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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. FDA-2000-P-0126] (formerly Docket No. 2000P-0685)

Milk and Cream Products and Yogurt Products; Proposal to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke its regulations on the standards of identity for lowfat yogurt and nonfat yogurt and amend the standard of identity for yogurt in numerous respects. This action is in response, in part, to a citizen petition submitted by the National Yogurt Association (the NYA). FDA tentatively concludes that this action will promote honesty and fair dealing in the interest of consumers and, to the extent practicable, will achieve consistency with existing international standards of identity for yogurt.

DATES: Submit comments by [insert date 75 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2000-P-0126, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

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FDA-200-P-0126

NPR

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):
Division of Dockets Management (HFA–305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

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I. Background

A. Current Standards of Identity for Yogurt, Lowfat Yogurt, and Nonfat Yogurt

In the **Federal Register** of January 30, 1981 (46 FR 9924), FDA published a final rule establishing standards of identity for yogurt (§ 131.200 (21 CFR 131.200)), lowfat yogurt (§ 131.203 (21 CFR 131.203)), and nonfat yogurt (§ 131.206 (21 CFR 131.206)). Interested persons were given until March 2, 1981, to file objections and request a hearing on the final rule. Twenty-one responses were filed objecting to specific provisions of the final rule and, in most cases, requesting a hearing. In response to those objections that raised genuine and substantial issues of fact that must be resolved through a public hearing, FDA stayed the effective date for provisions regarding certain milk products and eggnog as well as the following: (1) Those provisions of §§ 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1) (redesignated as §§ 131.200(d)(1), 131.203(d)(1), and 131.206(d)(1), respectively) that restricted the type of milk-derived ingredients that may be used to increase the nonfat solids content of cultured milk and yogurts to those listed in these sections; (2) those provisions of §§ 131.200(a), 131.203(a), and 131.206(a) that excluded the use of reconstituted dairy ingredients as basic ingredients in the manufacture of yogurts; (3) those provisions of §§ 131.200(c), 131.203(c), and 131.206(c) (redesignated as §§ 131.200(d), 131.203(d), and 131.206(d), respectively) insofar as they excluded the addition of preservatives to yogurts; (4) those provisions of §§ 131.200(a), 131.203(a), and 131.206(a) that set a minimum titratable acidity of 0.9 percent, expressed as lactic acid; and (5) the provision in § 131.200(a) that the 3.25 percent minimum milkfat level applies to yogurt after the addition of one or more of the optional sources of milk solids not fat listed in § 131.200(c)(1) (redesignated as § 131.200(d)(1)) (47 FR

41519 at 41523, September 21, 1982). To date, due to competing priorities and limited resources, FDA has not held a public hearing to resolve these issues and the effective date for these provisions remains stayed. Therefore, these provisions were never in effect. Consequently, cultured milk and yogurts may deviate from the relevant standards in the previously mentioned respects. For example, although the current standards do not permit the use of certain ingredients such as preservatives or a reconstituted dairy ingredient as a basic ingredient, because of the stayed provisions, FDA has not taken enforcement action against the use of these ingredients in yogurt, lowfat yogurt, or nonfat yogurt. Similarly, yogurt is not required to meet the 0.9 percent minimum titratable acidity requirement in stayed provisions §§ 131.200(a), 131.203(a), and 131.206(a).

B. The National Yogurt Association Petition

The NYA submitted a citizen petition on February 18, 2000 (Docket No. FDA–2000–P–0126 (formerly Docket No. 2000P–0685); hereafter referred to as the petition) requesting that FDA revoke the standards of identity in part 131 (21 CFR part 131) for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206) and amend the standards of identity for yogurt (§ 131.200) and cultured milk (§ 131.112).

