingredients regulations in 21 CFR chapter I, subchapters A and B and in 9 CFR part 424 have specific names for different ingredients and functional use categories, which should be incorporated into the revised food standards.

To ensure that it is as easy as possible to monitor compliance with food standards, FSIS is proposing 9 CFR 410.1(a)(14), which states that the food standard should be based on the finished product. FSIS can most easily assess the compliance with a food standard when it is based on the finished product. For example, FSIS could verify that chicken tetrazzini is comprised of 15 percent chicken by weighing the poultry in the finished product (9 CFR 381.167). Some of the existing FSIS food standards are based on products as they are formulated for processing, such as when the ingredients are assembled for cooking. For example, the standard for meat stews requires that stews such as "beef stew" or "lamb stew" shall contain not less than 25 percent of meat of the species named on the label, computed on the weight of the fresh (that is, uncooked) meat (9 CFR 319.304). Therefore, to assess compliance with the standard, FSIS needs to observe the product's formulation or it needs to review relevant establishment records. In these cases, FSIS has traditionally monitored compliance at the point of formulation, while it is being assembled for cooking. FSIS is considering doing more of its consumer protection monitoring on a finished product basis, which would include in-distribution monitoring for compliance with standards.

FSIS believes that monitoring compliance with standards based on an analysis of the finished product would protect the public because consumers purchase products once they are finished, not at the point of formulation. By enforcing standards for finished products, FSIS could better ensure that products meet consumer expectations. In addition, enforcing standards for finished products would reduce compliance costs for FSIS, because monitoring for compliance when a product is in-distribution requires less staff time and

is, therefore, less expensive for FSIS than monitoring compliance at the point of product formulation.

FSIS requests comment on how it should determine the compliance of a food with a standard based on the finished product. FSIS is interested in verification methods that can be used when the product is no longer in the plant. Any such verification methods will have to be able to measure the important characteristics of the finished product.

Although FDA food standards establish certain requirements about the product formulation, such as the ingredients or types of ingredients permitted in the manufacturing of a food, the essential characteristics of the food are based on the finished product, rather than at the point of formulation or at intermediate stages during manufacturing. Therefore, FDA does not believe there is a need for a parallel provision for this principle in the proposed FDA food standards principles.

FSIS is also proposing 9 CFR 410.1(a)(15), which states that the food standard should identify whether the product is ready-to-eat or not ready-to-eat. FSIS is proposing this principle to ensure that manufacturer, consumer, and agency expectations for the product are the same. The existing FSIS food standards do not specifically require the food conforming to the standard to be ready-to-eat or not ready-to-eat. As part of its consumer focus group research, FSIS is asking whether this information should be required to appear on the label of the standardized food. FSIS believes that whether a product is ready-to-eat or not ready-to-eat is part of the basic nature of the food.

Therefore, this proposed principle would protect the public by ensuring that standardized products meet consumer expectations. Due to the basic nature of standardized foods regulated by FDA, FDA does not believe that there

is a need for FDA food standards to address whether the food is ready to eat or not. Therefore, there is no parallel provision for this principle in the proposed FDA food standards principles.

In proposed 9 CFR 410.1(b), FSIS is proposing that a petition to establish a new food standard should include a comprehensive statement that explains how the proposed new standard conforms to the general principles that apply to the new standard. In addition, FSIS is proposing that a petition to revise an existing food standard should include a comprehensive statement that explains how the proposed revision to the existing standard conforms to the general principles that apply to the proposed revision. Also in proposed 9 CFR 410.1(b), FSIS is proposing that a petition to eliminate an existing standard should include a comprehensive statement that explains how the standard proposed to be eliminated does not conform to any one of the first four general principles. Similarly, in proposed § 130.5(c), FDA is proposing that, for petitions to FDA, this comprehensive statement should be provided as part of the "Statement of Grounds" currently required in a FDA citizen petition under 21 CFR 10.30.

The agencies are proposing that any revision to a food standard proposed in a petition to revise an existing food standard must be consistent with all of the general principles that apply to it. Therefore, according to this proposed rule, petitioners could consider proposing limited changes to existing standards. However, we recommend that petitioners consider all of the general principles and suggest appropriate changes to an existing standard that make that entire standard consistent with all of the general principles that apply to that standard.

If a petitioner proposes a revision that is consistent with the general principles that apply to the proposed revision but the revision does not include all of the changes that are needed to modernize the entire standard, the relevant agency will review the entire existing standard in light of all of the general principles to determine whether revisions in addition to those that the petitioner has requested are necessary to modernize the food standard. This process will ensure that there is a complete and thorough review of the food standard to address all relevant issues and incorporate all necessary revisions to the standard at one time, rather than through multiple rulemakings. Although we would not deny a petition solely because it proposed only limited changes to a standard, provided the proposed changes are consistent with the general principles that apply to them, it is likely that we would more quickly publish a proposed and final rule revising the standard, in response to a petition, if a petitioner has considered an entire existing standard in light of all the applicable general principles.

Finally, under proposed 9 CFR 410.1(c) and 21 CFR 130.5(d), we are proposing that petitions seeking to establish or revise a food standard that is not consistent with the applicable general principles will be denied. In addition, we are proposing that petitions seeking to eliminate a food standard that do not demonstrate that the food standard is inconsistent with any one of the first four general principles will be denied. The petitioner would be notified of the reason for the denial.

We would encourage organizations or individuals submitting petitions to establish, revise, or eliminate a food standard, under these proposed regulations, to confer with different interest groups (consumers, industry, the academic community, professional organizations, and others) in formulating

them. We would recommend that petitioners seek out and document the support of consumers and industry for any recommended changes to the standards regulations to encourage communication with interested groups and to ensure broad support for any proposed standards. Petitioners could document consumer and industry support by including the written concurrence of representatives of various consumer and industry groups in the petitions submitted. Additionally, petitioners could include a statement of any meetings and discussions that have been held with interest groups. Appropriate weight would be given to petitions that reflect a consensus of different interest groups.

