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Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

FSIS Docket Clerk
Food Safety and Inspection Service
Department of Agriculture
Room 102, Cotton Annex Bldg
300 12th Street, S.W.
Washington, D.C. 20250-3700

Citizen Petition

to Modernize Food Standards

On the behalf of the food industry associations listed below, I am submitting this petition to request the Commissioner of Food and Drugs and the Administrator of the Food Safety and Inspection Service (FSIS) to issue, respectively, regulations of general applicability to modernize the food standards. This request is submitted to the Food and Drug Administration (FDA) under section 403 of the Federal Food, Drug, and Cosmetic Act (FDCA), and 21 C.F.R. § 10.30, and to FSIS pursuant to Section 1(n)(7) of the Federal Meat Inspection Act (FMIA) and Section 4(h)(7) of the Poultry Products Inspection Act (PPIA).

The American Frozen Food Institute (AFFI) is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 482 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally.

The American Meat Institute (AMI) represents the interests of packers and processors of beef, pork, lamb, veal and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb and veal products and 70 percent of the turkey products in the U.S. Headquartered in Washington, D.C., the Institute provides legislative, regulatory, public relations, technical, scientific and educational services to the industry.

The Chocolate Manufacturers Association (CMA) is the not-for-profit trade association representing the majority of manufacturers and distributors of cocoa and chocolate products in the United States. The association was founded to fund and administer research, promote chocolate to the general public and serve as an advocate of the industry before Congress and government agencies.

Food Products Association (FPA) is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

The Grocery Manufacturers Association (GMA) represents the world's leading branded food, beverage and consumer products companies. Since 1908, GMA has been an advocate for its members on public policy issues and has championed initiatives to increase industrywide productivity and growth. GMA member companies employ more than 2.5 million workers in all 50 states and account for more than \$680 billion in global annual sales. The association is led by a board of member company chief executives.

The International Dairy Foods Association (IDFA) is the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA comprises three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA).

Juice Products Association (JPA) is the trade association for the fruit and juice products industry, including juice processors, packers, extractors, and brokers as well as marketers of fruit juices and vegetable juices, juice beverages, fruit jams, jellies and preserves and similar products. Juice products include orange juice, grapefruit juice and other citrus juice products, apple juice, cranberry juice, grape juice, tropical fruit juices and vegetable juice products and other juice beverages. JPA also represents juice industry suppliers and food testing laboratories and includes firms engaged in the trading of frozen concentrated orange juice futures and/or options contracts on behalf of JPA processor members.

Producer-directed and consumer-focused, the National Cattlemen's Beef Association (NCBA) is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

The National Fisheries Institute (NFI) is the nation's leading advocacy organization for the seafood industry. Its member companies represent every element of the industry from the fishing vessels at sea to the national seafood restaurant chains. From responsible aquaculture, to a marketplace supporting free trade, to ensuring consumers have the facts on the health benefits of fish and shellfish, NFI and its members support and promote sound public policy based on scientific research.

The National Meat Canners Association (NMCA) is the national trade association representing manufacturers of shelf stable meat, poultry and seafood products. Companies whose primary or secondary businesses lie in sterile processed meat products comprise the association's membership.

The North American Millers' Association is the trade association representing the wheat, corn, oat and rye milling industry. NAMA's 48 member companies operate 170 mills in 38 states and Canada. Their aggregate production of more than 160 million pounds per day is approximately 95 percent of the total industry capacity.

The Snack Food Association is an international trade association of more than 700 member companies that represent snack manufacturers and suppliers to the snack industry. SFA membership includes smaller regionally-based snack food companies in addition to large nationally-branded snack food manufacturers.

ACTION REQUESTED

This petition respectfully requests that FDA amend 21 C.F.R. Part 130, and that FSIS amend 9 C.F.R. Chapter III, Subchapter E, to add a regulation of general applicability (i.e., a "horizontal" regulation) to modernize food standards. The petitioners specifically propose regulations (Appendices A and B) to permit, within stated boundaries, a standardized food to vary from the applicable standard for a legitimate purpose, such as the use of a beneficial new technology. Although no single regulation can modernize all food standards in all respects, a well-designed horizontal approach can address areas of greatest immediate need. Such an approach will promote the efficient use of agency resources and remove barriers to innovation that constrain industry and limit improvements that have the potential to increase honesty and fair dealing in the interest of consumers. Of key importance, it will enable manufacturers to bring to consumers a wider selection of traditional foods with improved nutritional profiles.

Both FDA and FSIS have already used a horizontal approach to update standards in certain respects, allowing variations from standards that are necessary to comply with a nutrient content claim or use safe and suitable ingredients, such as binders. The proposed actions represent a logical extension of this settled precedent. As with existing horizontal regulations, the proposed regulations would themselves be a type of food standard and would set uniform national boundaries for the relevant food.

Based on a review of the current standards framework, the petitioners have identified six categories of variations that should be allowed to provide needed flexibility. These categories would permit, within carefully defined boundaries, variations from food standards to accomplish the following beneficial objectives:

- Addition of ingredients intended solely for technical, nondistinctive effects, such as emulsifiers, stabilizers, or antimicrobial agents
- Use of safe and suitable flavors and flavor enhancers in foods generally, and use of safe and suitable ingredients such as salt substitutes, sweeteners, and vegetable fats and oils where appropriate

- Use of advanced or more efficient technologies to produce ingredients of all types, such as enzyme technologies that enhance the properties of egg yolk used in mayonnaise
- Use of alternate manufacturing processes, also known as “alternate make” procedures, for those standards that specify particular processes
- Changes to a product’s basic shape in response to consumer demands, such as “chunky” stewed tomatoes
- Improvements in nutritional properties that do not rise to the level of a defined nutrient content claim (e.g., reducing calories by 10% rather than requiring a minimum 25%), or use of nutritious ingredients like whole grains

A regulation allowing flexibility along these lines would effect broad standards reform, allowing use of advantageous new technologies, processes and ingredients, and facilitating measures to improve product quality, satisfy consumer demands, and make food products more nutritious. The resulting flexibility would reduce barriers to innovation, benefiting consumers, the agencies, and industry. The proposed regulation would not, however, replace or undermine existing policies or requirements. For example, the existing framework for nutrient content claims would not be affected. In addition, this petition recognizes that flexibility involving certain ingredients (e.g., milk protein concentrate in cheese) and criteria (e.g., meat minimums) would probably trigger considerable controversy and make it difficult to achieve consensus. In the interest of advancing the numerous worthy objectives outlined above, the petitioners do not seek to include such ingredients or criteria in the proposed horizontal framework.

STATEMENT OF GROUNDS

On May 20, 2005, FDA and FSIS jointly issued a *Federal Register* notice soliciting comments on a proposed rule to modernize food standards by establishing a set of general principles to guide the creation, revision, or elimination of food standards.^{1/} In response to that notice, GMA submitted comments to the agencies, supporting the principles generally, but also suggesting a more innovative approach to promulgate one rule of general applicability to provide flexibility to all food standards at once. As promised in those comments, this petition provides further detail and support for the proposed regulatory framework. A chart summarizing the proposed regulatory framework is attached as Appendix C.

^{1/} 70 Fed. Reg. 29214 (May 20, 2005).

A. Background

1. The Role of Food Standards Has Changed Over Time.

Pursuant to the FDCA, standards shall be established “[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers,”^{2/} and under the FMIA and the PPIA, standards may be established by the Secretary of Agriculture “whenever he determines such action is necessary for the protection of the public.”^{3/} The need for, and role of, food standards has changed significantly since these statutory mandates were enacted by Congress. Since the decades of the 1950s to 1970s, when most of the standards were adopted through rulemaking, the consumer, the marketplace, and the food label have evolved.

Food standards were initially created in 1938 to prevent fraud and to make purchasing decisions easier for consumers.^{4/} Prior to 1938, the agencies lacked the authority to take enforcement action against fraudulent products that purported to be a traditional food yet were formulated with ingredients widely viewed at the time as inferior (and often less costly).^{5/} Food standards were developed to give the agencies this authority.

At the time the first standards were issued, product names were typically the only piece of information available to consumers to help them to determine the contents of food packages.^{6/} In the late 1930s, and for many years afterward, there were no nutrition labeling rules, few ingredient labeling requirements, and no regulations to govern common or usual names for non-standard foods. Indeed, as discussed below, it was not until 1990 that standardized foods were first required to provide complete listings of all ingredients on their labels.

Early standards also were premised on consumer expectations corresponding to how foods typically were prepared in the home. Food standards, therefore, were much like government-regulated recipes that helped consumers to make purchasing decisions by ensuring

^{2/} FDCA § 401 (21 U.S.C. § 341).

^{3/} FMIA § 7 (21 U.S.C. § 607); PPIA § 8 (21 U.S.C. § 457).

^{4/} See, e.g., H. Thomas Austern, *The F-O-R-M-U-L-A-T-I-O-N of Mandatory Food Standards 2 Food, Drug, Cosm. L.Q.* 532, 541-42 (1947); Richard A. Merrill and Earl M. Collier, Jr., “Like Mother Used to Make”: An Analysis of FDA Food Standards of Identity, 74 *Colum. L. Rev.* 561, 576 (1974). [Appendix D.]

^{5/} See, e.g., Merrill and Collier, *supra* note 4; see also 61 *Fed. Reg.* 47453 (Sept. 9, 1996). [Appendix E.]