In its petition, NYA stated that its recommended standard establishes that yogurt is a food product containing a minimum level of certain live and active cultures; takes into account current industry practices; recognizes the need to allow for use of future technologies; and establishes a clear, consistent, modernized, and flexible yogurt standard that would benefit both industry and consumers. Specifically, NYA recommended a yogurt standard that (1) requires a minimum level of active cultures of 10^7 colony-forming units (CFU) per gram

(g); (2) requires an acidity of pH 4.6 or lower; (3) requires a minimum level of total dairy ingredients of 51 percent; (4) provides for pre-culture homogenization and pasteurization; (5) permits the use of reconstituted milk and whey protein concentrate as “standard dairy ingredients;” (6) provides for the use of any milk-derived ingredients as optional dairy ingredients; (7) permits the use of safe and suitable sweeteners, emulsifiers, and preservatives; (8) permits the optional use of any safe and suitable ingredients added for nutritional or functional purpose; and (9) makes provisions for lowfat and nonfat yogurts based on total fat content of the food per reference amount customarily consumed (RACC).

In addition, NYA requested that the current standard of identity for cultured milk be amended to “conform” to its recommended standard for yogurt. Specifically, NYA recommended that FDA revise the cultured milk standard to (1) provide for the alternate term “fermented milk;” (2) require a minimum level of total dairy ingredients of 51 percent; (3) permit the use of reconstituted milk and whey protein concentrate as “standard dairy ingredients;” (4) provide for the use of any milk-derived ingredients as “optional dairy ingredients;” (5) permit the use of safe and suitable sweeteners, emulsifiers, and preservatives; and (6) permit the use of any safe and suitable ingredients added for nutritional or functional purposes.

NYA pointed out that several provisions of the standards of identity for cultured milk, yogurt, lowfat yogurt, and nonfat yogurt are currently stayed (47 FR 41519) (as discussed in section I.A of this document). NYA contended that these stayed provisions create multiple gaps in the standards for which no guidelines exist and, as a result, the integrity of the food “yogurt” is not maintained.

According to NYA, yogurt has been characterized for centuries by its live and active cultures and, thus, a minimum content of live and active cultures is crucial to the yogurt standard of identity to promote honesty and fair dealing in the interest of consumers. NYA noted that consumers identify yogurt with live and active cultures and expect yogurt to contain a significant amount of these cultures when they purchase the product but have no assurance under the current standard that the yogurt will contain such cultures. NYA maintained that its recommended standard recognizes the defining characteristics of yogurt and establishes that yogurt is a product of fermentation of certain characterizing cultures and that the finished food contains a significant quantity of these live and active cultures, consistent with consumer expectations.

NYA also stated that the recommended amendments to the standard for cultured milk would further serve consumer interest. Under its proposed actions, NYA maintained that foods otherwise satisfying the standard of identity for yogurt that do not contain the required level of the characterizing live and active cultures would not be named “yogurt;” rather, they would be named “cultured milk” or “fermented milk.” Consequently, NYA stated, consumers would not be misled into believing that these foods contain a significant amount of live and active cultures.

NYA also maintained that its recommended amendments would ensure that aspects of yogurt labeling, such as the use of nutrient content claims, are consistent with the requirements of the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535). NYA stated that its recommended standard maintains the three yogurt types (full fat, lowfat, and nonfat yogurts) so manufacturers can continue to make lowfat and nonfat yogurts without

meeting the nutritional equivalence requirement described in § 130.10(b) (21 CFR 130.10(b)). In addition, NYA maintained that its recommended standard would change the milkfat content requirements of lowfat and nonfat yogurts to be consistent with the nutrient content claim requirements for the terms “low fat” and “nonfat” established under the NLEA and codified in § 101.62(b) (21 CFR 101.62(b)).

Additionally, NYA noted that food technology has advanced and industry practices related to yogurt manufacturing have changed since the yogurt standards have been in place. Consequently, NYA asserted that the current yogurt standards impede the yogurt industry and do not allow manufacturers to implement advances in food technology. NYA stated that its recommended standard establishes a modernized, flexible standard of identity for yogurt that takes into account current industry practices and recognizes the need to allow for use of future technologies.