However, under the present regulations, documentation of the support of interest groups would not be an acceptable substitute for the information or data that is needed to substantiate statements and claims made in the petition. Thus, petitions that make claims about consumer expectations or beliefs for the purposes of defining the basic nature and essential characteristics of a food should also provide information or data that substantiate those claims. Marketing data, food formulary compilations, studies of restaurant menus, and consumer survey and focus group research data are potentially acceptable data sources to substantiate statements and claims made in the petition.

Finally, this proposed rule is not intended to and, when finalized, will not by itself change the existing food standards nor result in the complete modernization of all of the food standards; rather, it will address the submission of petitions to establish, revise, or eliminate individual food standards and the evaluation of such petitions by us. The proposed general principles are the agencies' first step in instituting a process to modernize their food standards. In the long term, the agencies expect that all food standards,

including those for which the agencies receive no petitions to revise or eliminate, will be modernized or eliminated. However, as noted in section I.E of this document (see the third option that the Work Group considered), limited resources and competing priorities make it unlikely that the agencies could complete a comprehensive review of all food standards on their own initiative in a timely manner. A more efficient means of modernizing a food standard or a category of food standards is through petitions that demonstrate that a food standard(s) has been reviewed for consistency with the proposed principles. Thus, in the event we do not receive a petition requesting that we establish, revise, or eliminate a particular standard, we may, when appropriate, propose to establish, revise, or remove a standard on our own initiative. We will follow the proposed general principles as we review existing standards to determine whether a standard should be established, removed, or revised to ensure that all standards are consistent with the relevant statutes and the general principles.

The agencies welcome petitions to consolidate variations in the physical attributes in standardized foods within a single food standard. We also welcome petitions to incorporate general requirements that pertain to multiple food standards of a commodity group into general regulatory provisions that address the commodity group (see proposed general principles 9 CFR 410.1 (a)(9) and (10) and 21 CFR 130.5(b)(9) and (10)). However, the agencies recognize that developing these types of petitions may require more time than developing petitions that pertain to a single food standard. We request comment on the best way to efficiently and effectively make standards consistent with these two general principles. In particular, we are interested in recommendations concerning the role we should take and the role the public

should take in revising the standards to make them consistent with these two general principles.

FSIS intends to eliminate all informal or "policy" standards in the Policy Book, which address the meat and poultry content of certain products or define methods of processing, for which it does not receive a petition requesting that it adopt the entry as a regulation. FSIS intends to follow this course of action because few of the standards in the Policy Book are consistent with the proposed general principles.

III. FSIS and FDA Requests for Information

After their submission of comments, a number of commenters on the FSIS and the FDA ANPRMs have informally indicated that they would like another opportunity to provide comments to us. This proposal provides that opportunity.

We request comments both on the general principles and on how to best implement them. In particular, we request comments on the usefulness of the general principles for evaluating petitions for new food standards and for revising or eliminating existing food standards. We are also seeking comments on how to enhance the usefulness of the principles as a guide to external groups or individuals in evaluating and preparing petitions to establish, revise, or eliminate food standards.

IV. Executive Order 12866: Cost Benefit Analysis

We have examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order

12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or more, adversely affecting in a material way a sector of the economy, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. We have determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866 because it raises novel legal or policy issues. The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requires cost-benefit and other analyses for significant regulatory actions. Section 1532(a) of the Unfunded Mandates Reform Act of 1995 defines a significant rule as "any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year * * *" We have determined that this rule is not a significant rule under the Unfunded Mandates Reform Act.

A. Need for the Rule

Under some conditions, standards of identity may be economically desirable because they reduce product search costs for consumers. Standards can reduce search costs by requiring products that bear certain standardized names to have the set of characteristics that most consumers expect products bearing that name to have. In this document, we call this set of characteristics the "basic nature" of a food. Standards are most effective at reducing search costs when most consumers' beliefs about the basic nature of a food are similar, and less effective when many consumers have different beliefs about the basic nature of a food.

However, as currently written, some standards may contain requirements that do not contribute to this useful economic function because they do not correspond to most consumers' beliefs or expectations about the basic nature of those foods. Such standards may increase, rather than decrease, overall search costs because they may cause consumers to impute differences to products that do not actually exist. Increasing search costs reduces product variety and inhibits the introduction of new products because, if search costs increase, then some consumers may be more willing to settle for familiar products rather than spending additional time comparing products and examining ingredient statements to find a product they prefer. Many new products are developed specifically to enhance the healthfulness of traditional products. Therefore, increasing search costs and inhibiting the introduction of new products may also generate health costs for consumers because, if search costs increase, then some consumers may be more willing to settle for familiar products rather than spending additional time comparing products and examining ingredient statements to find similar but healthier products. In addition, standards that contain unnecessary elements or that fail to provide flexibility in terms of allowable food technology, may generate unnecessary production costs, and impede technological innovation in the food industry. Such standards may also serve as effective barriers to competition, thereby raising product prices and transferring resources from consumers to producers. Finally, some standards may be inconsistent with international standards, which may impede international trade. Impeding international trade may also restrict competition and lead to higher product prices.

The benefits of appropriate standards and the costs of inappropriate standards suggest that we need to develop: (1) A list of principles that will

govern our assessment of the standards; and (2) a system to facilitate the timely revision, implementation, and elimination of standards regulations, as appropriate.

B. Regulatory Options

We considered the following regulatory options:

1. Take no action;

2. Take the proposed action;

3. Eliminate all food standards;

4. Establish principles for assessing standards (only); and

5. Establish principles for assessing standards, but allow external parties to administer those principles.

1. Option One: Take No Action

By convention, we treat the option of taking no new regulatory action as the base line for determining the costs and benefits of the other options. Therefore, we associate neither costs nor benefits with this option. The consequences of taking no action are reflected in the costs and benefits of the other options.

2. Option Two: Take the Proposed Action

The proposed action has two primary components: (1) The establishment of a set of principles that we will use when assessing food standards, and (2) a statement of the system by which we intend to revise, eliminate, or establish standards in response to petitions submitted by external parties or on our own initiative.

a. *Benefits.* One benefit of establishing a set of principles for assessing food standards is that it simplifies our assessment of standards. First, it eliminates

the need for us to develop and explain the basis for accepting or rejecting proposed changes to standards in a piecemeal fashion. Establishing principles ensures that we use a consistent and systematic approach when assessing standards.