^{6/} See e.g., Austern, *supra* note 4, at 559 (describing use of a panel of “[e]ight women . . . around a table in the Department of Agriculture Building” to judge whether a canned pea product would be satisfactory if identified “simply as ‘peas’”).

consistency of similar products and preventing companies from substituting inferior ingredients or, otherwise “watering down” their products to increase profits. Moreover, as a general rule, technology permitted few accepted ways to make a food product, so flexibility in manufacturing or formulation was not a widespread need. Accordingly, standards at their inception were very effective at protecting consumer expectations, with no negative impact on innovation.

For many years, standards also played an important role in ensuring food safety and wholesomeness. Significantly, for the first few decades that most food standards were in effect, there were no food additive rules, prompting the agencies to use standards of identity to ensure that common foods contained only safe and suitable ingredients. There also were no formal rules to guide use of good manufacturing practices until 1969, and there were no formal requirements for a modernized food safety system (HACCP, or Hazard Analysis Critical Control Points) until the 1990s for seafood, meat, poultry, and later juice products. Thus, early standards promoted “honesty and fair dealing” and “protection of the public” by regulating not only identity, but safety and wholesomeness, as well.

Development of standards as a primary consumer protection tool made good sense at a time when the food standards were able to keep pace with growth in the food products category. For a time, FDA and FSIS struggled to adopt new standards to address the ever-growing number of food products offered by food processors in the face of demand for high quality, convenient, and affordable foods. By the 1980s, however, FDA and FSIS devoted fewer resources to the creation of food standard regulations. The agencies attempted to keep up with the marketplace through the development of informal standards, such as those memorialized in the FSIS *Food Standards and Labeling Policy Book* (“Policy Book”).^{7/} These efforts tapered in the mid-1990s although a large number of such standards remain and are applied routinely by FSIS.

Today, the role of standards has changed significantly as laws and regulations, other than food standards, now ensure food safety and provide informative labeling. In contrast to 1938, FDA and FSIS now have detailed regulatory requirements that ensure food safety and wholesomeness,^{8/} so standards no longer are expected (or necessary) to fulfill this role. FDA has recently confirmed that “food standards are not the primary means to ensure food safety” and that “[o]ther provisions in the Act specifically serve this function.”^{9/}

^{7/} The principles outlined in this petition apply equally to formal and informal standards. Although this petition does not propose specific changes to any informal standards, the agencies are encouraged to consider embracing a horizontal approach in the administration of informal standards, such as those set out in the FSIS Policy Book.

^{8/} These include regulations mandating current good manufacturing practices (GMPs)(21 C.F.R. Part 110 and 21 C.F.R. Part 129) and hazard analysis and critical control point systems (HACCP)(21 C.F.R. Part 120 and 9 C.F.R. Part 417).

^{9/} Letter dated April 12, 2006 from FDA to Roger Lane Carrick.

The newer laws and regulations have provided modern consumers with access to increased required information to guide product choices, including full ingredient labeling and full nutrition labeling. As FDA explained in 1995:

The 1990 amendments require that virtually all foods bear nutrition labeling. This information, plus the full ingredient list that is now required, ensures that consumers will have vastly more information about the make-up of a particular food product than was available in 1938. This information should make it immediately apparent if a marketer is attempting to sell a debased or watered down food.^{10/}

Thus, a major basis for the specificity and rigidity of food standards became obviated by these new rules, which have now been in effect for over a decade and apply to both FDA-regulated and FSIS-regulated foods. The inflexible nature of food standards, therefore, is a reflection of the historical development of food regulations. The greater flexibility proposed by this petition largely addresses those features of the food standards that are obsolete due to the development of food labeling and safety regulations.

2. Consumer Expectations Have Changed Over Time.

There also have been significant changes from the consumer purchasing perspective. Today, there is an enormous emphasis on diversity and individuality that did not exist in 1938. In fact, today's increasingly sophisticated consumers demand more from traditional foods, a reflection of the ever-changing concept of prepared foods. They want variety, healthfulness, convenience, value, novelty, ethnically-oriented foods, and sometimes, several or all of the above. Modern conveniences, such as the freezer and the microwave, and consumer habits, such as increased demand for "on the go" and "nutritionally improved" products, have also influenced how consumers view and consume food.^{11/}

Innovation offers nearly limitless opportunities to respond to rapidly changing consumer preferences and expectations—the driving force behind food standards. Because notice-and-comment rulemaking is required to adapt food standards to a changing marketplace, however, food standards are often an impediment to the innovation necessary to meet consumer needs. It is this inherent rigidity in food standards that this petition seeks to address. ^{12/}

The rigid nature of food standards also stands as an impediment to improving the nutritional profile of many foods. In the 2005 *Dietary Guidelines for Americans* and the

^{10/} 60 Fed. Reg. 67469, 67497 (Dec. 29, 1995).

^{11/} Sloan, A. Elizabeth, "What, When, and Where Americans Eat: 2003," *Food Technology*, 57: 48-66, (Aug. 2003). [Appendix F.]

^{12/} Adding flexibility of the type requested is clearly within the agencies' statutory authority, as evidenced by existing regulations employing a horizontal approach.

MyPyramid food guidance system, the federal government has encouraged consumers to seek out and consume more healthful varieties of foods. One of the fundamental goals of the Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, which mandated nutrition labeling of FDA-regulated foods and guided the implementation of USDA's self-initiated nutrition labeling reform, was "to encourage product innovation through the development and marketing of nutritionally-improved foods."^{13/} In 2004, a report by FDA's Obesity Working Group recommended research to identify regulatory barriers to the marketing of healthful foods. Although both FDA and FSIS have added substantial flexibility in regulations allowing certain foods to vary from a standard for the purpose of complying with a nutrient content claim (i.e., 21 C.F.R. § 130.10 and 9 C.F.R. §§ 319.10 and 381.172), many beneficial improvements are still precluded. For example, a food can vary from a standard if it bears a claim for a 25% reduction in calories, but not a 15% reduction; fiber can be added to macaroni to make a "high fiber" macaroni, but "whole wheat macaroni" is not permitted unless it contains 100% whole wheat flour, even though many consumers may be more likely to repeatedly consume a whole wheat product with some amount of refined grains. Thus, the marketplace has been unable to completely meet both consumer needs and government expectations in a reasonable way.

As consumers have grown more sophisticated, so has the marketplace. In the 1920s, grocery stores contained, on average, only 700 items; this increased to 14,000 by 1980 and to more than 30,000 items in recent years.^{14/} Many of these items are made possible by improved technology that creates an array of products and ingredients not previously available. It is noteworthy that the vast majority of products marketed today (over 75%) are not standardized products, yet are well accepted by both consumers and the government. Intense competition ensures that food products that fail to meet consumer expectations will not survive in the marketplace.

Consumer expectations still define the basic nature of a food. There are, however, no generally held consumer expectations today concerning the precise technical elements by which commonly recognized, standardized foods are produced. Consumers, therefore, are not likely to have formed expectations as to production methods, aging time, or specific ingredients used for technical improvements, including manufacturing efficiencies. If food standards are to be truly modern, they must be designed in a way that allows beneficial technologies, safe and suitable ingredients, and nutritional improvements that are consistent with the basic nature and essential characteristics of the food.

^{13/} 58 Fed. Reg. 2302 (January 6, 1993).

^{14/} Food Marketing Institute News Release, "America Celebrates the 75th Anniversary of the Supermarket" (Aug. 1, 2005). [Appendix G.]

3. The Government's Approach to Food Standards Has Evolved in Response to These Changes.

Given the significant evolution of the role of food standards, consumer expectations, and the resulting marketplace, both FDA and FSIS already have recognized the importance of flexibility. Beginning in the 1960s, FDA has consistently sought to broaden its standards-related policies to incorporate more flexibility. For example, in 1965, FDA departed from a strict recipe approach and began to allow “safe and suitable ingredients” in standards, such as the safe and suitable “batter and breading ingredients” permitted in breaded shrimp products.^{15/} In 1973, FDA recognized the value of new technologies and decided to narrow the scope of “imitation” products and address common or usual names for non-standardized foods.^{16/} FDA also has provided for the use of “alternate make” in some food standards.^{17/} In 2003, FSIS, too, sought to provide flexibility in food standards by promulgating regulations authorizing the use of safe and suitable binders and antimicrobial products where existing standards permit these types of ingredients.^{18/}

Perhaps the most significant development in terms of standards flexibility occurred in 1993 and in 2005, when FDA and FSIS, respectively, adopted regulations allowing food products to vary from a standard for the purpose of making a nutrient content claim. The agencies have confirmed this natural progression. As FDA stated, with regard to food standards, “its policies have always evolved, even in the absence of significant legislative amendments to the act.”^{19/}

International developments underscore the importance of a modern food standards system. In 1994, Congress enacted the Uruguay Round Agreements Act, which included two new international trade agreements that are relevant to the U.S. food standards system—the Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”) and the Agreement on Technical Barriers to Trade (“TBT Agreement”). These agreements are intended to facilitate trade by encouraging the adoption of international standards, guidelines, and recommendations, such as food standards issued by the Codex Alimentarius Commission. The petitioners support harmonization of U.S. standards with international standards, particularly Codex, where such harmonization is scientifically justified, consistent with U.S. law, and

^{15/} 30 Fed. Reg. 2860 (Mar. 5, 1965).

^{16/} 38 Fed. Reg. 6964 (Mar. 14, 1973) (issuing final rule to govern the common or usual name of non-standardized food); 38 Fed. Reg. 20702 (Aug. 2, 1973) (issuing final rule to provide that a food substituting for another food is not required to be labeled as an “imitation” unless nutritionally inferior to that food).

^{17/} See, e.g., 21 C.F.R Part 133 (the cheese standards).

^{18/} 9 C.F.R. §§ 319.1(b) and 381.155(b).

