1250 H Street NW, Suite 900
Washington, DC 20005
P: 202.737.4332 | F: 202.331.7820
WWW.IDFA.ORG

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Horizontal Approaches to Food Standards of Identity Modernization; Request for Comments; Docket No. FDA-2018-N-2381

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) docket on Horizontal Approaches to Food Standards of Identity Modernization. The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate $159 billion in wages and $620 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy companies and cooperatives to food retailers and suppliers. Together, they represent 90 percent of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. IDFA can be found at www.idfa.org.

IDFA thanks FDA for prioritizing food standards modernization as part of the agency's multi-year strategy on nutrition innovation and for opening a separate docket to receive comments on this important issue. Food standards modernization is a longstanding priority for IDFA members. We are aware of FDA's resource constraints in this area and have supported an increase in appropriations for FDA's Office of Nutrition and Food Labeling to prioritize efforts regarding standards of identity.

Executive Summary

We welcome the agency's interest in food standards modernization, as this remains a key priority for IDFA and its members. In our more detailed comments that follow, IDFA encourages FDA to consider the following potential pathways to updating the food standards:

(1) Citizen Petitions: Prioritize reviewing and responding to individual citizen petitions requesting changes to the food standards, including issuing a modernized yogurt standard of identity and allowing the use of fluid filtered milks in standardized cheeses;

(2) Horizontal Approach to Food Standards Modernization: Take a horizontal approach to food standards modernization, looking to the 2006 food industry petition as a starting point;

(3) Temporary Marketing Permit (TMP) Process Changes: Streamline and revise the temporary marketing permit (TMP) process so that companies can seek needed flexibility in the standards, including consideration of converting the permit application process into a notification process; and

(4) Legislative Changes to the Process for Amending Standards: Explore legislative changes that could facilitate more timely updates to the dairy standards and modernize the standards framework.

Importantly, these options for modernizing the food standards are not mutually exclusive and we encourage FDA to pursue multiple options on parallel tracks.

Food Standards Modernization

A large segment of the current food standards of identity – 37 percent of the 280 federal food standards – are for dairy products, and these standards are significantly outdated and stand in the way of using new technologies, ingredients, and novel processes for dairy foods.

IDFA endorses the idea of useful food standards that promote honesty and fair dealing in the consumers' interest by providing for the development of nutritionally enhanced products, technological advances in food production, consistency with international food standards to the extent feasible, and clear guidance for manufacturers and enforcement agencies. However, many of the dairy standards are outdated and do not reflect current processing technologies, nor do they provide much needed flexibility to allow for future technological advancement and innovation to meet consumer demand. IDFA believes the food standards would benefit greatly from increased flexibility while preserving the underlying purposes of the standards and the distinct characteristics of each standardized food. IDFA would like to recommend several potential pathways to the agency for modernizing the food standards.

FDA Should Act on Existing Citizen Petitions While Considering a Horizontal Approach

IDFA has submitted or signed onto numerous petitions to FDA requesting flexibility in the dairy standards.[1] We ask that FDA prioritize reviewing and responding to those citizen petitions that have

[1] These petitions include IDFA's requests filed regarding Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements (Sept. 8, 2017) (FDA-2017-N-5094), as well as requests that FDA modernize the yogurt standards of identity; amend the vitamin D fortification levels in the milk and milk products standards to allow for levels of fortification that align with the new daily intake recommendations for vitamin D; amend the optional ingredient sections of the milk and milk product standards of identity to allow for use of milk protein concentrate (MPC) and ultrafiltered (UF) milk to align with international Codex standards; amend the cheese standards of identity to allow for use of ultrafiltered milk and permit milk derived ingredients to be labeled as "milk"; amend the standards of identity for Colby and cheddar cheese to allow for use of antimycotics (mold inhibitors) that are permitted in all other cheese standards; amend the cheese standards of identity to allow for salt alternatives to be used in addition to salt; remove the

been submitted, including issuing a modernized yogurt standard of identity. IDFA has filed separate comments to the agency with specific information and requests regarding modernization of the yogurt standards.