A second benefit is that the principles apprise external parties of the framework we intend to use when assessing standards, thereby reducing the costs for external parties to petition us to change standards. In the absence of principles, external parties would need to spend time reviewing past rulemakings to piece together the factors we consider relevant in assessing standards. Also, in the absence of established principles, external parties may expend resources developing petitions that we would be unable to accept, and we would expend resources evaluating such petitions. If the principles allow external parties to present more acceptable petitions, then we will be able to act on the petitions more quickly and make necessary changes to the standards regulations more quickly. This means that benefits for consumers and industry will take place more quickly than would otherwise have been the case. A third benefit is that establishing the set of principles specified in this proposed rule ensures that we assess standards with respect to their ability to reduce consumers' search costs, while also reducing the likelihood that standards will impose unnecessary costs, or reduce competition and thereby increase prices.

The proposed rule would establish a system by which we intend to revise, eliminate, or establish standards in response to petitions submitted by external parties or on our own initiative and would generate benefits by encouraging external parties to submit such petitions. External parties may already submit such petitions, and we already consider them. However, by stating that such petitions will henceforth be the primary means for initiating changes to the

standards' regulations, we are making it clear to interested parties that they should submit petitions if they desire changes in the standards, rather than wait for us to act on our own initiative. The total social costs of revising, eliminating, or establishing standards are probably lower if external parties participate in the process than if they do not because external parties are often in the best position to identify problem areas. Such a system also transfers some of the costs that we currently bear in assessing standards to private individuals and groups, thereby allowing us to reallocate our resources to issues that may have greater public health significance, while still allowing us to address standards reform in a timely fashion. However, this public health benefit is probably small because we have been unable to devote significant resources to standards reform to date. We do not know the net effect of this transfer on social costs because private expenditures on standards also displace activity associated with social benefits. We have insufficient information to quantify these benefits. However, we will also conduct cost-benefit, regulatory flexibility, and other relevant analyses for all proposed and final regulations changing the standards regulations.

b. *Costs.* One of the potential costs of establishing the proposed principles results from the possibility that we might finalize a set of principles that do not maximize the net social benefits from standards regulations. This could generate costs because we will be assessing the standards with respect to those principles. If the principles in the final rule do not maximize net social benefits within the statutory framework of food standards, then we might deny some changes to the standards that would have net social benefits, or might accept some changes that would have net social costs. However, we believe that this potential cost is small because we believe the principles as stated maximize

net social benefits, and because we can revise the principles in response to comments or in subsequent rulemakings, if necessary.

A second potential cost of establishing the proposed principles results from the inherent limitations of the approach to standards that we have adopted in the proposed principles. Under the proposed principles, a standard must reflect the basic nature of a food and its essential characteristics.

Standards may accommodate certain variations of a food, provided those variations preserve the basic nature of the food and its essential characteristics. For example, shredded, grated, or diced forms of cheese would be permitted because they do not alter the basic nature of the food. However, this restriction may also generate certain costs. For example, if we did not require that standards preserve the basic nature of the food and its essential characteristics, the information the standards provide for consumers might be reduced. Without such restrictions, a particular standard might be able to cover more diverse compositions of a particular food under a single name and thus address a greater variety of consumer health and dietary needs and preferences. Under this alternate approach, a "cheese" could be made with non-milk ingredients to be free of lactose or milk protein, and "bread" could be made using soy flour to improve the protein composition of the food. Under the proposed principles, such variations of these foods would not be permitted because they do not preserve the basic nature of these foods consistent with consumer expectations and beliefs. Such foods, however, can be marketed using nonstandardized names (although we recognize that, in some cases, having to market under a nonstandardized name may be costly and, therefore, may create a disincentive to create such foods). To the extent the proposed general principles lead to an increase in the number of foods covered by standards,

the costs described here and other costs associated with standards will increase.

Another potential cost of establishing a system to revise, eliminate, or establish standards in response to petitions submitted by external parties is that the goals and interests of such parties may differ from our goals. For example, external parties that work for for-profit entities will presumably submit petitions only if they believe that the changes requested in their petitions will increase their profits by more than the cost of preparing the petitions. Such parties might request changes that raise profits in a manner consistent with the proposed principles, such as by eliminating unnecessary or inappropriate requirements, or in a manner that is inconsistent with the proposed principles, such as by restricting competition or preventing the introduction of new products or technology. Similarly, external nonprofit (or not-for-profit) groups also may have incentives, such as increasing their political visibility or funding, that cause their goals to diverge from our goals. In both cases, we think this cost will probably be small for three reasons. First, we will be able to identify inappropriate recommendations during the petition review process because they will be inconsistent with the proposed principles. Second, we do not intend to accept statements about consumer beliefs or expectations for the purposes of defining the basic nature of a food without data or evidence supporting such statements. Third, we will publish proposed rules for any prospective changes to the standards regulations. Other interested parties will be able to comment on those changes and help us identify any inappropriate recommendations that we may have overlooked during our initial review of the petition.

Another potential cost of establishing a system that relies primarily on petitions submitted by external parties is that some standards that ought to be revised, eliminated, or established may be difficult for interested external parties to identify as such. This is most likely to be a problem for standards that contain requirements that do not reflect what most consumers believe is the basic nature of those foods, but that also do not generate significant costs for industry. Such standards may increase consumer search costs, inhibit the introduction of new products, and indirectly adversely affect consumer health. However, the typical consumer may have insufficient knowledge of the existing standard or the effects of that standard and thus not know to submit a petition requesting changes to the standard. A similar situation exists with products that do not currently have a standard, but for which a standard would generate potential benefits for consumers. Again, the typical consumer may have insufficient information or resources to submit a petition that establishes the case for such a standard. We expect these costs to be small for the following two reasons: (1) Consumer groups may have sufficient resources and interest to investigate and submit petitions that include information on consumer expectations and beliefs in cases in which individual consumers would not, and (2) although we envision that petitions will be the driving force behind most changes in the standards regulations, we may, in some cases, continue to propose changes to the standards regulations on our own initiative. Finally, involving external parties in the standards review process would generate social costs if: (1) Those parties would not have prepared petitions in the absence of the proposed action, (2) we would have assessed the need for those changes on our own initiative in the absence of the proposed action, and (3) the costs of the external parties are above and beyond the costs we would have

faced. Under these conditions, this rule would cause additional social resources to be expended on making changes to the standards regulations. These costs are probably small because we have no information suggesting that external parties' costs of submitting petitions is significantly different from our costs of investigating the need for comparable changes in the regulations.