^{19/} 56 Fed. Reg. 60512, 60517 (Nov. 27, 1991).

otherwise appropriate. Flexibility in U.S. standards will promote equivalence with Codex standards and support an ongoing U.S. leadership role in Codex.

4. The Procedural Difficulties and Delays in Amending the Current Food Standards Are Daunting.

Given the growing need to update individual food standards, the lack of resources to do so in a reasonably efficient and reliable manner is particularly concerning. Over the years and with good reason, the agencies' priorities for allocating their limited resources have focused mainly on public health and safety issues and have shifted away from economic-based issues like food standards. Accordingly, a considerable backlog of pending food standard petitions has accrued. At FDA, for example, numerous standards petitions are pending, and many of these have been pending for five or more years.^{20/} This difficulty in anticipating an agency response to a food standard petition is a disincentive to those who otherwise may invest the resources in filing such a petition, and it has been compounded by the difficulty and length of time required to obtain temporary marketing permits.

To highlight the need to streamline the process for amending food standards, one need look no further than the circumstances surrounding the pending rulemaking to amend the colby cheese and cheddar cheese standards. In 1985, the National Cheese Institute (NCI) submitted a citizen petition to FDA, requesting that the agency amend sixteen standards of identity to provide for the use of safe and suitable antimycotic agents on the surface of certain cheeses during manufacture. FDA found NCI's requests to have merit, concluding that "the use of antimycotics will reduce waste in the manufacture of cheese and is in the best interest of both consumers and industry."^{21/} Accordingly, FDA issued two proposed rules in 1987. The first

^{20/} See, e.g., Docket No. 1994P-0286 (U.S. Tuna Foundation petition to amend portions of the canned tuna standard)(July 28, 1994); Docket No. 1995P-0078 (Calorie Control Council petition to permit the removal of fat from standardized foods)(withdrawn and resubmitted to Docket No. 96P-0143); Docket No. 1997P-0043 (American Bakers Assoc. petition to amend definitions and standards of identity for bakery products)(Feb. 4, 1997); Docket No. 1997P-0142 (International Jelly & Preserve Assoc. petition to repeal standards of identity for artificially sweetened jam)(Apr. 7, 1997); Docket No. 1998P-0047 (Association for Dressing & Sauces petition to amend identity standards for mayonnaise, French dressing, and salad dressing)(Jan. 16, 1998); Docket No. 2000P-0685 (National Yogurt Association petition to revise yogurt standards)(Feb. 18, 2000); Docket No. 2000P-0586 (National Cheese Institute and GMA petition to amend the milk and nonfat milk standards)(June 13, 2000); Docket No. 2000P-1491 (Kraft Foods, Inc. petition to amend definition and standard of identity for parmesan cheese)(Aug. 30, 2000); Docket No. 2000P-1572 (State of Alaska petition to adopt standard of identity for glacier water)(Oct. 18, 2000); Docket No. 2003P-0132 (International Ice Cream Association petition to amend the standards for frozen desserts)(Mar. 31, 2003); Docket No. 2003P-0171 (Del Monte Corp. petition to amend the standard of identity for canned tomatoes)(Apr. 23, 2003); Docket No. 2005P-0295 (Alaska Birch Syrupmakers Association petition to amend standard for Pure Birch Syrup and Birch Breakfast Style Syrup) (July 26, 2005); Docket No. 2005P-0332 (American Bakers Association petition to amend the standards for bakery products)(Aug. 18, 2005).

^{21/} 52 Fed. Reg. 35426, 35426-27 (Sept. 21, 1987).

addressed twelve standardized cheeses,^{22/} while the second focused on colby cheese, cheddar cheese, colby cheese for manufacturing, and cheddar cheese for manufacturing. FDA made clear that its decision to issue two separate proposals was prompted solely by administrative convenience because the cheddar-colby standard revisions would also permit the use of salt substitutes in these standardized cheeses and repeal the standards of identity for low sodium colby and low sodium cheddar.^{23/} Although a final rule updating the twelve cheese standards that were the subject of the first proposal published on August 4, 1989,^{24/} the colby-cheddar proposal was never finalized due to resource limitations at the agency. It has now been nearly twenty years, and FDA has yet to complete the rulemaking for these two cheeses, even though there is every reason to believe that FDA has no concerns about the appropriate use of antimycotic agents.

Accordingly, a realistic approach to food standards modernization must take account of the agencies' resource dilemma. It simply is not feasible to think that the agencies could make meaningful and timely changes on a standard-by-standard basis if notice-and-comment rulemaking is required for each of the codified standards, which now number over 280 at FDA and over 65 at FSIS. All of these factors, including the current role of food standards and the difficulty in efficiently amending and revising them, suggest a compelling need for FDA and FSIS to evaluate carefully how best to promote "honesty and fair dealing in the interest of consumers," to ensure "protection of the public," and to develop an approach to food standards that will best ensure that the standards keep up with the times and the global marketplace.

5. The Agencies' "General Principles" Provide an Excellent Catalyst for the Next Generation of Food Standards Reform.

FSIS and FDA have recognized the importance of modernizing the food standards system and published a set of joint "General Principles" in a proposed rule issued in May 2005.^{25/} Many of these principles are incorporated into this petition, namely:

- The food standard should protect the public and promote honesty and fair dealing in the interest of consumers.
- The food standard should describe the basic nature and reflect the essential characteristics of the food.
- The food standard may be used as a vehicle to improve the overall nutritional quality of the food supply.

^{22/} *Id.*

^{23/} 52 Fed. Reg. 35435 (Sept. 21, 1987).

^{24/} 54 Fed. Reg. 32050 (Aug. 4, 1989).

^{25/} 70 Fed. Reg. 29214 (May 20, 2005).

- The food standard should permit maximum flexibility in the food technology used to prepare the standardized food.
- The food standard should provide for any alternative manufacturing process that accomplishes the desired effect.
- The food standard should describe ingredients as broadly and generically as feasible.
- The food standard should be harmonized with international food standards to the extent feasible.
- The food standard should be simple, easy to use, and consistent among all standards, including only those elements necessary to define the basic nature and essential characteristics of the food and eliminating unnecessary details.

This proposed rule showed insight into the kinds of issues that must be addressed in modernizing the food standards program. The primary missing element of that proposal, however, is an efficient process to effectuate these changes, as the agencies proposed to implement those principles through the lengthy standard-by-standard, notice-and-comment rulemaking process. Continued reliance on a “vertical” approach for each food standard is not realistic or feasible, nor is reliance on a “vertical” standard-by-standard approach necessary to accomplish the goals of food standards. Rather, this petition calls upon the agencies to take the logical and necessary next step—not simply to recognize the enormous value of the *content* of those general principles, but to implement them through a different *process* that would provide sweeping improvements through issuance of a single, “horizontal” regulation.

B. The Agencies Should Adopt a Horizontal Approach to Food Standards Modernization.

1. The Agencies Have Clear Precedents for a Horizontal Approach.

A generally applicable regulation by which all standards could be updated, rather than a vertical approach dictating standard-by-standard amendments, would be a direct extension of approaches that the agencies have previously taken to update food standards. FDA and FSIS both have improved the flexibility of the standard-setting process by allowing for variations for the purpose of meeting nutrient content claim criteria, and FSIS has allowed flexibility to use binders and antimicrobial products where existing standards permit these types of ingredients.^{26/} When FDA promulgated 21 C.F.R. § 130.10 in 1993, it recognized the unique benefits of this approach. In the *Federal Register* notice announcing the final rule, FDA commented:

^{26/} 9 C.F.R. §§ 319.1(b) and 381.155(b).

[E]stablishing a general definition and standard of identity for modified versions of standardized foods that qualify for use of a nutrient content claim is a more efficient way to provide consumers with these foods than having to issue temporary marketing permits to each manufacturer desiring to market test a new modified food and, ultimately, establishing individual new food standards for each new modified version.^{27/}

Most recently, FSIS embraced flexibility in adopting a similar rule for meat and poultry products:

The rule allows FSIS to rely more on labeling requirements and less on restrictive recipe-type standards to carry out its mandate to ensure that the labels of meat and poultry products are truthful and not misleading to consumers.^{28/}

This horizontal approach, already applied by the agencies in the nutrient content claim and ingredient contexts, could be equally applied to other aspects of the food standards, as explained more fully below.

2. The Key to the Horizontal Approach is to Provide Needed Flexibility While Still Maintaining the Basic Nature and Essential Characteristics of the Food.

A horizontal regulation would benefit the agencies, the food industry, and consumers. A single regulation that adds flexibility to all standards at once would promote honesty and fair dealing, keep pace with the dynamic marketplace by allowing for advances in technology and nutrition science, meet the general principles outlined in the agencies' 2005 proposal, and facilitate legitimate international trade. The key to this horizontal approach is to provide flexibility in the food standards to permit needed innovation, while still maintaining the core of the food standards—the basic nature and essential characteristics of the food.

By providing flexibility to update food standards, a horizontal regulation simply would be placing standardized foods on equal footing with non-standardized foods. That is, ingredients that are recognized as safe for use in non-standardized foods could be used in standardized foods; processes recognized as efficient for the production of non-standardized foods could be used to produce standardized foods; and, ingredients/nutrients recognized as beneficial in non-standardized foods could be used in standardized foods as well. By no means would the proposed horizontal regulation represent preferential treatment for the standardized foods. The goal is simply parity with non-standardized foods.

^{27/} 58 Fed. Reg. 2431, 2432 (Jan. 6, 1993).

^{28/} 70 Fed. Reg. 33803, 33804 (June 10, 2005).