Another key issue for the dairy industry is the opportunity to include new types of filtered milk as permitted ingredients for standard of identity cheeses. Codifying the addition of the fluid forms of both ultrafiltered milk and microfiltered milk to the definition of Milk in CFR Title 21, Part 133 – Cheese and related cheese products, would recognize advances in technology with the potential to yield better, more consistent cheeses, and reduce the need for costly dairy plant expansions – costs borne by dairy farmers, dairy manufacturers, and consumers alike.

IDFA encourages FDA to continue its work to respond to the pending dairy industry requests on standards of identity, particularly those for yogurt and various forms of filtered milk in cheesemaking. Nonetheless, the long backlog of petitions before the agency illustrates the limitations of the current citizen petition process as a tool to update the standards.[2] Although the need to update individual food standards is clear, the resources to do so are seemingly unavailable. Over the years and with good reason, the agency's priorities for allocating its limited resources have shifted from largely economic concerns to public health and safety concerns. Additionally, dairy product standards of identity are subject to a more formal rulemaking process than for other foods, where any individual may, upon issuance of a final rule, request an evidentiary hearing.

While receiving responses to these petitions remains an important priority for IDFA members and we ask that FDA continue its work to review and respond to the petitions, in order to truly modernize the food standards and to effectively address the agency's resource constraints, we strongly encourage the agency to consider a "horizontal" approach to food standards modernization that would allow

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labeling requirement for "not-smoked" on the labeling of non-smoked provolone cheese; review flavor labeling requirements in the ice cream standard to reflect advancements in flavors with other natural flavors to allow for use of the labeling term "with other natural flavors"; amend the ice cream standard of identity to allow for use of newer milk derived proteins such as milk protein concentrate (MPC) and ultrafiltered milks; allow sweet cream buttermilk and whey to be added to the collective ingredient terms "milkfat and nonfat milk" for ice cream and frozen desserts in the ice cream standard of identity; and amend the milk, acidified milk, cultured milk, and yogurt standards of identity to permit optional use of the labeling term "whole".

[2] In addition to the outstanding petitions noted above, at the time of the filing of the Grocery Manufacturers Association Citizen Petition to modernize foods standards, there were several other additional petitions outstanding. *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-1572 (State of Alaska petition to adopt standard of identity for glacier water)(Oct. 18, 2000); 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).

specific categories of flexibility across all of the food standards (in contrast to a "vertical" approach of updating each individual food standard through notice-and-comment rulemaking). Such horizontal changes could address many of the requested changes that are the subject of the pending petitions.

Looking to past agency successes, we believe that by taking a "horizontal" approach, FDA can go further to truly modernize food standards. Indeed, by issuing a single regulation that adds flexibility to all food standards at once, the agency could provide needed updates without the enormous resource investment required to change standards in separate notice-and-comment rulemaking proceedings. FDA could use the framework of its precedent in 21 C.F.R. § 130.10, which took a horizontal approach to improving flexibility in all food standards by allowing for variations for the purpose of meeting nutrient content claim criteria. IDFA encourages the agency to consider this type of approach so that it can make a real difference and do more than simply preserve the status quo.

FDA Should Re-Examine the 2006 Industry Petition on Food Standards Modernization

As a starting point for a horizontal approach to food standards modernization, IDFA encourages the agency to look to the 2006 citizen petition submitted by the Grocery Manufacturers Association (GMA) and eleven other food industry trade associations.[3] IDFA is very interested in engaging in a dialogue to obtain the agency's feedback on the 2006 petition. We note that the petition was intended to be a "menu" of requested areas of flexibility, rather than an approach that would need to be adopted wholesale or not at all. The petition included six categories of requested flexibility, to be applied on a horizontal basis to all food standards. The six categories included within the 2006 petition are as follows, with dairy-specific examples noted where applicable.