Based on the preceding discussion of why we expect the social costs associated with this rule to be small and the benefits to be relatively substantial, we believe that the benefits of establishing the proposed principles outweigh the costs.

c. *Description of the affected industry.* FSIS regulations contain approximately 80 standards for meat and poultry products. Most of these standards are for heat-treated products; however, some are for raw products (such as ground beef, hamburger, and cuts of raw poultry). Therefore, all processing plants may produce at least one type of standardized product. According to the 1999 Report of the Secretary of Agriculture to the U.S. Congress, there are 1,067 meat processing plants, 168 poultry processing plants, and 3,130 meat and poultry processing plants (4,347 total processing plants). Most standards are for heat-treated products. Based on the 1997 Census of Manufacturers information, there are 1,630 establishments producing readyto- eat and partially heat-treated meat and poultry products; FSIS used this estimate in the proposed rule entitled "Production of Processed Meat and Poultry Products" (66 FR 12611). These plants would produce heat-treated, standardized meat and poultry products.

FDA regulations contain over 280 food standards covering a variety of different foods. Determining the exact number of affected firms would be time consuming and would not be justified by the significance of that information

for this analysis. A significant proportion of the 26,361 establishments identified under the North American Industry Classification System (NAICS) classification "food manufacturing" in the 1997 Economic Census probably produce at least some products that are governed by FDA food standards.

3. Option Three: Eliminate All Food Standards

Another option would be to eliminate or significantly reduce the number of food standards. The benefit of eliminating all food standards is that it would also eliminate all of the social costs potentially generated by those standards. One such cost is our expenditures, and the expenditures of external parties, that are currently devoted to analyzing, developing, promulgating, modifying, and enforcing standards. Other social costs that would be eliminated include compliance costs, indirect inhibition of new technologies, and limitations on competition. Finally, this option would eliminate the ability of standards to perpetuate consumer beliefs or expectations that may lead some consumers to make product choices that are less healthful than they might otherwise make (a potential effect that is significantly reduced by nutrient content claim regulations).

The cost of eliminating all standards is that many consumers would face increased search costs because they would lose the assurances provided by standards that standardized products exhibit the basic nature that those consumers expect those products to have. Although we could continue to pursue the objective of maintaining the accuracy of the information conveyed by product names through regulations against adulteration and misbranding, enforcing those regulations would require more agency resources, and would generally be a less effective method of pursuing that objective. Another cost of eliminating Federal standards is that the Federal Government would no

longer have a reference point for negotiating international food standards for the purpose of facilitating international trade with countries and organizations of countries that maintain such standards.

We have insufficient information to quantify the costs and benefits of this option or to compare them to those of the proposed option. However, the benefits of this option would be quite similar to those of the proposed option because the proposed principles will eliminate or significantly reduce the social costs associated with standards regulation. However, as explained previously, the expenditure, social, search, and loss of reference point costs of this option would probably be greater than the same costs of the proposed option. Therefore, this option would probably lead to lower net benefits than the proposed option.

4. Option Four: Establish Principles for Assessing Standards (Only)

We could also establish the proposed principles for assessing standards but rely solely on our own resources to develop proposals for changing the standards regulations. The costs and benefits of this option would be generated solely by the establishment of the proposed principles, and would correspond in type to the costs and benefits we discussed for Option Two. However, we believe this option would have lower net benefits than Option Two because it would result in fewer petitions to establish, revise, or eliminate food standards. If we do not specify that we are relying on petitions to initiate changes to food standards regulations, some external parties may wait for us to act on our own initiative. Acting on our own initiative would eliminate the benefit of transferring cost to external parties because we would have to allocate our limited resources toward revising, eliminating, and establishing new standards without the aid of information from petitions.

5. Option Five: Establish Principles for Assessing Standards, but Allow External Parties to Administer Those Principles

A final option would be for us to allow external parties to revise, eliminate, and establish food standards using the proposed principles. The benefits and costs of the first component of this option, establishing the proposed principles, would be essentially the same as the corresponding benefits and costs discussed under Option Two.

The benefit of the second component of this option, allowing external parties to administer mandatory standards, is that it would allow us to reallocate resources to areas that may have greater public health significance than standards. This reallocation, and its potential public health consequences, would be greater than that discussed under Option Two because under this option we would not devote resources to reviewing petitions, writing proposed rules, reviewing public comments, writing final rules, or enforcing final rules.

One of the primary costs of allowing external parties to administer standards is that their objectives may diverge from ours. This cost would be greater than the similar cost discussed under Option Two because under Option Five we would transfer additional responsibilities to external parties. For example, although the proposed principles provide general directions for decisionmaking, they do not set forth in detail all potentially relevant considerations that might need to be dealt with. Although we could produce additional and more detailed principles, we would probably not be able to provide principles that are sufficiently detailed to cover all potentially relevant considerations and situations. Among the issues on which we might need to provide additional information to external parties would be the following: (1) Evaluating data on consumer perceptions and beliefs, or on scientific or

technical issues, (2) soliciting and analyzing comments from consumers and other interested parties, (3) adjudicating conflicts between interest groups, (4) analyzing the costs and benefits of proposed changes, (5) addressing the impact of changes on small entities, and (6) assessing the impact of changes on international trade. Providing this type of additional and more detailed information would also generate costs, which would reduce the benefits of this option. In addition, if we administer the standards, then there may be situations in which it would be apparent to us that we need to revise the principles. External parties may not have a sufficient appreciation of the overall objectives of standards to recognize such situations.