C. The Advance Notice of Proposed Rulemaking

In the **Federal Register** of July 3, 2003 (68 FR 39873), FDA published an advance notice of proposed rulemaking (ANPRM) consistent with section 701(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(1)), which directs the Secretary of Health and Human Services (the Secretary) to publish proposals made by petition to amend or repeal a dairy food standard so long as the petition includes reasonable grounds for the action requested, and to provide interested persons with an opportunity to present their views. In the ANPRM, FDA requested comment by October 1, 2003, on whether the actions proposed in the petition would promote honesty and fair dealing in the interest of consumers. In response to a request to allow additional time to comment, FDA reopened the comment period on October

29, 2003 (68 FR 61639). The reopened comment period ended on January 27, 2004.

In the ANPRM, FDA requested data and information concerning the need for, and the appropriateness of, the amendments requested by NYA, including the revocation of the standards for lowfat and nonfat yogurt and the revision of the standards for yogurt and cultured milk. FDA specifically requested comment on several provisions set forth in the petition, including those related to the use of any safe and suitable ingredient added for nutritional or functional purposes, the measurement of acidity of yogurt, the presence of live and active cultures in yogurt, and vitamin A addition to yogurt, and the need to amend the cultured milk standard of identity to conform to NYA's recommended yogurt standard.

FDA pointed out in the ANPRM that NYA recommended a number of changes to the standards of identity for yogurt and cultured milk. First, NYA recommended that FDA permit the use of any safe and suitable ingredient added for nutritional or functional purposes. NYA stated that this provision is necessary to maintain enough flexibility in the standards to permit the use of novel ingredients as they are developed. FDA acknowledged the need for food standards to permit flexibility in food technology so long as that technology does not alter the basic nature or essential characteristics of the food. FDA stated that the existing provisions in § 130.10 already provide for the addition of substances for nutritional purposes to standardized foods. FDA also noted that flexibility in the use of ingredients for functional purposes may be achieved by specifying the ingredients by functional use category, e.g., "emulsifiers" or "preservatives," rather than by listing the specific ingredients. FDA asked for comment on the need for any functional ingredient categories,

in addition to the ones recommended in the petition, in the manufacture of yogurt.

Second, NYA recommended a maximum pH of 4.6 for yogurt, stating that this level reflects the lower end of titratable acidity levels found in common industry practice and that measuring pH, rather than titratable acidity expressed as lactic acid, reflects the current industry practice and is a more accurate and convenient method of measuring acidity. FDA asked for comment both on the maximum pH recommended by NYA and the use of pH rather than titratable acidity to measure the acidity of yogurt.

Third, NYA recommended that FDA require a specific amount of live and active cultures in yogurt based on an assertion that consumers expect yogurt to contain significant amounts of live and active cultures. In its recommended new yogurt standard, NYA required yogurt to contain a minimum of 10^7 CFU/g of live and active cultures at the time of manufacture. NYA also suggested that manufacturers may test their yogurt products to demonstrate that the products, under proper distribution and storage conditions, would be expected to contain at least 10^6 CFU/g of live and active cultures through the manufacturer's designated code life for the product and at the anticipated time of consumption. FDA asked for comment on the following topics: (1) Whether the presence of live and active cultures is an essential characteristic of yogurt and, if so, in what amounts; (2) the appropriateness of NYA's suggested provision that manufacturers "may" conduct tests to ensure the presence of live and active cultures through the assigned code life for the product; and (3) whether NYA's recommended standard of identity for yogurt would adequately ensure the presence of appropriate amounts of live and active cultures in yogurt throughout the shelf life of the product and at the point

of purchase or consumption. FDA also asked whether any alternative provisions may be needed to fulfill this requirement.