1. Addition of ingredients intended solely for technical, nondistinctive effects, such as emulsifiers, stabilizers, or antimycotic agents including alternative ingredients in the same category as ingredients already allowed by the standard (e.g., an acidifying agent that substitutes for an acidifying agent specifically provided for by the standard, allowing the use of categories of technical ingredients for which there is no express provision in the standard, the use of an emulsifier where the standard does not specifically allow emulsifiers, and ingredients authorized by the standard in only limited contexts)
    a. e.g., adding microbial inhibitors like lysozyme or nisin to cheeses; allowing the use of antimycotic agents on bulk cheese where the standard only allows for this use in consumer packages

2. Use of safe and suitable flavors and flavor enhancers generally and use of safe and suitable ingredients such as salt substitutes, sweeteners, and vegetable fats and oils where appropriate
    a. e.g., use of salt substitutes in standardized cheeses; use of natural dairy flavors in standardized cheeses; use of non-nutritive sweeteners in milk and milk products

3. Use of advanced technologies or more efficient technologies to produce ingredients, provided the ingredient performs a function equivalent to the traditional ingredient, and the finished food must retain the essential characteristics of the standardized product
    a. e.g., reconstituted milk used in yogurt; ultrafiltered and microfiltered milk in cheese

4. Use of "alternate make" procedures

[3] Citizen Petition to Modernize Food Standards, October 25, 2006, FDA Docket No. 2007P-0085.

a. e.g., flexibility to use alternate minimum aging periods for cheese so long as the product has the same physical and organoleptic characteristics; technologies other than heat treatment if sufficient to ensure microbiological safety or prevent spoilage, such as high-pressure processing; addition of cream to yogurt after culturing

5. Changes to product's basic shape, form, size or similar features of product appearance in response to consumer demand
    a. e.g., "whipped" forms of yogurt that incorporate gases as an ingredient

6. Improvements in nutritional properties that do not rise to the level of a defined nutrient content claim or use of nutritious ingredients like whole grains
    a. e.g., a 10% reduction in calories or sodium rather than a minimum 25%; a 10% increase in protein by grams rather than a minimum 10% more of the daily value

Additionally, in the time since the 2006 petition was submitted, IDFA has identified two further areas of horizontal flexibility that would benefit our members and consumers:

7. Expand the use of milk-derived ingredients permitted in standardized dairy foods to allow "any milk, or milk-derived ingredient"[4]
    a. e.g., ultrafiltered milk, MPC, microfiltered milk, and others in dairy products

8. Revisit the regulation on nutritionally modified standardized foods in 21 C.F.R. § 130.10 to identify additional opportunities to provide flexibility in this standard, which has historically been interpreted fairly narrowly
    a. e.g., ultrafiltration of milk or added MPC or whey protein isolate to milk to produce "High Protein, Reduced Sugar Milk"

We appreciate that FDA may be concerned that allowing variations on a horizontal basis may change the basic character or essential characteristics of a standardized food. Just as the agency accomplished with § 130.10, however, FDA could set qualifying objective criteria for flexibility in the standards. For example, a variation in manufacturing process could be permitted so long as it results in no significant change to the essential qualities or performance characteristics of the standardized product. FDA has long applied such objective measures in the area of cheese standards having alternate make provisions.

A horizontal regulation would benefit FDA, 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 innovation in the marketplace by allowing for advances in technology and nutrition science, facilitate legitimate international trade and provide regulatory clarity and certainty that will encourage investment. 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 more 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

[4] This change could be accomplished on a horizontal basis by amending the general definition provisions in 21 C.F.R. § 130.3 or in the dairy-specific sub-parts.

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. We look forward to engaging with the agency on the 2006 petition and potential changes to the food standards that could be made on a horizontal basis. We are attaching and incorporating by reference as Appendix A proposed regulatory language from the 2006 GMA Citizen Petition to accomplish horizontal changes across the standards of identity. We are also attaching as Appendix B a summary chart of the proposed changes to modernize food standards, as well as information on the proposed parameters and limitations in each of the change categories.