It should also be noted that this option is not legally feasible at this time: legislative action would be needed to amend the act, FMIA, and PPIA in order for external parties to develop standards having the force of law. Without such changes, standards established by external parties would be voluntary.

Allowing external parties to administer voluntary standards could lead to benefits similar to those of allowing them to administer mandatory standards if the voluntary standards were combined with a voluntary labeling system under which firms that produce products meeting the voluntary standard could communicate that fact to consumers. Setting aside the issue of the benefits of the proposed principles, which we have already discussed, the benefit of establishing a system in which external parties would administer voluntary standards is that such a system would essentially eliminate compliance costs for industry because firms would not participate in the voluntary system unless doing so generated net profits. Although a system in which external parties would administer voluntary standards would ensure that any activity that firms take to comply with such standards would not generate net social costs

(assuming no market failures), it would not eliminate the private costs associated with that activity. In addition, voluntary standards might eliminate some of the potential social costs of mandatory standards in that they would accommodate at least some degree of consumer variability by allowing standards to be used by those consumers who share the same beliefs about the basic nature of the relevant products as expressed in the standards, and ignored by those who do not.

The social cost generated by establishing a system by which external parties would administer voluntary standards would be the loss of some of the benefits currently generated by mandatory standards. The benefits of voluntary standards are likely to be lower than the benefits of mandatory standards for the following four reasons: (1) Consumers who find the voluntary standards useful would need to spend at least some time distinguishing standardized products from nonstandardized products, so any reduction in search costs from voluntary standards would be less than that generated by mandatory standards; (2) external groups would probably not be able to enforce voluntary standards to the same degree that we can enforce mandatory standards, so standardized designations may become unreliable; (3) voluntary standards would not provide a useful reference point for negotiating international food standards for the purposes of facilitating international trade with countries and organizations of countries that maintain such standards; and (4) in order for consumers to know whether the information conveyed via voluntary standards is valuable for them, they would need to develop some understanding of the standards. The costs associated with this activity might be quite high for some consumers.

We do not have sufficient information to quantify the costs and benefits of this option or to compare them to those of the proposed option. However, based on the preceding discussion, this option is unlikely to lead to higher net benefits than the proposed option.

6. Summary

For the reasons discussed previously, we believe that taking the proposed action will generate net social benefits, and also that the social costs of taking the proposed action are likely to be small. We found that most of the other options were likely to have lower net benefits because they had lower benefits, higher costs, or both.

V. Regulatory Flexibility Analysis

We have examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We have made an initial determination that this proposed rule will not have a significant impact on a substantial number of small entities.

Under the proposed rule, small entities would only incur direct compliance costs when they decide to voluntarily submit a petition using the general principles. These entities would only submit a petition when it is clear that the benefits generated from submitting the petition outweigh the costs of developing and submitting one. However, this proposed rule could generate costs other than direct compliance costs to the extent that it encouraged external parties to submit petitions, and thereby increased the number of proposed changes to standards that small entities may wish to analyze.

Although this decision would also be voluntary, the competitive position of small entities could be impaired if they did not undertake this activity and other external parties attempted to use standards reform to gain a competitive advantage. However, this impact would probably be minimal because: (1) It would be difficult or impossible for external parties to misuse standards reform because requested changes would need to conform to the principles set forth in this proposed rule, (2) we intend to consider evidence of consensus within affected industries, including small businesses when making our decisions in regard to requested changes, (3) we do not intend to accept statements about consumer beliefs or expectations about the basic nature of a food without data or evidence supporting such statements, and (4) we intend to analyze the impacts on small entities of any proposed changes to the standards regulations.

With respect to the number of affected firms that are small entities, the 1999 Report of the Secretary of Agriculture to the U.S. Congress identifies 1,067 meat processing plants, 168 poultry processing plants, and 3,130 meat and poultry processing plants (4,347 total). The majority of these establishments would qualify as small businesses under the Small Business Administration definition of a small business. All of these plants may produce at least one type of standardized product because there are both raw and heattreated standardized products. However, most of the standards are for heattreated products. FSIS estimates that there are approximately 1,485 small establishments producing ready-to-eat or heat-treated products, and many of these products are standardized products. This number is based on data from the 1997 Census of Manufacturers. FSIS used this data to estimate the number of small businesses that would be affected by the proposed rule on performance standards for the production of processed meat and poultry

products, published in the **Federal Register** of February 27, 2001 (66 FR 12590). In addition, there are approximately 26,361 establishments identified in the 1997 Economic Census as belonging to the NAICS classification "food manufacturing." All of these establishments may produce at least some products that are governed by FDA food standards. The vast majority of these establishments would qualify as small businesses under the Small Business Administration definition of a small business.

VI. Executive Order 12988: Civil Justice Reform

FSIS: This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are pre-empted by the FMIA and the PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA. However, States and local jurisdictions may exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States.

The proposed rule is not intended to have retroactive effect. If this proposed rule is adopted, administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted before there is any judicial challenge of the application of the proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA and PPIA. 65

VII. Executive Order 13132: Federalism

FSIS: Executive Order 13132, "Federalism," requires that agencies assess the federalism implications of their policy statements and actions, i.e., the effects of those statements and actions on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The FMIA and the PPIA pre-empt State and local laws in regard to the manufacture and distribution of meat and poultry products in interstate or foreign commerce. Therefore, FSIS policy statements and actions affect federalism within the context of these statutory pre-emptions.

States and local jurisdictions are pre-empted by the FMIA and PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are within their jurisdiction and outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

However, under section 301 of the FMIA and section 5 of the PPIA, a State may administer a State meat and poultry inspection program provided that it has developed and is effectively enforcing State meat and poultry inspection requirements at least equal to those imposed under titles I and IV of the FMIA and sections 1 to 4, 6 to 10, and 12 to 22 of the PPIA. These titles contemplate continuous ongoing programs. When a State can no longer effectively enforce

meat and poultry inspection requirements at least equal to Federal requirements, it must be "designated" by the Secretary of Agriculture and all plants within that State must operate under Federal inspection. When FSIS revises its meat and poultry inspection requirements, States that administer their own inspection programs may be affected, since they must continue to enforce requirements at least equal to those of FSIS. To minimize any additional costs States must incur to modify their inspection programs, FSIS grants the States significant flexibility under the 'equal to' provisions of the FMIA and PPIA. Further, States are eligible to receive up to 50 percent Federal matching funds to cover the costs of their inspection program.