In this regard, standardized foods would continue to be subject to all the same food safety and labeling regulations as non-standardized foods. It is also important to emphasize that the existing food standards regulations would remain in place. Just as with 21 C.F.R. § 130.10 and 9 C.F.R. §§ 319.10 and 381.172, a new horizontal regulation would provide a cross-cutting overlay across the broad array of existing food standards, not remove or replace them. This ensures the continued requirements that standardized foods retain their basic nature and essential characteristics.

3. A Horizontal Regulation Needs Clear Boundaries to Prevent Abuse.

The petitioners recognize the importance of balancing the flexibility offered by a new regulation of general applicability with objective criteria that set reasonable boundaries around that flexibility. Such a balance will allow reasonable variations in the food standards, while ensuring that changes do not meaningfully alter the basic nature and essential characteristics of standardized foods. Boundaries were built into 21 C.F.R. § 130.10 and 9 C.F.R. §§ 319.10 and 381.172, and they should be incorporated into a new horizontal regulation, as well.

To alter a standardized food pursuant to 21 C.F.R. § 130.10, for example, several objective criteria must be met. A food must meet the general requirements set forth in § 101.13 for foods bearing nutrient content claims, as well as the requirements of the regulations that define the particular nutrient content claim that is used. The food may not be nutritionally inferior, as defined in §101.3(e)(4), to the standardized food. The performance characteristics of the food must be similar to those of the standardized food, or otherwise provide notice to the consumer (e.g., if appropriate, “not recommended for cooking”).^{29/} Ingredients not provided for by the standard must be safe and suitable ingredients used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food. And, when such ingredients are used, a label declaration must be made to highlight that the ingredient is not typically in the standardized food.^{30/}

These types of boundaries have placed objective limits on the flexibility granted by § 130.10. This petition suggests similar boundaries to ensure that a new regulation of general applicability also will provide for innovation in an efficient, sweeping fashion, while at the same time protecting the role of food standards and consumer expectations associated with product names.

^{29/} The modified product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product, and any clarifying label statements provided for consumers must comply with the requirements of 21 C.F.R. §101.13(d).

^{30/} 21 C.F.R. § 130.10.

C. The New Horizontal Regulation Should Provide Flexibility in Six Key Areas.

Standards reform is needed to eliminate unnecessary barriers to beneficial new technologies, processes, and ingredients that allow for greater manufacturing efficiencies, and to permit measures to improve product quality, satisfy consumer demands for variety, and make food products more nutritious. A careful review of the agencies' regulations, temporary marketing permits granted over the years, and petitions seeking reform of food standards reveals that flexibility would be especially beneficial in six key areas. Flexibility in these areas would allow, within appropriate boundaries, variations from established standards for the following reasons:

- Addition of ingredients intended solely for technical, nondistinctive effects, such as emulsifiers, stabilizers, or antimycotic agents
- Use of safe and suitable flavors and flavor enhancers in standardized foods generally, and use of safe and suitable ingredients such as salt substitutes, sweeteners, and vegetable fats and oils when appropriate
- Use of advanced or more efficient technologies to produce ingredients of all types, such as enzyme technologies that enhance the properties of egg yolk used in mayonnaise
- Use of alternate manufacturing processes, also known as "alternate make" procedures, for those standards that specify particular processes
- Changes to a product's basic shape in response to consumer demands, such as "chunky" stewed tomatoes
- Improvements in nutritional properties that do not rise to the level of a defined claim (e.g., reducing calories by 10% rather than requiring a 25% minimum reduction), or use of nutritious ingredients like whole grains

An appropriate regulation that allows for changes such as these in a thoughtful and controlled manner would greatly reduce barriers to innovation, benefiting consumers, the agencies, and the industry. The regulation would itself be a type of food standard, and the resulting food would still be a standardized food, but with greater latitude to meet the needs of a modern marketplace. ^{31/}

^{31/} As a type of food standard, a horizontal regulation would have preemptive effect under the FDCA, FMIA, and PPIA.

1. Safe and Suitable Ingredients Used Solely for Technical, Nondistinctive Effects

The modern marketplace offers a wide selection of ingredients designed to provide one or more important “technical” effects in food, such as antimicrobial activity, emulsification, or pH control. In recognition of the generally interchangeable nature of such technical, nondistinctive ingredients, food standards have been increasingly revised to permit broad ingredient categories (e.g., “emulsifying agents”) instead of specific ingredients (e.g., “monosodium phosphate”). This flexibility makes good sense because such ingredients are typically used at very low levels (e.g., less than 2%), are not directly perceptible to consumers, and therefore do not serve to distinguish one product from another. Although consumers may be aware of the end result—e.g., improved quality—of these ingredients, the ingredients themselves are not usually considered to be distinguishing components of any food, standardized or non-standardized.

Despite the progress made on some standards, far too much specificity remains in the regulations, especially those administered by FDA. To allow much-needed flexibility in this area, a horizontal regulation should provide for the general use of safe and suitable ingredients intended solely for a technical, nondistinctive effect. The type of ingredients eligible for this flexibility would include those listed in 21 C.F.R. § 170.3(o) with the exception of flavoring agents, flavor enhancers, nutritive ingredients, and sweeteners, which are addressed under other categories.

The petitioners propose that a horizontal approach allow for two types of flexibility with respect to technical ingredients: the ability to substitute an ingredient in a particular category for one already listed in the standard (e.g., to use any safe and suitable anti-caking agent where the standard lists one agent specifically); and the ability to add a technical ingredient not mentioned in the standard. Regulatory precedent supports both approaches.

a. Substitution

In 2003, FSIS sought to provide flexibility in food standards by adopting regulations authorizing the use of safe and suitable binders and antimicrobial products where existing standards permit these types of ingredients.^{32/} At that time, FSIS determined “that conducting rulemaking to amend individual food standards of identity to permit the addition of new ingredients on a case-by-case basis is not an efficient use of Agency resources and results in unnecessary delays for the use of safe and suitable binders and antimicrobial agents by meat and poultry establishments.”^{33/} Because FSIS, at the time, received approximately two to three petitions annually addressing antimicrobials or binders, it tailored its regulation to these

^{32/} 9 C.F.R. §§ 319.1(b) and 381.155(b).

^{33/} 68 Fed. Reg. 22576, 22577 (Apr. 29, 2003).

functional use categories. No reason was given, however, that would limit this approach to those two categories.

The reasonable approach embraced by FSIS applies to the broad range of functional use categories. Thus, the concept from this FSIS regulation should be expanded to cover all FSIS standards and used as a model for FDA as well. The outcome would be a new regulation that permits the substitution of safe and suitable ingredients used solely for technical, non-distinctive effects where ingredients in the same functional use categories are already permitted in the individual food standard.

The effect of this proposed change can be seen in the following example. The current “pineapple juice” standard is very specific and provides for the use of one defoaming agent—dimethylpolysiloxane.^{34/} In contrast, the current “syrup” standards are much more flexible and permit the use of any approved “defoaming agent.”^{35/} In fact, FDA has approved the use, with certain limitations, of many defoaming agents.^{36/} The purpose of the proposed food standards regulation would be to give all standards allowing use of a particular defoaming agent, like the pineapple juice standard, the same flexibility as now exists for the syrup standards. In this way, all standards providing for the use of a technical ingredient within a particular use category should have the flexibility to use other safe and suitable ingredients within the same category.

This one modification, to allow the substitution of safe and suitable ingredients used solely for a technical purpose, would add considerable flexibility, benefiting consumers, industry, and the regulatory agencies. The approach would be a natural extension of flexibility the agencies have already afforded food standards in other areas. As FSIS stated in establishing its horizontal regulation to permit increased flexibility for the use of binders and antimicrobial ingredients:

[T]he objective to be accomplished by this direct final rule is to provide for efficient use of Agency resources and to provide establishments greater flexibility in the formulation of meat and poultry products with a standard of identity and composition in 9 C.F.R. parts 319 and 381 which already permit the use of ingredients of these types.^{37/}

Based on these principles, if a standard already provides for the use of an ingredient in a particular technical category, the development and marketing of products subject to the standard

^{34/} 21 C.F.R. § 146.185.

^{35/} 21 C.F.R. §§168.130-180.

^{36/} 21 C.F.R. § 173.340.

^{37/} 68 Fed. Reg. 22576, 22577 (Apr. 29, 2003).

should not be hindered by the inability to use readily exchangeable ingredients, especially since non-standardized products are subject to no such restrictions.

b. Addition

The new regulation should also provide for the general use of safe and suitable technical ingredients in standardized foods, so long as such ingredients are not expressly prohibited by the standard or an agency requirement. In other words, the use of ingredients intended solely for a technical, non-distinctive effect should not be precluded in standardized foods simply because the standard does not list the ingredients or the particular conditions of use. Like the flexibility to make appropriate substitutions, this modification would put standardized foods on a level playing field with non-standardized foods.

This flexibility could be applied in at least two ways. First, ingredients already allowed (i.e., safe and suitable) for use in a particular type of non-standardized food could also be used in standardized food. For example, as finalized in 1982, the yogurt standard did not allow for preservatives, ingredients that are used for a purely technical effect in a wide variety of food products. Following objections filed in response to this limitation, FDA stayed the standard in this respect and decided to exercise enforcement discretion, allowing use of preservatives pending a hearing that was never scheduled. For well over twenty years, preservatives have been allowed in yogurt without any apparent issues. Indeed, in its petition to update the yogurt standards, the National Yogurt Association asked FDA to amend the standard to allow preservatives on a permanent basis. FDA's treatment of yogurt provides useful precedent and a real-life example of how small changes of a technical nature can be made to a standardized food without jeopardizing the product's basic nature or essential characteristics.