FDA Should Revise the Temporary Marketing Permit Process

As another potential pathway to providing flexibility in the food standards while managing the agency's resource constraints, IDFA recommends that FDA consider making revisions to the process for obtaining a temporary marketing permit (TMP).

By way of brief background, the TMP process allows a company to request permission to deviate from an applicable standard "for the sole purpose" of obtaining data necessary for reasonable grounds in support of a petition to amend the food standard. In considering TMP petitions, FDA must ensure the interests of the consumer are adequately safeguarded. The initial TMP typically covers a 15-month test period, and can be extended until FDA publishes a final regulation either modifying the standard of identity in the manner requested or terminating the proposed rulemaking. Following the initial test marketing period, FDA may extend an invitation to other companies through a Federal Register Notice to participate in a TMP by submitting limited information.

The current TMP process is set out in 21 C.F.R. § 130.17. The requirements for this process were created within FDA's discretion under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the process is not subject to specific statutory requirements. It could, therefore, be amended either by regulation or by enforcement discretion, similar to how FDA operated the generally recognized as safe (GRAS) notification process for nearly two decades under a proposed rule. In light of the difficulty of undertaking rulemaking, we believe it would be appropriate for FDA to consider making changes to the TMP process by issuing a guidance document or exercising enforcement discretion.

IDFA has identified a number of potential changes to the TMP process that would allow companies to more readily explore novel ways to produce standardized foods under a TMP while still protecting consumers. Expanding the availability of the TMP process would alleviate some of the current backlog in citizen petitions to amend the food standards, and would encourage companies to explore more efficient technologies and nutritional improvements to provide consumers with innovative and healthful products. The following are IDFA's initial recommendations for potential changes to the TMP process. Again, this is a menu of options that do not necessarily need to be adopted wholesale.

Table 1. Potential Changes to the TMP Process

Current Process	Proposed Change
TMPs typically apply to a single standard of identity	Allow initial applications to apply to multiple standards of identity (e.g., all cheese standards)
Initial TMP typically covers a 15-month test period	Allow the initial TMP to last for a longer period, such as 18 months or two years, which would provide companies

Current Process	Proposed Change
	with more certainty and flexibility than a short 15-month test period
TMPs are submitted by individual company applicants; after the initial TMP period, additional companies may be invited to join the TMP upon submission of specific information including detailed information regarding manufacturing locations, amount of product, labels, product formula and the manufacturing process. Changes to the information submitted require an updated TMP request	Allow multiple companies or trade associations to submit TMP petitions and to be part of the initial TMP. This could be accomplished in part by removing several of the company-specific requirements in the permit application (e.g., the areas of distribution, the amount of food to be distributed). Alternatively, if FDA maintains an approach where the initial TMP is granted to a single company, FDA could remove the requirement that companies submit information to join the TMP after the initial test period, and instead, FDA could publish a notice allowing all companies to rely on the TMP. This would be akin to granting a variance from the standard for the industry and would relieve both industry and the agency of the burden of submitting and reviewing multiple, detailed TMP applications and labels.
TMP must include the proposed label, which often is interpreted to require submission of a label for all affected stock keeping units (SKUs)	Clarify that labels need not be submitted for all affected SKUs, and that instead, a representative label or a description of how the label may differ from the standardized food label (e.g., ingredient statement will declare potassium chloride as an ingredient with an asterisk stating "*ingredient not in regular ___") would suffice
Once initial TMP ends, the company may apply for an extension, which must be accompanied by a petition to amend the affected food standard	Remove the requirement to submit a petition, particularly in light of the current backlog in petitions requesting changes to the food standards. Replace the petition requirement with a process where the company would submit to FDA a notification of intent to deviate from the standard permanently. If FDA does not object to the deviation, it would be permitted. FDA could then separately consider amending the underlying standard to reflect the deviation.
The TMP is granted upon review and approval by FDA	Convert the process into a notification process, similar to the GRAS notification process (e.g., company submits data and information for proposed deviation; FDA has a particular period to object, otherwise the company can proceed with marketing). A notification process would have the advantage of requiring fewer agency resources.