FDA: FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has concluded that this proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required. FDA is interested in comments from elected State and local government officials and others on: (1) The need for the proposed guiding principles rule to modernize food standards; (2) the proposed guiding principles' provisions; and (3) any other issues raised by this proposed rule that possibly affect State laws and authorities.

VIII. Environmental Impact

FSIS: FSIS has been granted a categorical exclusion from the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) requirements by USDA regulations (7 CFR 1b. 4) unless the Administrator of FSIS determines that such an action may have a significant environmental effect. FSIS has determined that this rule would not have a significant environmental effect.

FDA: FDA has determined under 21 CFR 25.30(h) that its part of this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

FSIS:

Title: General Principles and Food Standards Modernization.

Type of Collection: New.

Abstract: FSIS is proposing to establish a set of general principles for food standards. The proposed general principles will specify the criteria that the agencies will use in considering whether a petition to establish, revise, or eliminate a food standard will be the basis for a proposed rule. Under this rule, petitions to establish, revise, or eliminate a standard should include a comprehensive statement that explains how the proposed new or revised standard conforms to the general principles or how the standard proposed to be eliminated does not conform to the general principles.

Estimate of burden: FSIS estimates that developing a petition to establish, revise, or eliminate a food standard that conforms to the general principles and developing the comprehensive statement that explains how the new or revised standard conforms to the general principles or how the standard proposed to be eliminated does not conform to the general principles will take an average of 40 hours.

Respondents: Manufacturers of meat and poultry products, trade organizations, consumer organizations, or unaffiliated individuals.

Estimated number of respondents: 6.

Estimated number of responses per respondent: 1.

Estimated total annual burden on respondents: 240 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th St. SW., Washington, DC 20250. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to John O'Connell, see address above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. Comments are requested by [*insert date 60 days after date of publication in the* **Federal Register**]. To be most effective, comments should be sent to the Office of Management and Budget (OMB) within 30 days of the publication date.

FSIS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies, in general, to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

FDA:

This proposed rule contains information provisions that are subject to review by OMB under the Paperwork Reduction act of 1995 (44 U.S.C. 3501–

3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Food Standards; General Principles and Food Standards Modernization

Description: This proposed rule would amend 21 CFR 130.5 to establish a list of 13 general principles that we would use when establishing, revising, or eliminating standards of identity. We wish to establish these principles to ensure that we apply consistent criteria when evaluating petitions relating to standards and to communicate these criteria to potential petitioners. Under this proposed rule, parties who petition us to establish a new standard or to revise an existing standard would need to provide a comprehensive statement explaining how the requested new standard or the requested revision is consistent with each of the relevant general principles, while parties who petition us to eliminate a standard would need to provide a comprehensive statement explaining how the standard to be eliminated is inconsistent with

any one of the first four principles. In addition, we encourage but do not require parties who petition us to revise a standard in any way to analyze the entire existing standard with respect to all of the general principles and to petition us to make all of the revisions that such an analysis might suggest.

Description of Respondents: Individual businesses and industry trade groups will probably generate most of the petitions. In addition, consumer advocacy groups might submit petitions, and we might also receive petitions from private individuals.

Burden:

Hour Burden Estimate

In table 1 of this document, we present an estimate of the total annual hourly burden for the proposed information collection requirements for petitions that seek to establish new standards or revise existing standards. The time and cost will vary considerably depending on the nature of the suggested changes in food standards, the nature and complexity of the standards involved, and the existing information that can be brought to bear on the relevant issues. The burden hours in table 1 of this document include only that portion of the compliance burden that goes beyond the burden associated with the general requirements that apply to all citizen petitions under 21 CFR 10.30, because only that portion represents a new information collection. The burden would be lower for petitions that seek to eliminate existing standards. However, the comments that we received on the ANPRM suggest that most petitions would involve revising existing standards or creating new standards. Therefore, we have based our burden estimates on those types of petitions. We received 10 petitions from 2000 through 2004, or approximately three petitions per year. The proposed rule might either increase or decrease the

number of petitions. However, we do not have sufficient information to estimate a change in the expected number of petitions. Therefore, we assume that we will continue to receive three petitions per year. In addition, we assume that each respondent will probably only submit one petition per year. Therefore, we estimate three respondents per year with an annual frequency of one response per year.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
130.5(b)	3	1	3	136	408

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In table 2 of this document, we list the various information collection activities and burden hours that we used to estimate the total hours per response that we present in table 1 of this document. In some cases, we present our burden estimate in terms of a range and average. The range reflects the fact that large firms probably do much of the required activity as a normal part of product development. These firms would simply need to compile existing information for the comprehensive statement that shows consistency with the relevant general principles. However, smaller firms, industry and consumer groups, and private individuals may not otherwise undertake the activity required for the comprehensive statement. Therefore, the burden for these entities could be significantly higher. We expect large firms will probably submit most petitions. Therefore, we have assumed average burdens near the low end of the estimated ranges. We estimate that the total annual hourly burden associated with this information collection would be 264 to 1,512 hours. Within this range, we estimate that the average total annual hourly burden would be 408 hours.