Second, ingredients allowed in a standard, but limited in a way that does not relate to the basic nature or essential characteristics of the food, could be "added" to new applications within the same standard. For example, the cheddar cheese standard provides for the application of "antimycotic agents" to the surface of slices or cuts in consumer-size packages, but not to cheese in bulk form. There is no scientific or other justification for this restriction, which, as described previously, is simply an anomaly of the rulemaking process and in conflict with almost all other cheese standards. An allowance to "add" new antimycotic uses not expressly sanctioned in a particular standard, but clearly consistent with the standard, would provide needed flexibility and remedy this apparent oversight.

The petitioners recognize that there will be some situations where addition of an ingredient intended solely for a technical effect, even if safe and suitable, may not be appropriate. For example, the use of a chemical preservative in fresh ground beef is likely to conflict with the FSIS policy on "fresh" products, and thus would not be allowed on that basis. Significantly, the FSIS policy on ingredient approvals, which ensures the safety and suitability of all ingredients used in FSIS-regulated meat and poultry products, can help ensure that ingredients

used in standardized products are acceptable. Limitations may be particularly appropriate for standardized foods that consist primarily of one ingredient, such as “ground beef.”^{38/}

2. Flexibility to Use Flavoring Ingredients, Salt Substitutes, Sweeteners, and Vegetable Fats and Oils

In contrast to ingredients used solely for technical effects, which are not distinguishable to consumers, ingredients such as flavors, flavor enhancers, salt substitutes, sweeteners, and vegetable fats and oils are more typically used to impart familiar and/or readily apparent properties to food. Such ingredients are used freely in non-standardized foods, so long as basic safety and related requirements are met; there is no reason why similar flexibility should not be allowed for standardized products. Thus, a horizontal approach to standards reform should allow for the appropriate use of these well-accepted ingredients.

As intended by the petitioners, this type of flexibility would permit the use of flavors and flavor enhancers in standardized foods generally, since such ingredients can be appropriately used in most foods. These ingredients could not be used, however, if expressly prohibited by the applicable standard.

Use of salt substitutes, sweeteners, and vegetable fats and oils, which are customarily added to a more narrow range of foods, should be generally allowed only where the standard already provides for at least one form of these ingredients. For example, where a standard provides for salt, a safe and suitable salt substitute could be used. Where a standard provides for any specific sweetening ingredient, any safe and suitable sweetening ingredient could be substituted (nutritive or non-nutritive) in its place. Where a standard allows for the addition of a particular vegetable fat or oil, the use of any safe and suitable vegetable fat or oil would be allowed. These limitations are necessary because there are certain foods to which salt, sweeteners, and vegetable fats and oils are not customarily added (e.g., macaroni products do not customarily contain sweetening agents; fruit jellies are not made with salt).

3. Beneficial Technologies to Produce Ingredients Used in Standardized Food

In the last several decades, food ingredient technologies have advanced significantly. At the same time, with an increasingly national and global food supply, issues of supply and manufacturing efficiencies can be challenging. These developments point to the need for a horizontal regulation to accommodate the production of key ingredients in standardized foods in innovative ways. In principle, the concept is a type of “alternate make” allowance for ingredients—in other words, permission to use appropriate optional procedures and technologies to produce key ingredients of standardized foods.

^{38/} See e.g., 9 C.F.R. §§ 319.15 and 319.107.

Optional procedures are reasonably considered appropriate if three criteria are met. First, both the ingredient listed in the standard and its more innovative counterpart must begin with the same starting material (e.g., egg yolk). Second, as used in the standardized food, the innovative ingredient must perform a function equivalent to the traditional form. Third, as discussed more fully below (Section D), the finished food must retain the essential characteristics of the product produced under the standard. Notably, the innovative ingredient is not necessarily physically, chemically, or otherwise equivalent to the ingredient listed in the standard, but must begin from the same point, perform the same function in the standardized food, and result in an equivalent finished product. Examples of ingredients that would benefit from this type of flexibility include egg yolk used in mayonnaise and dairy ingredients used in ice cream, cheese, or yogurt.

For example, certain enzyme technologies are now available to modify an egg yolk to introduce emulsification properties that are superior to traditional egg yolk ingredients. The ingredient is still egg yolk, but in an improved form; when used in mayonnaise, it still acts as an emulsifier, but with a superior mode of action. So long as a finished mayonnaise made with this ingredient retains equivalent physical, chemical, organoleptic, and other properties expected of mayonnaise, and all components are safe, suitable, and properly labeled, innovations such as these should be allowed.

The use of reconstituted milk as a basic dairy ingredient in yogurt provides a good example of variances that promote manufacturing efficiencies. For more than twenty years, FDA has not objected to the production of yogurt using reconstituted milk, even though the standard as initially finalized excluded the use of reconstituted condensed or dry milk as basic ingredients in yogurt. The issue arose as a result of objections filed in response to the final rule: objectors noted that exclusion of reconstituted ingredients would adversely affect yogurt manufacturers in the South, where fluid milk supplies were said to be often insufficient, causing the price of yogurts to be unnecessarily inflated in those areas. Pending a hearing that never occurred, FDA stayed the exclusion of reconstituted ingredients and advised that it would not object to their use in yogurt. Over two decades later, the National Yogurt Association petitioned FDA to revise the standard to provide for this now-accepted practice.

Although any technically equivalent ingredient that produces an acceptable finished product should be allowed under this type of provision, the petitioners appreciate that the agencies may wish to exclude certain ingredients or technologies that, due to sharply opposing views from stakeholder groups, have been controversial. For example, over the years, the use of milk protein concentrate (MPC) in the production of cheese has resulted in considerable controversy, even though MPC can be used to produce cheese products of high quality. In the interest of advancing the numerous worthy objectives proposed in this petition, the petitioners would not object to carving out ingredients like MPC, for which it may be difficult to achieve consensus, from the proposed horizontal framework.

4. Alternate Manufacturing Processes

Many food standards identify specific methods that must be used in the processing and preparation of covered foods. For instance, the standard for “Country Ham” specifies not only the ingredients that must be used in the products, but also the length of time required for salt penetration.^{39/} Certain egg standards specify procedures for removing glucose, while other standards require or permit specific processes, such as pasteurization, processing by heat to prevent spoilage, or homogenization. Specifically identified procedures reflect the limits of prevailing food technology at the time the standards were drafted and mandate certain processes that, at the time of their adoption, were deemed appropriate to achieve end-product characteristics associated with the standardized food. Thus, at the time many standards were finalized, a prescriptive approach to processing provided the means to ensure the desired outcome, yet was not recognized as limiting innovation.

Since most of the food standards were promulgated, food technology has evolved, and food manufacturers now can use alternative processes to reach results equivalent to those of processes mandated by many of the standards. Indeed, FDA has recognized that it is “almost impossible to keep food standards up-to-date with advances in food technology and nutrition.”^{40/} In recognition of this principle, the agency has provided for the use of alternative processes in some food standards, as long as the basic nature and essential characteristics of the finished food remain the same. For example, many of the cheese standards contain so-called “alternate make” provisions, which allow preparation of the cheese according to specified procedures “or by any other procedure which produces a finished cheese having the same physical and chemical properties.”^{41/}

Using these existing “alternate make” provisions as a model, the agencies should provide for alternative processes to be used in all standards where specific processes are dictated. This would provide the flexibility for manufacturers to use improvements in food technology, without requiring standard-by-standard amendments. For example, if a company is able to develop a preferred alternative to the optional glucose-removing procedures identified in the egg products standards, it should be allowed to do so if the procedures do not change the basic nature or essential characteristics of the egg products at issue. Similarly, appropriate flexibility should be allowed for technologies other than thermal treatment that are scientifically acceptable to ensure microbiological safety or to prevent spoilage.

Flexibility in terms of alternate make should be allowed anywhere a standard requires a specific manufacturing or other approach, not simply where a standard designates a particular “procedure.” For example, in the cheese standards, minimum aging periods are not

^{39/} 9 C.F.R. § 319.106.

^{40/} 56 Fed. Reg. 60512, 60513 (Nov. 27, 1991).

^{41/} See e.g., 21 C.F.R. § 133.113 (“cheddar cheese”).

presently included in the “make” procedures per se, yet they clearly dictate how the product is to be made. Flexibility is just as important for minimum aging as it is for other areas, since advanced enzyme technologies now allow an alternative way to produce a cheese with the same essential characteristics as a cheese made under the existing standards.

The “alternate make” approach could also apply where the standard itself is designed to address processing techniques. For example, the standard for “Barbequed Beef” requires dry heat cooking by burning hardwood or hot coals for a period sufficient to create the characteristic brown crust of barbequed meats.^{42/} Yet, manufacturers of barbequed beef now have modern processes to produce a food with the “brown crust” and “rendering of surface fat” that characterizes barbequed meats, without “the burning of hard wood or the hot coals” as currently required by the standard.^{43/} This approach would be consistent with FSIS’ revised policy with regard to roasted products. Although FSIS policy formerly required that “roasted” only be used to describe meats cooked by use of a dry heat method, the Policy Book now provides that “roasted may be used to describe products that have been subjected to cooking methods that result in a roasted appearance.”^{44/}

5. Changes to Product Form or Shape

Product appearance is an important part of food marketing and innovation. In many cases, the form or shape of a food may be readily changed without altering its basic nature or essential characteristics. To accommodate these types of changes, which can be critical to satisfying consumer demands for improved function, variety, and novelty, a horizontal regulation should allow changes in product form or shape that do not alter the basic nature or essential characteristics of the food.