IDFA will separately request a meeting with FDA to discuss potential changes to the TMP process.

<u>FDA Should Explore Potential Legislative Changes to the Process for Amending the Dairy Standards</u>

In addition to considering a horizontal approach to food standards modernization and potential changes to the TMP process, IDFA encourages FDA to explore potential legislative changes to the process for amending the dairy standards of identity. We understand senior FDA officials have recognized the current process for amending the food standards is not working. This recognition is

borne out by the infrequency with which the food standards are updated. Our review of the standards suggests there have only been four changes to food standards made in the last 25 years, as well as one new standard issued for white chocolate. Dairy product standards of identity are subject to a heightened statutory requirement where, after issuing a final rule, any interested person can request that FDA hold a formal evidentiary hearing.[5] Under this process, FDA is incentivized to make only those changes that would not result in the potential for an evidentiary hearing, and the last change to a dairy standard was in 1994, more than 20 years ago.

For these reasons, FDA should look not only to ways in which the standards can be substantively amended, but also ways in which the process by which the standards are amended and issued can be improved. To this end, IDFA would like to discuss the process for food standards modernization with the agency to explore legislative proposals that would amend the formal rulemaking requirement for dairy foods while still ensuring an opportunity for public input on the standards. This could include adopting the same notice-and-comment rulemaking process to which other standards are subject, or adopting a less resource intensive process, such as an administrative order process. [6]

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We appreciate the agency's efforts to prioritize food standards modernization. Thank you for the opportunity to participate in this important process.

Respectfully submitted,

Cary P. Frye
Senior Vice President, Regulatory Affairs

Enclosures:

Appendix A – Draft FDA Regulation for Standard of Identity Reform from GMA's 2006 Citizen Petition

Appendix B – Summary Chart of Food Standards Modernization Proposals

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5 21 U.S.C. § 371(e).

6 Such a statutory change to the FFDCA has been made before, modifying the mechanism for classifying a medical device from rulemaking to administrative order. *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 608(a), 126 Stat. 993, 1055 (2012) and FFDCA § 513(e). In addition, this type of statutory change has been considered in legislation to reform the over-the-counter drug approval process from notice-and-comment rulemaking to an administrative order process. *See* Over-the-Counter Drug Safety, Innovation, and Reform Act, S. 2315, 115th Cong. § 101 (2018).

APPENDIX A

DRAFT FDA REGULATION FOR STANDARD OF IDENTITY REFORM FROM THE GROCERY MANUFACTURERS' CITIZEN PETITION TO MODERNIZE FOOD STANDARDS

Sec. 130.18 What variations from a standard of identity are permitted?

(a) *Description*. This regulation establishes a general definition and standard of identity for foods that vary from a standardized food for a beneficial purpose. In addition to variations described in other sections of this part, foods that substitute (see Sec. 101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter and that use the name of that standardized food in their statement of identity may vary from the applicable standard of identity for one or more of the following reasons:

(1) Use of a safe and suitable ingredient solely for a technical, nondistinctive effect not authorized by the standard. Flexibility is allowed to use, among other possible ingredients, alternative ingredients in the same category as ingredients already allowed by the standard (e.g., an acidifying agent that substitutes for another acidifying agent specifically named in the standard), ingredients for which no provision is expressly made in the standard (e.g., an emulsifier where the standard does not presently identify permitted emulsifiers), and ingredients authorized by the standard, but only in a limited context (e.g., antimycotic agents allowed for use on the surface of cheese in consumer packages, but not on cheese in bulk form). Ingredients authorized by this section are of the type identified in Sec. 170.3(o), with the exception of flavoring agents, flavor enhancers, nutrient supplements, non-nutritive sweeteners, and nutritive sweeteners.

(2) Use of safe and suitable flavoring agents and flavor enhancers, except that no flavoring agents or flavor enhancers may be used if prohibited by the applicable standard.