In addition, FDA sought comment on vitamin A addition to lowfat and nonfat yogurt. FDA previously proposed to revoke a number of lowfat and nonfat standards, i.e., §§ 131.122 (sweetened condensed skimmed milk), 131.123 (lowfat dry milk), 131.132 (evaporated skimmed milk), 131.135 (lowfat milk), 131.136 (acidified lowfat milk), 131.138 (cultured lowfat milk), 131.143 (skim milk), 131.144 (acidified skim milk), 131.146 (cultured skim milk), 131.185 (sour half-and-half), 131.187 (acidified sour half-and-half), 131.203 (lowfat yogurt), 131.206 (nonfat yogurt), and 133.131 (lowfat cottage cheese) to ensure that the use of nutrient content claims in the labeling of these products would be consistent with the provisions of the NLEA (60 FR 56541, November 9, 1995). FDA revoked all of the previously mentioned standards except for lowfat yogurt and nonfat yogurt on November 20, 1996 (61 FR 58991). FDA delayed final action on its proposal to revoke these standards for 120 days because of the technical difficulties and economic considerations associated with their revocation (61 FR 58991 at 58999). FDA acknowledged that, if the standards for lowfat and nonfat yogurts were revoked, modifying the standardized food yogurt to make the nutrient content claims “lowfat” or “nonfat” under the provisions of § 130.10 would require vitamin A addition to make the product nutritionally equivalent to full fat yogurt. FDA also acknowledged that such a vitamin addition requirement could potentially result in significant relabeling, reformulation, and equipment costs to manufacturers. The agency believed that its decision to defer, for a limited time, action on the standards of identity for yogurt products would provide an appropriate balance between the problem the industry was facing and

consumers' interest in consistently and fairly labeled foods. FDA also advised of its intention at the end of the 120-day period to move to resolve the inconsistencies between the use of the terms "lowfat" and "nonfat" in the names of standardized yogurt and the definitions for these terms established under the nutrient content claims regulations (61 FR 58991 at 58999). As FDA noted in the ANPRM, this issue is yet to be resolved. In fact, the 1995 proposed rule to revoke the lowfat and nonfat yogurt products was subsequently withdrawn (69 FR 68831, November 26, 2004) as part of the agency initiative to withdraw certain proposed actions that were over 5 years old and no longer considered viable candidates for final action at that time. This action was taken to reduce the agency's regulatory backlog and focus its resources on public health issues current at that time.

According to the yogurt standard recommended by NYA, manufacturers would continue to be able to make lowfat and nonfat yogurts without having to meet the nutritional equivalence requirement. FDA asked whether the yogurt industry is better able and equipped to meet the nutritional equivalence requirements of § 130.10 than it was in 1996, when FDA deferred action on this issue. FDA also asked for comment on the need and appropriateness of continuing to exempt yogurt, unlike other standardized foods making low fat and nonfat nutrient content claims, from the nutritional equivalence requirement.

Finally, NYA recommended that FDA revise the current standard of identity for cultured milk (§ 131.112) so that if the food otherwise meets the yogurt standard but does not contain the characterizing cultures at the required levels, then the food would qualify as cultured milk or could alternatively be named "fermented milk." FDA pointed out in the ANPRM that the standard

of identity for cultured milk has been in place for several decades and, in light of consumer experience with cultured milk, the agency asked for comment on the need to amend the standard for cultured milk and the appropriateness of the amendments requested by NYA.

D. Comments on the ANPRM

In response to the ANPRM, FDA received a total of 65 responses, each containing one or more comments, from industry, trade associations, consumers, government, and academia. Overall, comments from industry broadly supported the need to modernize the yogurt standards to allow recent technological advances in food processing and to incorporate flexibility in yogurt manufacturing while preserving the basic nature and essential characteristics of yogurt. One milk producers' association opposed revising the current yogurt or cultured milk standards, while several consumers expressed concerns on different provisions recommended by NYA.

Comments from industry strongly supported the establishment of a single yogurt standard that provides for varying levels of fat content and that reflects today's manufacturing practices while taking into account the stayed provisions of the current yogurt standards. These comments also expressed broad support of NYA's petition to the extent that the amended standard would expressly permit those industry practices that are not now restricted under the stayed provisions of the current standard. For example, some comments stated that, since certain provisions of the current yogurt standards were stayed, virtually all domestically-produced yogurt utilizes reconstituted dairy ingredients as basic ingredients and, therefore, these comments recommended that the modernized yogurt standard account for this typical industry practice. Similarly, the comments stated that, since certain other provisions were stayed,

a wide range of milk-derived ingredients that provide a technical or functional purpose are used as optional ingredients in the manufacture of yogurt, and several comments from industry supported NYA's recommended amendment that would permit this practice. There was also broad support to amend the standards to bring the fat content of lowfat and nonfat yogurts in line with the provisions of the NLEA.