For example, there should be no barriers to marketing products like “chunky” tomatoes (as opposed to whole, diced, sliced, or wedges), “whole” canned pineapple (as opposed to slices, spears, chunks, etc.), or bread in packages weighing less than ½ pound. In each case, only the physical form—not the basic nature or essential characteristics of the food—is changed. Significantly, the nature of all changes of this type is immediately apparent to the consumer.

Similarly, macaroni products are described in the relevant standard of identity in terms of “macaroni” (i.e., a tube-shaped product of a particular size), “spaghetti,” and “vermicelli” shapes. The shape of a macaroni product, however, does not affect its status as a food prepared by drying formed units of dough made from appropriate ingredients and water. Thus, there is no reason why a product that complies with the compositional elements of the standard but that is sold in a different shape, such as cartoon characters or shells, should not be

^{42/} 9 C.F.R. § 319.80.

^{43/} 9 C.F.R. § 319.80.

^{44/} FSIS Policy Book (Aug. 2005).

identified as a “macaroni product” or “enriched macaroni product.” Indeed, this practice is arguably permitted by the standard as currently written, but the proposed regulation would clarify the status of these products.

6. Nutritional Improvements

Current regulations provide for appropriate deviations from food standards for the purpose of complying with a nutrient content claim; however, other nutritional modifications to standardized foods are limited, even though such improvements are routinely made to non-standardized foods. FDA and FSIS should revise their regulations to place manufacturers of standardized foods on the same footing as manufacturers of non-standardized foods, so long as the standardized foods retain their basic nature and essential characteristics.

As discussed above, the federal government has long encouraged industry to produce, and consumers to eat, a variety of healthful foods. A major goal of the NLEA and its resulting regulations was “to encourage product innovation through the development and marketing of nutritionally-improved foods.”^{45/} Further, through the *Dietary Guidelines for Americans* and the development of the MyPyramid guidance system, the government has encouraged consumers to seek out healthful options. The *Dietary Guidelines* and MyPyramid also recognize the value of taking small but gradual steps to improve health.

Recent data indicate that consumers are responding, as the number of health-conscious Americans is at an all-time high. According to a survey, two-thirds of Americans say they eat healthier than they used to.^{46/} And, one-third now say they select foods primarily based on nutritional content.^{47/} A 2002 Harvard University survey found that 54% of (adult) respondents read nutrition labels on food items most or all of the time.^{48/} Sixty-two percent read magazines or books about food and nutrition at least sometimes.^{49/} These figures reveal that Americans are increasingly committed to selecting appropriate foods for health.

More than a decade ago, FDA and FSIS recognized that reform was needed to allow marketing of nutritionally improved versions of standardized foods. In 1991, FDA noted consumers’ “strong desire” for more healthful versions of standardized foods and said that its

^{45/} 58 Fed. Reg. 2302 (January 6, 1993).

^{46/} Sloan, *supra* note 11, at 49.

^{47/} *Id.*

^{48/} Taeku Lee and J. Eric Oliver, Public Opinion and the Politics of America’s Obesity Epidemic, John F. Kennedy School of Government, Harvard University Faculty Research Working Papers Series, #RWP02-017 (May 2002). [Appendix H.]

^{49/} *Id.*

objective “is to facilitate, not to hinder, consumer’s selection of healthful alternative foods.”^{50/} In 1993, FDA recognized that the horizontal approach in § 130.10 “is a more efficient way to provide consumers with these foods than having to issue temporary marketing permits to each manufacturer desiring to market test a new modified food and, ultimately, establishing individual new food standards for each new modified version.”^{51/} FSIS echoed these views when it applied similar flexibility to meat and poultry products in §§ 319.10 and 381.172. FSIS recognized that such flexibility was “needed to facilitate the development and availability of substitute standardized meat and poultry products that have reductions in constituents that are of health concern to some people, e.g., fat, cholesterol, and sodium.”^{52/} FSIS has also recognized “that some of the current standards may impede innovation, or slow the introduction into the marketplace of products with reductions in certain constituents of health concern to some people.”^{53/}

The innovative approach taken in the agencies’ regulations for nutritionally improved standardized foods has allowed considerable flexibility to modify standardized foods for the purpose of meeting agency-defined nutrient content claims. This flexibility has resulted in an abundance of beneficial products not previously allowed, such as low fat ice cream, reduced fat cheese, and low fat pepperoni. As useful as the current framework is, however, it remains bound by the agencies’ nutrient content claim criteria. As a result, the framework readily allows the addition of nutrients that can be used to qualify for claims such as “fortified” or “enriched” (i.e., those with a reference daily intake), but does not similarly provide for the use of beneficial ingredients like whole grains or phytosterols. Along the same lines, the framework allows modifications needed to reduce the calories in a product 25%, but does not provide for more modest improvements (e.g., 15% reductions) that are unrestricted in non-standardized foods. These examples reveal two categories of nutritional improvements that should be allowed in a new horizontal regulation: the addition or increase of safe and suitable ingredients that impart nutritional benefits, and measures designed to decrease calories and other nutrients targeted for decreased consumption, such as saturated fat or cholesterol.

a. Adding/Increasing Beneficial Ingredients and/or Nutrients

To provide for continued progress in the development and marketing of healthful standardized foods, a horizontal regulation should allow the addition of safe and suitable ingredients or nutrients that impart nutritional benefits. ^{54/} Flexibility would be particularly

^{50/} 56 Fed. Reg. 60512, 60513 (Nov. 27, 1991).

^{51/} 58 Fed. Reg. 2431, 2432 (Jan. 6, 1993).

^{52/} 70 Fed. Reg. 33803, 33804 (June 10, 2005).

^{53/} 61 Fed. Reg. 47453 (Sept. 9, 1996).

^{54/} This petition is not seeking to change existing fortification policies. Rather, it is seeking to allow nutritionally valuable ingredients to be added to standardized foods to the same extent that they are able to be added to nonstandardized foods. Although FSIS does not presently allow the fortification of meat

valuable to help consumers implement recommendations in the *Dietary Guidelines* and MyPyramid guidance system.

For example, consumers and industry would benefit from more opportunities to add whole grains to standardized foods, especially macaroni products. Increasing Americans' whole grain consumption is a centerpiece of the 2005 edition of the *Dietary Guidelines*, and food companies have responded by offering scores of new non-standardized food products with whole grains, including breads, cereals, and convenience foods. The standards of identity for whole wheat products like macaroni, however, require 100% whole wheat content or no whole wheat content. This restricts industry's ability to produce products with a meaningful yet more moderate amount of whole grains (e.g., 51%) for consumers who may not prefer, or may not be used to, the taste of 100% whole grain products. Although it is always possible to market products with a moderate whole grain content as a non-standardized food, this precludes use of the names that are most familiar and descriptive (e.g., "macaroni").

The petitioners believe that this policy needs to change. Federal policy should promote the flexibility to add whole grains to as many food products as is feasible, especially widely consumed grain foods such as macaroni products. By providing consumers with a wide variety of choices for consuming whole grains, the number of consumers who eat meaningful amounts of whole grains on a regular basis could be increased.^{55/}

Flexibility is also appropriate to allow the use of other beneficial ingredients in standardized foods, such as plant stanol/sterol esters. Standardized foods, however, should still be required to follow the same rules applied to non-standardized foods. No "advantage" for standardized foods is being sought here. Rather, the goal is to place standardized foods on an equal footing with non-standardized foods so as to greatly increase the number of food choices that are marketed with an improved nutritional profile.

b. Decreasing Calories and Nutrients Such as Saturated Fat or Cholesterol

or poultry products, the agency may decide to do so at some point in the future; the changes proposed in this petition would provide for needed flexibility in the event of a policy change.

^{55/} Although there is a clear place in the market for 100% whole grain products, there is an equally valid place for products containing meaningful amounts—but less than 100%—of whole grains. In providing comments to FDA on the draft guidance on whole grains earlier this spring, GMA provided FDA with sample menus showing how consumers could achieve the recommended levels of whole grain consumption from products with meaningful amounts of whole grains added, together with the resulting caloric levels. These menus demonstrate the usefulness of food options with less than 100% whole grains.

A horizontal regulation to provide for additional types of healthful standardized foods should also provide for modifications intended to achieve moderate *decreases* in calories and nutrients such as saturated fat or cholesterol, even if those decreases do not qualify for a nutrient content claim. A decrease should be permitted if it represents a measurable difference per reference amount customarily consumed (RACC) as compared to the food prepared in accordance with the standard, and such differences would result in a change to the nutrition information for the product, measured on the basis of the RACC.

Even modest reductions in calories, saturated fat, and similar nutrients can facilitate overall improvements and increase the likelihood that consumers will meet dietary goals. Moreover, at a time when consumers are urged to control intake of calories, saturated fat, and similar nutrients, there is no reason why a standard should keep the nutritional profile of a food product from moving in a positive direction, where it is possible to do so without changing the basic nature or essential characteristics of the food.

For example, even a small decrease in calorie content would represent an improvement in the nutrient profile of a food, especially if it is a commonly consumed food. A decrease of less than 25%, however, is not enough of an improvement to qualify for the nutrient content claims “less” or “reduced.” The regulatory framework, therefore, permits large reductions in the content of certain nutrients in a standardized food, but fails to permit smaller, yet potentially significant, reductions of those same nutrients. These smaller reductions would help consumers to make incremental dietary improvements and should be encouraged.