TABLE 2.—AVERAGE HOURLY BURDEN OF INFORMATION COLLECTION ACTIVITIES PER PETITION

Information Collection Activity	Average Hours
(1) Legal, technical, and scientific interpretation of new information collection requirements (all principles): 8 hours.	8
(2) Social scientific analysis of consumer surveys, focus groups, or market data, or scientific and technical analysis of restaurant menus or food formulary compilations to demonstrate or infer consumer expectations and beliefs relating to product identity, the relationship of observable and non-observable product attributes to product identity, the relationship of product uniformity to product identity, the significance of the order of terms in the name of the food (if the new or revised standard involves a newly standardized product name containing more than one term), and consumer valuation of observable and non-observable product attributes and product uniformity (Principles 1 to 4, 6, 7, and 12): 8 to 320 hours, average 40 hours.	40
(3) Plain English editorial review to produce language that is clear, easily understood, simple, and easy to use (Principles 5 and 8): 4 hours.	4
(4) Technical and scientific evaluation of whether the new or revised standard permits the maximum level of flexibility in terms of food technology subject to considerations of consumer expectations, nutritional quality, and safety, including an analysis of other suitable alternative manufacturing processes. We estimate the cost of generating or compiling of some of the necessary information on consumer expectations under another activity. The new elements for this activity include the safety and nutritional quality review and the investigation of the impact of flexibility in terms of food technology on product attributes that are related to consumer expectations. Burden: 16 to 120 hours, average 32 hours.	32
(5) Legal and scientific analysis of whether petitioners have described any ingredients featuring in the new standard or revised standard as broadly and generically as possible (Principle 6): 8 hours.	8
(6) Legal, scientific, and technical analysis of relevant Codex standards and preparation of a rationale for any differences between Codex standards and the new or revised standards (Principle 7). In general, the rationale for any differences will probably involve referencing consumer expectations and beliefs. We estimate the burden of compiling or generating that information under Activity 2. Burden: 8 hours.	8
(7) Legal, scientific, and technical review of other food standards to establish that the new or revised standard is consistent with existing FDA food standards (Principles 8 and 11): 8 hours.	8
(8) Legal, scientific, and technical analysis of ingredient technology, manufacturing processes, and food composition to eliminate unnecessary details (Principle 8): 8 hours.	8
(9) Scientific and technical review to demonstrate that the new or revised standard allows for variation in the physical attributes of the food (Principle 9): 8 hours.	8
(10) Legal and scientific review of existing labeling and ingredient regulations to establish that the new or revised standard is consistent with those regulations (Principle 11): 8 hours.	8
(11) Scientific review of existing food standards and current scientific nomenclature reference works to establish if the names of ingredients and functional use categories in new and revised standards are consistent with those used in other food standards and with current scientific nomenclature (Principle 13). Petitioners could review of ingredient names and functional use categories in other food standards as part of the general review of those standards under Activity 8. However, the review of nomenclature reference works would be an additional activity. Burden: 4 hours	4
Total Time Burden	136

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to fax comments regarding information collection by [*insert date 30 days after date of publication in the* **Federal Register**] to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer, FDA, Fax 202–395–6974.

X. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in

particular minorities, women, and persons with disabilities, are aware of this proposed rule, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2005_Proposed_Rules_Index/index.asp.*

The Regulations.gov Web site is the central online rulemaking portal of the U.S. Government. It is being offered as a public service to increase participation in the Federal Government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or department or agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov/.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides an automatic and customized notification when popular pages are updated,

including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

XI. Comments

FSIS: See information under **DATES**, and **ADDRESSES**, and section X of this document.

FDA: Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. CFSAN/FSIS, Memo on standards focus groups, May 30, 2001.

2. Cates, S.C., Consumer Attitudes Toward Potential Changes in Food Standards of Identity, volume 1: Final Report to the FDA, September 2000.

List of Subjects

9 CFR Part 410

Food grades and standards, Food labeling, Frozen foods, Meat inspection, Oils and fats, Poultry and poultry products.

21 CFR Part 130

Food additives, Food grades and standards.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Chapter III

Authority and Issuance

■ For the reasons discussed in the preamble, FSIS is proposing to amend chapter III of title 9 of the Code of Federal Regulations by adding new part 410 to subchapter E to read as follows:

PART 410–PRODUCT COMPOSITION

Authority: 21 U.S.C. 601–695; 21 U.S.C 451–472; 7 CFR 2.18, 2.53, 7 U.S.C. 2219(a).

§410.1 Procedure for establishing, revising, or eliminating a food standard.

(a) A food standard proposed in a petition to establish a new food standard in part 319 or part 381, subpart P, of this chapter must be consistent with all of the following general principles that apply to the new standard. Any revision to a food standard proposed in a petition to revise an existing food standard in part 319 or part 381, subpart P, of this chapter must be consistent with all of the following general principles that apply to the proposed revision to the existing standard. The agency will consider a petition that proposes

eliminating a food standard if it is demonstrated that the current food standard is not consistent with any one of the ~~first four~~ general principles.

(1) The food standard should protect the public.

(2) The food standard should describe the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers' expectations of product characteristics and uniformity.

(3) The food standard should reflect the essential characteristics of the food. The essential characteristics of a food are those that define or distinguish a food or describe the distinctive properties of a food. The essential characteristics of a food may contribute to achieving the food's basic nature or may reflect relevant consumer expectations of a food product. For example, foods may be defined or distinguished by their ingredients, compositional characteristics, physical characteristics, nutrient levels, or the manner in which they are produced.

(4) The food standard should ensure that the food does not appear to be better or of a greater value than it is.

The food standard may be used as a vehicle to improve the overall nutritional quality of the food supply.

(5) The food standard should contain clear and easily understood requirements to facilitate compliance by food manufacturers.

(6) The food standard should permit maximum flexibility in the food technology used to prepare the standardized food so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality or safety, of the food. The food standard should provide for any suitable, alternative manufacturing process that accomplishes the

desired effect, and should describe ingredients as broadly and generically as feasible.

(7) The food standard should be harmonized with international food standards to the extent feasible. If the food standard is different from the requirements in a Codex standard for the same food, the petition should specify the reasons for these differences.

(8) The food standard provisions should be simple, easy to use, and consistent among all standards. Food standards should include only those elements that are necessary to define the basic nature and essential characteristics of a particular food, and any unnecessary details should be eliminated.

(9) The food standard should allow for variations in the physical attributes of the food. Where necessary to provide for specific variations in the physical attributes of a food within the food standard, the variations should be consolidated into a single food standard.

(10) Whenever possible, general requirements that pertain to multiple food standards of a commodity group should be incorporated into general regulatory provisions that address the commodity group.

(11) Any proposed new or revised food standard should take into account whether there are labeling or ingredient regulations in this chapter that are affected by, or that cover, the new or revised food standard, so that any requirements in the standard are consistent with labeling or ingredient regulations.