While in agreement with NYA that the yogurt standards need to be modernized, some other comments opposed some of the amendments sought by NYA. For example, NYA recommended that yogurt contain a specific amount of live and active cultures. Some comments from industry and academia supported this requirement and noted the health benefits associated with live and active cultures in yogurt. However, other industry comments strongly opposed requiring that yogurt contain live and active cultures. These comments did not agree with NYA that live and active cultures are an essential characteristic of "yogurt" nor did they agree with NYA that consumers expect a minimum live and active culture content of 10^6 CFU/g or any other specified amount. These comments pointed out that NYA neither presented any evidence to support its contention that consumers expect a certain specified amount of live and active cultures in yogurt nor provided a technical rationale or criteria to evaluate whether the proposed 10^6 CFU/g is the appropriate level. In addition, one major trade association noted in its comments that members of its organization were unable to reach an agreement on whether the presence of live and active cultures is an essential characteristic of yogurt and whether the amount of cultures recommended by NYA is the appropriate level.

Similarly, comments to other provisions that NYA requested in its petition also were mixed. NYA's recommended revisions to the standards would not

permit heat treatment of yogurt after culturing and would require yogurt that is heat-treated after culturing to be named “cultured milk” or “fermented milk” rather than “yogurt, heat-treated after culturing” as is permitted by the current standards. While some comments from the domestic industry supported this provision, others from industry, both domestic and international, and one comment from a foreign government strongly opposed this provision. They stated that processors should be permitted to market heat-treated yogurt, provided that the heat treatment is appropriately declared on the label, as is the current practice, and that changing the name of this food now to “cultured milk” or “fermented milk” would be confusing to consumers.

With respect to NYA’s recommended provision that would permit yogurt to contain non-nutritive sweeteners and be labeled simply “yogurt” without a specific declaration of the non-nutritive sweetener in the name of the food, comments were varied. While comments from industry supported this provision, several consumers and at least one State government agency strongly opposed this provision, stating that consumers have become accustomed to identification of aspartame in the name of the food¹ and that removal of this identification would be misleading to consumers and could prove harmful to those individuals with phenylketonuria.

Several consumers, dairy farmers, and milk producers, and one State government agency strongly opposed NYA’s recommended provisions that any milk-derived ingredient should be permitted as an optional ingredient and that any safe and suitable ingredient should be permitted for a nutritional or

¹ Specifically concerning the labeling of lowfat and nonfat yogurts that are sweetened with aspartame, the agency previously advised that provided the lowfat and nonfat yogurt products conform to the relevant standards of identity prior to the addition of aspartame, the descriptors “lowfat (or nonfat) yogurt with aspartame sweetener” and “lowfat (or nonfat) yogurt sweetened with aspartame” are acceptable statements of identity for these products (Ref. 1).

functional purpose. These comments cited concerns including the use of imported, cheaper, and inferior quality substances, which would adversely affect the quality of the yogurt; the potential health risks associated with unregulated, imported products; and the unfair economic disadvantage to U.S. dairy plants.

Comments were varied on the use of whey protein concentrate as a basic ingredient and the minimum amount of dairy ingredients by weight of yogurt. Most comments from industry supported the use of whey protein concentrate as a basic ingredient but other comments, primarily from consumers and dairy farmers, opposed this provision, citing product quality concerns. With respect to NYA's recommended provision that yogurt contain a minimum of 51 percent dairy ingredients by weight of yogurt, comments from an industry group supported the provision, but other comments from consumers expressed concern that this provision could allow yogurt to contain up to 49 percent non-dairy ingredients and still be characterized as "yogurt." The existing standards for yogurt, lowfat yogurt, and nonfat yogurt do not include requirements with respect to the proportion of dairy ingredients in the finished food. Rather, the standards restrict the use of non-dairy ingredients to a limited and specific list of substances that fulfill a technical or functional purpose.