A smaller, incremental reduction in calories or a nutrient such as saturated fat, when implemented in a widely consumed food, would create a much larger reduction in the population-wide intake than would a higher (25% or more) reduction in a “niche” food category. Therefore, the larger public health gains would be in encouraging small, incremental reductions in popular food products. This is especially so since consumers increasingly view “reduced” or “low” claims unfavorably, associating such claims with poor taste. These same consumers, however, when presented with a food whose Nutrition Facts panel accurately reflects a lower saturated fat level, may be more likely to choose to purchase and eat that food, even without a claim like “reduced saturated fat” on the principal display panel.

This consumer trend runs counter to the fact that many of the current FDA standards dictate that foods contain minimum levels of fat, which effectively bars modest reductions. Increased opportunities to improve the nutritional profile of standardized foods in moderate ways would allow food companies to reduce calories and nutrients for which decreased intake is recommended, without changing the basic nature or essential characteristics of the food.

For example, a cheese product with 10% or 20% fewer calories is still a cheese product—with milk as its characterizing ingredient—it just has fewer calories. Similarly, plant source proteins may be used to replace a portion of the fat in an Italian sausage product without changing the basic nature of that product, as FSIS regulations already recognize in providing for

the addition of such proteins to qualify for a nutrient content claim like “reduced fat.” ^{56/} In both cases, this petition would allow flexibility to make the same types of changes already allowed to qualify for a nutrient content claim, but for the purpose of more modest improvements. There is no reason, therefore, not to permit this degree of flexibility, and there are important public health reasons to do so.

It is important to emphasize that, to qualify for this flexibility, these reductions could not adversely affect the basic nature and essential characteristics of the food. Consistent with existing FSIS regulations for standardized products named by use of a nutrient content claim, the requested flexibility would not affect or permit deviations from required meat content minimums. ^{57/}

It is equally important that this petition does NOT seek the ability to “claim” modest reductions in food labeling. There is no intention to create a competing claim structure to the existing nutrient content claim regulations. Indeed, the existing regulations governing nutrient content claims should continue to apply. For modest reductions in calories or nutrients, food companies should simply list the accurate amounts in the Nutrition Facts panel so that consumers would have the information. Again, all existing FDA and FSIS rules governing claims would continue to apply.

As described elsewhere in this petition, flexibility to make modest reductions in calories and certain nutrients is a logical extension of existing government regulations. The only differences would be that: (1) the reductions would be smaller, though still measurable, and (2) communication to consumers would be through the Nutrition Facts panel rather than through a claim on the principal display panel. This type of “reduction without fanfare” would improve the overall healthfulness of the food supply and provide consumers with more, and more healthy, choices.

D. Boundaries Should Be Established to Preserve the Basic Nature and Essential Characteristics of the Standardized Food

The primary role of standards is to establish boundaries that define the basic nature and essential characteristics of the standardized food. Boundaries take on added importance where there is discretion to produce a standardized food in different ways. For example, many cheese standards allow use of “alternate make” procedures so long as equivalency is demonstrated in terms of physical, chemical, nutritional, and organoleptic

^{56/} See, e.g., 9 C.F.R. §§ 319.10(c)(6), 381.172(c)(6).

^{57/} 70 Fed. Reg. 33803, 33809 (2005) (explaining that plant source proteins may not be used to replace the meat or poultry content of a product when a product standard specifies a minimum meat or poultry content requirement, but that such proteins may be used in place of the fat component of a standardized product).

characteristics. Similarly, the agencies' current regulations for nutritionally-improved standardized foods (i.e., 21 C.F.R. § 130.10 and 9 C.F.R. §§ 319.10 and 381.172) describe detailed boundaries addressing the types of modifications permitted, limitations, and labeling. This precedent provides useful guidance regarding the boundaries that can be used to shape modern food standards.

To ensure that the six areas of flexibility proposed in this petition are implemented in a suitable way, the petitioners have identified specific boundaries that may be used to preserve the basic nature or essential characteristics of standardized food. These boundaries may be divided into two types: (1) boundaries applying to the first five flexibility categories, all of which address relatively minor changes such as interchangeable technologies or ingredients; and (2) boundaries for nutritional improvements, which raise unique issues.

1. Most Categories: Broad Equivalency

Recommended boundaries are the same or similar for the first five flexibility categories proposed in this petition. That is, comparable boundaries are proposed to guide the use of ingredients intended solely for a “technical” effect; safe and suitable ingredients such as flavors, flavor enhancers, sweeteners, salt substitutes, and vegetable fats and oils; ingredients produced using advanced or alternative technologies; alternate make procedures for finished food products; and different forms or shapes for a finished standardized food. These boundaries address nutrition, performance characteristics, permitted ingredients, and labeling.

a. Nutrition

Food products covered by the proposed horizontal framework must not be nutritionally inferior to the conventional standardized food. As is required under 21 C.F.R. § 130.10, safe and suitable ingredients must be added to restore nutrient levels, if necessary.

“Nutritional inferiority” has been defined by FDA as “[a]ny reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content” so long as the food bears nutrition labeling.^{58/} A reduction is considered “measurable” if it equals or exceeds 2% of the daily value (i.e., DRV or RDI, as applicable) for protein, potassium, or most vitamins and minerals (except selenium, molybdenum, chromium, and chloride).^{59/} A food should not be considered to be nutritionally inferior to its conventional standardized counterpart, however, if it contains a measurable reduction in a nutrient that may be voluntarily added to the food under the applicable standard (e.g., vitamin A in yogurt products).

^{58/} 21 C.F.R. § 101.3(e)(4).

^{59/} 21 C.F.R. § 101.3(e)(4); *id.* § 101.9(c)(8)(4).

b. Performance Characteristics

The performance characteristics of a food include physical, chemical, and organoleptic properties, functional uses, and shelf life. FDA, FSIS, and industry have considerable experience assessing equivalency of performance characteristics under existing “alternate make” provisions and the agencies’ current regulations for nutritionally improved foods (i.e., 21 C.F.R. § 130.10 and 9 C.F.R. §§ 319.10 and 381.172).

The relevant physical and chemical properties (e.g., moisture, pH) of products allowed under the proposed horizontal standard must be equivalent to the current standardized food. For foods that are changed only in terms of form or shape (e.g., “whole” pineapple or “macaroni products” in the shape of shells), all physical properties other than the intended change must be equivalent.

Modernized versions of standardized foods also must be equivalent to (or, if applicable, better than) the conventional counterpart in terms of the most relevant organoleptic properties. The most significant organoleptic qualities include taste, texture, and sometimes smell, as determined by recognized procedures for sensory testing. Although organoleptic properties can also include color, this property is reasonably considered to be of lesser significance, since consumer preferences for color can vary and evolve over time. For maximum flexibility, any product colors deemed acceptable based on recognized testing procedures should be permitted.

Equivalency should also be shown for functional properties and shelf life. In some cases the updated version of the food may have functional properties or shelf life that represent improvements as compared to the conventional food.

c. Ingredients

Ingredient controls are important to ensure that modernizing changes do not adversely affect the basic nature or essential characteristics of standardized foods. As described below, the proposed horizontal approach would maintain existing requirements to use only “safe and suitable” ingredients, disallow the use of ingredients prohibited by a conventional standard, and require the continued presence of significant amounts of ingredients mandated in the relevant standard.

Safe and suitable ingredients. All ingredients used in any standardized food, including foods covered by the proposed horizontal standard, must be “safe and suitable.” The term “safe and suitable ingredient ” already has well-established meaning for both FDA and FSIS. FDA has defined “safe and suitable” to mean that the ingredient:

- (1) Performs an appropriate function in the food in which it is used.
- (2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

- (3) Is not an unapproved food additive or color additive (i.e., either is not a “food additive” or “color additive,” or is used in accordance with an authorizing FDA regulation).^{60/}

In the horizontal regulations governing binders and antimicrobial ingredients in standardized meat and poultry products, FSIS has defined “safe and suitable” in the same manner as FDA. The agencies also adopted this meaning of “safe and suitable” in their 2000 Memorandum of Understanding outlining the responsibilities of each agency during the joint review of new ingredients or new uses of previously approved ingredients.^{61/} This well-established concept is therefore appropriate for use in a new regulation to modernize the existing array of food standards.

Ingredients prohibited by a conventional standard. The proposed horizontal standard would also disallow the use in any standardized food of ingredients prohibited by an underlying standard. For example, the mayonnaise standard prohibits the use of any spice that imparts to mayonnaise a color simulating that of egg yolk. This petition does not seek to change existing prohibitions of this type.

Continued presence and function of “mandatory” ingredients. Variances of the type described in the first five flexibility categories must be consistent with ingredients mandated by a standard. Thus, mandatory ingredients must continue to be present in the food in an equivalent amount, and must not be replaced by ingredients from another source (e.g., non-egg emulsifying agents may not be used in place of egg yolks in mayonnaise). The overall framework will protect the continued role of mandatory ingredients, either because the allowed variances will have no effects on any ingredients (i.e., involve alternative processes or changes in shape), or because permitted changes in ingredients will be carefully restricted. Significantly, the only allowed ingredient changes are those that are minor (e.g., added flavors) or that permit the use of only interchangeable ingredients (e.g., the substitution of enzyme-modified egg yolk for egg yolk).

d. Labeling

Labeling requirements for foods produced in compliance with the five horizontal categories described above will be the same as for all other foods. The modernized versions of the standardized food will be subject to the same identity statement, ingredient labeling, and nutrition labeling requirements as other foods, including standardized and non-standardized products.

Where flavors are added, the foods will bear appropriate flavor labeling in accordance with existing requirements. Similarly, where the form of the food is changed (e.g., “whole” pineapple), the product identity will include the appropriate descriptive terms, based on

^{60/} 21 C.F.R. § 130.3.