(3) Use of a safe and suitable nutritive or non-nutritive sweetener in place of any sweetener expressly authorized by the standard.

(4) Use of a safe and suitable salt substitute where the standard provides for the addition of salt.

(5) Use of a safe and suitable vegetable fat or oil in place of a specific vegetable fat or oil named in the standard.

(6) Use of one or more alternative processes to produce an ingredient that substitutes for an ingredient listed in the standard, if (a) the substitute ingredient is made from the same food as the ingredient listed in the standard (e.g., egg yolk); (b) the substitute ingredient is used for a functional effect (e.g., emulsification) that is equivalent to that provided by the ingredient listed in the standard; and (c) the finished food produced using the substitute ingredient is equivalent to the food prepared pursuant to the standard of identity regulation, as required by paragraph (b) of this section.

(7) Use of one or more alternative processes that result in a finished product equivalent to the food prepared pursuant to the standard of identity regulation, as required by paragraph (b) of this section.

(8) Changes made to enhance product form, shape, size, or similar features of product appearance, in a purely physical way (e.g., canned pineapple in a “whole” form).

(9) Use of safe and suitable ingredients, processes, or other measures that enhance the nutritional properties of the food in a meaningful way, but not to the degree required to comply with Sec. 130.10.

(i) A nutritional enhancement made by adding a valuable ingredient is meaningful if the addition meets criteria established in an FDA-authorized health claim, or in the absence of an authorized health claim, if qualified nutritionists would generally recognize the addition as meaningful.

(ii) A nutritional enhancement intended to reduce calories or food components for which decreased intake may be indicated, such as saturated fat, is meaningful if the enhancement results in a measurable reduction per reference amount customarily consumed (RACC) and a change in the nutrition labeling for the product required under Sec. 101.9.

(b) *Limitations*. (1) A food produced using modifications described in paragraph (a) of this section shall not be nutritionally inferior, as defined in Sec. 101.3(e)(4) of this chapter, to the standardized food produced under parts 131 through 169 of this chapter. For purposes of this paragraph, a food shall not be considered nutritionally inferior to a standardized food if it fails to contain a nutrient that is optional in the standard (e.g., vitamin A in yogurt).

(2)(i) A food produced using modifications described in paragraphs (a)(1) to (a)(7) of this section shall have equivalent or superior performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) as the standardized food produced under parts 131 through 169 of this chapter.

(ii) A food produced used modifications described in paragraph (a)(8) of this section shall have performance characteristics equivalent to the standardized food, with the exception of the intended change in physical form.

(iii) A food produced used modifications described in paragraph (a)(9) of this section shall have performance characteristics as provided in paragraph (c)(2) of this section.

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

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

(c) *Compliance with the applicable standard*. (1) A food produced using modifications described in paragraphs (a)(1) to (a)(8) of this section shall deviate from the standard only to the extent needed to accomplish the desired flexibility. The food shall comply with the standard in all other respects.

(2) A food produced using modifications described in paragraph (a)(9) of this section shall deviate from the standard only to the extent needed to accomplish the desired nutritional improvement, or as otherwise allowed or required in this section. The food shall comply with the relevant standard in all other respects, except as provided in sub-paragraphs (i), (ii), (iii), and (iv) of this paragraph.

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

(ii) Other ingredients. Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (a) of this section.

(iii) Water and fat analogs may be added to replace fat and calories.

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

(3) This regulation does not authorize any variation inconsistent with the basic nature or essential characteristics of the standardized food. For example, the amount of peanuts in a product identified as “mixed nuts” cannot be increased beyond the 80% maximum weight authorized for any individual nut ingredient by Sec. 164.110.

(d) *Nomenclature*. The name of a substitute food that complies with all parts of this regulation is the applicable standardized term and any additional terms necessary to describe added or different characterizing ingredients or properties, including characterizing flavor labeling required by 101.22(i).

(e) *Label declaration*. (1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter and part 130.