With respect to NYA's recommended amendments to the cultured milk standard, a few comments supported, while several other comments from industry (both domestic and international) and milk producers opposed NYA's recommended provisions. The comments that opposed the amendments stated that it would not be appropriate to amend the cultured milk standard simply to include products that do not fit into the NYA's recommended yogurt standard and that have never been considered by the industry or consumers

to be cultured milk. Some of these comments also noted that NYA's petition did not address the consumer confusion that might occur from including semisolid yogurt-type products (that otherwise meet NYA's recommended yogurt standard but do not contain the characterizing cultures at the specified levels) in the cultured milk standard, which has long been associated with fluid products. A major trade association also noted that its members could not reach agreement on this issue. Specific comments will be discussed in the proposed amendment section where appropriate.

II. The Proposal

A. Legal Authority/Statutory Directive

Section 401 of the act (21 U.S.C. 341) directs the Secretary to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers. Under section 701(e) of the act, any action for the amendment or repeal of any definition and standard of identity under section 401 of the act for any dairy product (e.g., yogurt) shall be begun by a proposal made either by the Secretary on his own initiative or by petition of any interested persons, showing reasonable grounds therefor, filed with the Secretary.

B. Proposed Amendments

Based on all available information, including the information presented in the petition and the comments to the ANPRM, FDA is proposing to amend the yogurt standard and revoke the lowfat and nonfat yogurt standards to promote honesty and fair dealing in the interest of consumers. This proposal is also consistent with FDA's proposed general principles for modernizing food standards (70 FR 29214, May 20, 2005). In addition, consistent with 21 CFR

130.6, which states that food standards adopted by the Codex Alimentarius Commission will be reviewed by FDA (and either will be accepted, with or without change, or will not be accepted), FDA reviewed the Codex Standard for Fermented Milks (CODEX STAN 243–2003) (herein after referred to as the Codex Standard) (Ref. 2), which encompasses the standard for “yoghurt” and provides that yoghurt may be spelled as appropriate in the country of retail sale. FDA reviewed the Codex Standard to harmonize, to the extent feasible, the proposed amendments with Codex provisions for “yoghurt,” while preserving the integrity, quality, and economic value that U.S. consumers expect of yogurt.

FDA tentatively concludes that the proposed amendments are necessary to modernize the current yogurt standard to permit flexibility and provide for technological advances in yogurt production, while preserving the basic nature and essential characteristics of yogurt consistent with consumer expectations and thus protecting consumer interest. FDA considered the different amendments recommended by NYA and tentatively concluded that some of NYA’s recommended amendments are not consistent with the basic nature and essential characteristics of yogurt or cultured milk. Each of the amendments recommended by NYA and FDA’s tentative conclusions are discussed here.

1. Yogurt

a. *Milkfat and milk solids not fat content of yogurt.* The current standard of identity for yogurt requires a minimum milkfat content of 3.25 percent and a minimum milk solids not fat content of 8.25 percent in yogurt prior to the addition of bulky flavoring ingredients (§ 131.200(a)). In response to an objection to the January 30, 1981, final rule that applying the milkfat minimum to yogurt which has been made to contain milk solids not fat at a level higher

than the minimum requirement of the standard will discourage manufacturers from using higher levels of milk solids not fat in yogurt because such addition would then require the use of more milkfat, FDA stayed the requirement that the minimum milkfat level is applied after the addition of optional dairy ingredients. FDA pointed out that the minimum 3.25 percent milkfat and the 8.25 percent milk solids not fat requirements apply prior to the addition of any bulky flavors and that while other optional dairy ingredients may be used to increase the milk solids not fat content of yogurt to above 8.25 percent, the standard does not provide for a proportionate decrease in the minimum milkfat content. FDA determined that whether the minimum milkfat requirement of 3.25 percent should apply to yogurt before or after the addition of optional dairy ingredients used to increase the milk solids not fat content should be resolved through a public hearing and stayed that requirement pending a public hearing (47 FR 41519 at 41521).