(12) The food standard should provide the terms that can be used to name a food and should allow such terms to be used in any order that is not misleading to consumers.

(13) Names of ingredients and functional use categories in a food standard should be consistent with other food standards in part 319 or part 381, subpart P, of this chapter, and relevant regulations in § 424.21 of this chapter, and, when appropriate, incorporate current scientific nomenclature.

(14) The food standard should be based on the finished product.

(15) The food standard should identify whether the product is ready-to-eat or not ready-to-eat.

(b) A petition to establish a new food standard should include a comprehensive statement that explains how the proposed new standard conforms to the general principles that apply to the new standard. A petition to revise an existing food standard should include a comprehensive statement that explains how the proposed revision to the existing standard conforms to the general principles that apply to the proposed revision. A petition to eliminate a food standard should include a comprehensive statement that explains how the standard proposed to be eliminated does not conform to any one of the ~~first four~~ general principles in paragraphs (a)(1) through (a)(4) of this section

(c) A petition that proposes the establishment or revision of a food standard in part 319 or part 381, subpart P, of this chapter, that is not consistent with the applicable general principles listed under paragraph (a) of this section will be denied, and the petitioner will be notified as to the reason for the denial. A petition that proposes the elimination of a food standard in part 319 or part 381, subpart P, of this chapter that does not demonstrate that the food standard is inconsistent with any one of the ~~first four~~ general principles listed under paragraph (a)(1) through (a)(4) of this section will be denied, and the petitioner will be notified as to the reason for the denial.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

Authority and Issuance

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that part 130 of chapter I of title 21 of the Code of Federal Regulations be amended as follows:

PART 130–FOOD STANDARDS: GENERAL

■ 1. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 341, 343, 371.

■ 2. Section 130.5 is amended by revising the section head and paragraph (b), redesignating paragraphs (c) and (d) as paragraphs (e) and (f), respectively, and adding new paragraphs (c) and (d) to read as follows:

§ 130.5 Procedure for establishing, revising, or eliminating a food standard.

* * * * *

per S. Drawson 5/17/05 JJ

(b) A food standard proposed in a petition to establish a new food standard in parts 130 to 169 of this chapter must be consistent with all of the following general principles that apply to the new standard. Any revision to a food standard proposed in a petition to revise an existing food standard in parts 130 to 169 of this chapter must be consistent with all of the following general principles that apply to the proposed revision to the existing standard. The Food and Drug Administration will consider a petition that proposes eliminating a food standard if it is demonstrated that the current food standard is not consistent with any one of the ~~first four~~ general principles. In paragraphs (b)(1)

(b)(4) by this section

(1) The food standard should promote honesty and fair dealing in the interest of consumers.

(2) The food standard should describe the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers' expectations of product characteristics and uniformity.

(3) The food standard should reflect the essential characteristics of the food. The essential characteristics of a food are those that define or distinguish a food or describe the distinctive properties of a food. The essential characteristics of a food may contribute to achieving the food's basic nature or may reflect relevant consumer expectations of a food product. For example, foods may be defined or distinguished by their ingredients, compositional characteristics, physical characteristics, nutrient levels, or the manner in which they are produced.

(4) The food standard should ensure that the food does not appear to be better or of a greater value than it is. The food standard may be used as a vehicle to improve the overall nutritional quality of the food supply.

(5) The food standard should contain clear and easily understood requirements to facilitate compliance by food manufacturers.

(6) The food standard should permit maximum flexibility in the technology used to prepare the standardized food so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality or safety, of the food. The food standard should provide for any suitable, alternative manufacturing process that accomplishes the desired effect, and should describe ingredients as broadly and generically as feasible.

(7) Consistent with § 130.6 of this chapter, the food standard should be harmonized with international food standards to the extent feasible. If the food standard is different from the requirements in a Codex standard for the same food, the petition should specify the reasons for these differences.

(8) The food standard provisions should be simple, easy to use, and consistent among all food standards. Food standards should include only those elements that are necessary to define the basic nature and essential characteristics of a particular food, and any unnecessary details should be eliminated.

(9) The food standard should allow for variations in the physical attributes of the food. Where necessary to provide for specific variations in the physical attributes of a food within the food standard, the variations should be consolidated into a single food standard.

(10) Whenever possible, general requirements that pertain to multiple food standards of a commodity group should be incorporated into general regulatory provisions that address the commodity group.

(11) The food standard should take into account any other relevant regulations in this chapter. For example, a proposed new or revised food standard should be consistent with common or usual name regulations for related commodities or products. Further, any specific requirements for foods intended for further manufacturing should be incorporated within the reference food standard rather than being provided as a separate food standard.

(12) The food standard should provide the terms that can be used to name a food and should allow such terms to be used in any order that is not misleading to consumers.

(13) Names of ingredients and functional use categories in a food standard should be consistent with other food standards and relevant regulations in this chapter, and, when appropriate, incorporate current scientific nomenclature.

(c) As part of the Statement of Grounds required by section § 10.30 of this chapter, a petition to establish a new food standard should include a comprehensive statement that explains how the proposed new standard conforms to the general principles that apply to the new standard. A petition to revise an existing food standard should include a comprehensive statement that explains how the proposed revision to the existing standard conforms to the general principles that apply to the ~~proposed revision~~. A petition to eliminate a food standard should include a comprehensive statement that explains how the standard proposed to be eliminated does not conform to any one of the ~~first four~~ general principles.

(d) A petition that proposes the establishment or revision of a food standard that is not consistent with the applicable general principles listed under paragraph (b) of this section will be denied, and the petitioner will be notified as to the reason for the denial. A petition that proposes the elimination of a food standard that does not demonstrate that the food standard is inconsistent with any one of the ~~first four~~ general principles listed under paragraph (b) of this section will be denied, and the petitioner will be notified as to the reason for the denial.

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Dated: 4-14-05
April 14, 2005.

Barbara Masters

Dr. Barbara J. Masters, Acting Administrator, FSIS.

Dated: APR 8 2005
April 8, 2005.

Lester M. Crawford,
Acting commissioner of Food and Drugs.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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