(2) If a food prepared using modifications described in paragraph (a)(9) is found to have discernable differences in organoleptic qualities as compared to the standardized food produced under parts 131 through 169 of this chapter, an explanatory statement highlighting the reasons for such differences shall be placed on the information panel (e.g., Regular ____ contains 11 g of fat per serving; this product contains 9 g of fat per serving).

APPENDIX B
DRAFT FSIS REGULATION FOR STANDARD OF IDENTITY REFORM

Changes Allowed to Modernize Food Standards While Retaining the Basic Nature and Essential Characteristics of Standardized Food						
Changes would be allowed to . . .	**Substitute or add ingredients used solely for a technical, nondistinctive effect**	**Add safe and suitable flavors, sweeteners, salt substitutes, or vegetable fats and oils**	**Use advanced or more efficient technology to produce ingredients**	**Use alternate make procedures for the finished food**	**Change product appearance, form, or shape**	**Improve nutrition by adding beneficial ingredients or decreasing calories or certain nutrients in moderate amounts**
EXAMPLES	Use one defoaming agent in place of another specifically listed agent in the standard; add a preservative where the standard doesn't provide for it; use an antimycotic agent in bulk cheese where the standard allows it only in consumer packages	Use safe and suitable flavors in cheese products; use a salt substitute where a standard allows salt; use any sweetening agent where the standard allows at least one sweetener; use a vegetable fat in place of another vegetable fat named in the standard (e.g., cacao fat)	Use enzyme-modified egg yolk in place of regular egg yolk; use reconstituted milk in yogurt	Use alternatives to pasteurization or other heat treatment, if demonstrated to provide same effect (e.g., same food safety effect or spoilage prevention); use different aging periods for cheese	Market "chunky style" stewed tomatoes; make different shapes of macaroni (e.g., cartoon characters) and still call it a "macaroni product"; sell canned pineapple "whole"; make small (less than ½ pound) loaves of "bread"	Reduce saturated fat in amounts less than the 25% required for a "reduced" claim; add phytosterols to standardized products; add 51% whole wheat flour to spaghetti and call it "whole wheat spaghetti" based on characterizing amount of whole wheat
Key parameters	An ingredient is "technical" and "nondistinctive" if its presence is not ordinarily perceptible to consumers[1]	Any safe and suitable flavors may be used except where expressly prohibited; sweeteners, salt substitutes, and vegetable fats and oils may be used where standards already allow for sweeteners, salt, or at least one specific vegetable fat or oil	Ingredient is interchangeable for a specific one listed in the standard because it (1) is from the same source as the listed ingredient; (2) performs an equivalent functional effect; and (3) retains essential characteristics of the finished food	The same approach as established "alternate make" procedures in the cheese standards, but allowed anywhere the standard identifies a specific procedure	Simple changes in physical form, not substance or content	Moderate decreases must result in a measurable difference per RACC and a change in the Nutrition Facts panel as compared to the standardized food; beneficial additions allow use of ingredients/nutrients to qualify for a health claim or in an amount deemed meaningful by qualified nutritionists

Changes Allowed to Modernize Food Standards While Retaining the Basic Nature and Essential Characteristics of Standardized Food						
Changes would be allowed to . . .	**Substitute or add ingredients used solely for a technical, nondistinctive effect**	**Add safe and suitable flavors, sweeteners, salt substitutes, or vegetable fats and oils**	**Use advanced or more efficient technology to produce ingredients**	**Use alternate make procedures for the finished food**	**Change product appearance, form, or shape**	**Improve nutrition by adding beneficial ingredients or decreasing calories or certain nutrients in moderate amounts**
Boundaries: Nutrition and Performance						
Nutrition	Not inferior: add ingredients if necessary to restore	Not inferior: add ingredients if necessary to restore	Not inferior: add ingredients if necessary to restore	Not inferior: add ingredients if necessary to restore	Not inferior: add ingredients if necessary to restore	Not inferior: add ingredients if necessary to restore
Performance characteristics: physical and chemical properties (other than nutrition)	Equivalent	Equivalent	Equivalent	Equivalent	Equivalent, with exception of intended change	Similar, using same principles as 130.10
Performance characteristics: organoleptic properties	Equivalent or better	Equivalent or better	Equivalent or better	Equivalent or better	Equivalent	Similar, using same principles as 130.10
Performance characteristics: functional uses and shelf life	Equivalent or better	Equivalent or better	Equivalent or better	Equivalent or better	Equivalent	Similar, using same principles as 130.10
Boundaries: Ingredients						
Safe and suitable	Yes	Yes	Yes	Yes	N/A	Yes
Use different sources of mandatory ingredients (i.e., can vegetable oil replace milkfat)?	No (e.g., a non-egg yolk emulsifying agent can't be used to replace egg yolk in mayonnaise)	No	No	N/A	N/A	No