^{61/} 68 Fed. Reg. 22576 (Apr. 29, 2003).

well-established labeling principles. The application of identical labeling requirements is justified because the enhanced versions will be required to be equivalent to the conventional standardized food, as described previously, in terms of performance, nutrition, and similar properties.

2. Nutrition Improvements: Based on Precedent for Standardized Foods Described by Nutrient Content Claims

The proposed framework for making nutritional improvements in food is inspired by, and builds upon, the success of the agencies' current requirements for standardized foods described by nutrient content claims (e.g., "reduced fat cheese"; "low fat pepperoni"). Significantly, the anticipated framework is not intended to replace or undermine the existing regulations, but simply represents a logical extension of their reach. Accordingly, the proposed boundaries are patterned after the boundaries described in the existing regulations for nutritionally improved foods, and address nutrition, performance characteristics, allowable ingredients, and labeling.

a. Nutrition

Food products covered by the proposed horizontal regulation must not be nutritionally inferior to the conventional standardized food. As is required under 21 C.F.R. § 130.10, safe and suitable ingredients must be added to restore nutrient levels if necessary to prevent inferiority.

"Nutritional inferiority" has been defined by FDA as "[a]ny reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content" so long as the food bears nutrition labeling.^{62/} A reduction is considered "measurable" if it equals or exceeds 2% of the daily value (i.e., DRV or RDI, as applicable) for protein, potassium, or most vitamins and minerals (except selenium, molybdenum, chromium, and chloride).^{63/} A food should not be considered to be nutritionally inferior to its conventional standardized counterpart, however, if it contains a measurable reduction in a nutrient that may be voluntarily added to the food under the applicable standard (e.g., vitamin A in yogurt).

Additionally, the nutritional improvement to the food should be meaningful. For purposes of this requirement, a reduction in calories or nutrients such as saturated fat is meaningful if it represents a measurable difference per RACC as compared to the food prepared in accordance with the standard, and such differences would result in a change to the nutrition information for the product, measured on the basis of the RACC.

^{62/} 21 C.F.R. § 101.3(e)(4).

^{63/} 21 C.F.R. § 101.3(e)(4); *id.* § 101.9(c)(8)(4).

The level of an ingredient added to impart a nutritional benefit is meaningful if it is sufficient to qualify for an FDA-authorized health claim or, in the absence of an authorized health claim, is considered meaningful by qualified nutritionists. The latter is a test of expert opinion among nutrition scientists similar in concept to the Generally Recognized as Safe (GRAS) standard and the Federal Trade Commission definition of “competent and reliable scientific evidence.” As a general rule, a level corresponding to 10% of a recommended or beneficial intake for a particular substance would be expected to satisfy this test.

b. Performance Characteristics

The existing framework for nutritionally-improved standardized foods (i.e., 21 C.F.R. § 130.10 and 9 C.F.R. §§ 319.10 and 381.172) requires that performance characteristics, such as physical properties, flavor characteristics, functional properties, and shelf life, of the modified food be similar to those of the standardized food. Thus, to make a nutritionally enhanced standardized food under the proposed horizontal framework, similar performance characteristics must be shown. In addition, as with the existing requirements for nutritionally enhanced foods, an enhanced food of the type proposed must perform at least one of the functions of the standardized food substantially as well as the standardized food.

As described in this petition, performance boundaries for nutritionally enhanced foods are more flexible than those proposed for the other five categories. For most of the flexibility categories, the performance characteristics of the technologically enhanced food must be equivalent to those of the conventional standardized food in all respects. For nutritionally enhanced foods, the performance must be “similar”; moreover, some of the functional uses may differ. This added flexibility is appropriate because nutritional enhancements, even those that are modest, have the potential to benefit the public health and should be granted greater latitude.

c. Ingredients

Ingredient requirements represent a third category of proposed boundaries for nutritionally enhanced foods. To prevent abuse and ensure that nutritional improvements do not adversely affect the basic nature and essential characteristics of enhanced standardized foods, the petitioners propose the following objective criteria:

- Any ingredient used must be “safe and suitable,” as described previously. Thus, any ingredient increased/added to the standardized food must meet recognized safety standards, such as being an approved food additive or generally recognized as safe (GRAS) for the intended use.
- Any ingredient specifically prohibited by a food standard may not be used.
- As provided in existing requirements, deviations from the ingredient provisions of the underlying standard are allowed if necessary to maintain

similar performance characteristics. The deviations must be the minimum necessary to achieve the nutritional improvement.

- Consistent with the allowances provided in other categories in the proposed framework, safe and suitable ingredients not provided for by a standard may be used for appropriate effects, including but not limited to improving texture, preventing syneresis, adding flavor, extending shelf life, improving appearance, or adding sweetness.
- As required under the existing regulations for nutritionally enhanced foods, mandatory ingredients must remain present in the enhanced food in a significant amount. Thus, in a food such as salad dressing, the oil content may be reduced, but a “significant” amount of oil must remain. The amount of a mandatory ingredient is “significant” if it is sufficient to perform the technical effect of the ingredient in the standardized food (e.g., contribute in a meaningful way to flavor, mouthfeel, nutritional properties, etc.). In addition, mandatory ingredients cannot be replaced with ingredients from another source (e.g., vegetable oil cannot replace milkfat in sour cream).

d. Variations in Non-ingredient Limitations

Under the existing horizontal framework for nutritionally enhanced foods, deviations from noningredient provisions of standards (e.g., moisture content, food solids content requirements, or processing conditions) are permitted for the purpose of achieving performance characteristics similar to the conventional standardized food. Deviations must be the minimum necessary to achieve the intended nutritional effect. The same requirements apply under the proposed expanded framework.

e. Labeling

To ensure that modified foods are described in a truthful and not misleading way, including any necessary disclosures, the petitioners propose the following specific labeling requirements:

- Product name—modest reductions. For modest reductions in calories or nutrients such as saturated fat, the enhanced food should bear the same product identity statement as the conventional standardized food. The use of the same name is justified both by the modest nature of the reduction, as well as overall consumer expectations regarding food industry trends towards healthier products. For instance, the level of fat and saturated fat in many meat products (e.g., pork) has decreased over the past few decades, but the leaner nature of the meat is not necessarily reflected in all product labeling. If reductions in nutrients result in perceptible organoleptic differences, however, a quantitative comparative declaration on the

information panel (e.g., “Regular mayonnaise, 11 g fat per serving, this product 9 g”) should be required.

- Product name—additions. Where an ingredient intended to impart nutritional value is added to a standardized food, the name of the food should reflect the addition if it is characterizing. Added ingredients or nutrients present at a nutritionally significant level would ordinarily be characterizing, though that must be judged on a case-by-case basis. For instance, the use of whole wheat flour in macaroni at levels consistent with an FDA-authorized health claim for whole grains is clearly characterizing (among other potential uses that also may be characterizing).
- Ingredients. Under the existing framework for standardized foods described by nutrient content claims, ingredients not provided for in the standard (and ingredients used in excess of the levels provided for) are specifically highlighted using the statement “*Ingredients not in regular ____.” The horizontal framework proposed in this petition contains no such requirement, however, because a basic premise of this petition is that consumer attitudes towards standardized foods have changed. Consumers have grown accustomed to innovation in the food industry and reasonably expect that the most useful ingredients will be used in any food product, standardized or not.
- Limitations in function. If a significant difference in a performance characteristic materially limits the use of the modified product compared to the use of the standardized product, the label must include a statement that informs the consumer of such differences (e.g., “not recommended for cooking,” “not recommended for frozen storage,” or “not suitable for roller grilling”).

SUMMARY AND IMPLEMENTATION OF CITIZEN PETITION

This Citizen Petition asks FDA and FSIS to develop a horizontal regulation to modernize food standards and provide added flexibility within six areas: (1) safe and suitable ingredients used solely for a technical purpose; (2) safe and suitable flavors, flavor enhancers, salt substitutes, sweeteners, and vegetable fats and oils; (3) alternative manufacturing processes for ingredients; (4) alternate manufacturing processes for finished products; (5) changes in form and shape; and (6) improvements to nutritional profiles. Some of these areas, or subsets of them, are more complex than others; some of these topic areas, or subsets of them, may be more applicable to FDA standards than FSIS standards, or vice versa. Further, the petitioners recognize that consensus may be readily achieved for some of the proposed categories, but other categories may be more challenging.

We encourage each agency to move forward promptly in all areas where broad agreement can be reached, and if necessary, to consider implementing this Citizen Petition in

stages (e.g., by issuing a joint proposed regulation covering some—but not all—of the topic areas covered, or by one agency issuing a proposed rule prior to the other agency). However accomplished, if the agencies agree with the general approach being recommended, we would urge the agencies to prioritize their actions and move as quickly as possible to pursue the broadest reform feasible.

ENVIRONMENTAL IMPACT

The action requested by the petition is not expected to have a significant effect on the quality of the human environment and is subject to categorical exclusion under 21 C.F.R. § 25.32(a).

ECONOMIC IMPACT

An economic impact statement under 21 C.F.R. § 10.30(b) is not required at this time.

The undersigned certify that, to the best of the petitioners' knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully submitted,



Mark F. Nelson, Ph.D.
Vice President, Scientific and Regulatory Policy
Grocery Manufacturers Association

And on behalf of:

American Frozen Food Institute
American Meat Institute
Chocolate Manufacturers Association
Food Products Association
International Dairy Foods Association
Juice Products Association
National Cattlemen's Beef Association
National Fisheries Institute
National Meat Canners Association
North American Millers' Association
Snack Food Association