Changes Allowed to Modernize Food Standards While Retaining the Basic Nature and Essential Characteristics of Standardized Food						
Changes would be allowed to . . .	**Substitute or add ingredients used solely for a technical, nondistinctive effect**	**Add safe and suitable flavors, sweeteners, salt substitutes, or vegetable fats and oils**	**Use advanced or more efficient technology to produce ingredients**	**Use alternate make procedures for the finished food**	**Change product appearance, form, or shape**	**Improve nutrition by adding beneficial ingredients or decreasing calories or certain nutrients in moderate amounts**
Use mandatory ingredients in a "significant" amount?	N/A – changes would not significantly affect levels of mandatory ingredients	N/A – changes would not significantly affect levels of mandatory ingredients	Yes – either will not affect mandatory ingredients or will allow only interchangeable mandatory ingredients	N/A – changes would not significantly affect levels of mandatory ingredients	N/A – changes would not significantly affect levels of mandatory ingredients	Yes, using same principles as 130.10 (i.e., minimum is smallest amount necessary to provide intended functional effect)
Ingredients "prohibited" by standard?	No	No	No	No	N/A	No
Other changes allowed as a result of the subject change (e.g., deviations from non-ingredient provisions)?	No	No	No	No	No	Yes, but must be the minimum necessary to maintain similar performance, as per 130.10 principles
Boundaries: Labeling						
Labeling	Same as standardized food; all ingredients declared unless exempt	Same as standardized food; all ingredients declared unless exempt; follow established flavor labeling requirements	Same as standardized food; all ingredients declared unless exempt	Same as standardized food	Same as standardized food; note change in form as appropriate	In general, same identity statement as standardized food; any reduction resulting in perceptible organoleptic changes are noted in explanatory information panel labeling (i.e., Regular ___, 11 g fat per serving, this product 9 g fat); nutrient additions are reflected in product identity if characterizing; for both additions and

Changes Allowed to Modernize Food Standards While Retaining the Basic Nature and Essential Characteristics of Standardized Food						
Changes would be allowed to . . .	**Substitute or add ingredients used solely for a technical, nondistinctive effect**	**Add safe and suitable flavors, sweeteners, salt substitutes, or vegetable fats and oils**	**Use advanced or more efficient technology to produce ingredients**	**Use alternate make procedures for the finished food**	**Change product appearance, form, or shape**	**Improve nutrition by adding beneficial ingredients or decreasing calories or certain nutrients in moderate amounts**
						decreases, limitations in function must be labeled (i.e., "not recommended for frozen storage")

1. An effect is considered "technical" and "nondistinctive" if the presence of the ingredient is not ordinarily perceptible to consumers, even though the end result (e.g., superior texture) may be. Most of the functional use categories listed in 21 C.F.R. 170.3(o) are purely technical, such as anticaking agents, antimicrobial agents, emulsifiers, etc. Exceptions are flavors, flavor enhancers, sweeteners, nutrient supplements, and vegetable fats and oils, which are addressed under other categories. Note that a "purely technical" ingredient may in fact be mandatory under the standard (e.g., egg yolk used as an emulsifying agent in mayonnaise).