NYA did not recommend a specific total fat content for yogurt. However, NYA requested that any level of fat above the level considered “low fat” (per § 101.62(b)(2)) should be permitted in a product named “yogurt.” Accordingly, NYA recommended that the total fat content of yogurt should be any level higher than 3.0 g per 225 g. NYA also noted that its recommended provision would measure the fat content on a finished food basis and, therefore, would provide consumers with more accurate information about the yogurt’s actual fat content.

Some comments in response to the ANPRM supported retaining the current 3.25 percent minimum milkfat content of yogurt and noted that this level is consistent with the fat content requirement for milk. FDA notes that NYA’s recommended minimum fat content of 3.0 g per 225 g would equate

to lowering the current minimum milkfat content of 3.25 percent to about 1.3 percent. NYA did not provide adequate justification for this change to the minimum fat content of yogurt. FDA agrees with NYA that it is appropriate to revise the existing lowfat and nonfat yogurt standards of identity to conform these foods with the nutrient content claims requirements for “low fat” and “non fat,” respectively, as discussed further in section II.B.2 of this document. However, NYA did not provide a justification for lowering the minimum fat content of yogurt that is named simply “yogurt” and whose labeling does not bear a claim related to its fat content. Furthermore, the yogurt standard with the minimum 3.25 percent milkfat requirement has been in place for over two decades (although the application of this level after the addition of optional dairy ingredients was stayed) and appears to be used in the manufacture of full-fat yogurts available in the marketplace today. According to the U.S. Department of Agriculture (USDA) National Nutrient Database for Standard Reference, Release 19 (2006), the total fat content of “yogurt, plain, whole milk” is 3.25 percent (Ref. 3), consistent with the minimum milkfat requirement of the current standard of identity for yogurt. With respect to the minimum milk solids not fat content of yogurt, neither NYA nor comments in response to the ANPRM requested a revision to the current requirement of 8.25 percent. In addition, FDA does not have any data or information to suggest that there is a need to reconsider the current requirement of a minimum of 8.25 percent milk solids not fat in yogurt. Therefore, FDA is maintaining the current requirements of a minimum amount of 3.25 percent milkfat and 8.25 percent milk solids not fat in yogurt.

With respect to the measurement of these components in yogurt, NYA requested that the minimum milk solids not fat content of 8.25 percent be

derived from basic dairy ingredients and, therefore, that this requirement be applied prior to the addition of any permitted optional ingredients. We agree that the optional dairy ingredients may be used to increase the milk solids not fat levels above the minimum required 8.25 percent, not to meet this minimum level. FDA previously clarified this purpose of the provision in the final rule establishing the current standard that permits optional milk-derived ingredients to increase the nonfat milk solids content (46 FR 9924 at 9927). In addition, as FDA noted in 1982, while § 131.200(a) of the current yogurt standard provides for the use of optional dairy ingredients to increase the milk solids not fat levels above the minimum required 8.25 percent, this provision was not intended to provide nor does it provide for a proportionate decrease in the minimum milkfat content of yogurt (47 FR 41519 at 41521).

FDA also believes that the addition of bulky flavoring ingredients such as fruits and fruit preparations lowers the milkfat and milk solids not fat levels of the resultant flavored yogurt. Therefore, to ensure the quality and compositional characteristics of the finished flavored yogurt, the milkfat and milk solids not fat requirements should apply to the yogurt portion prior to the addition of bulky flavoring ingredients. Comments in response to the ANPRM did not provide any specific comments on this issue. Furthermore, applying the milkfat and milk solids not fat requirements prior to the addition of flavoring ingredients only is consistent with the Codex Standard, which applies milkfat, milk protein, and other compositional criteria to the fermented milk part only, before flavoring ingredients are added.

For these reasons, FDA tentatively concludes that requiring a minimum milkfat content of 3.25 percent and a milk solids not fat content of 8.25 percent in yogurt prior to the addition of any bulky flavoring ingredients would

promote honesty and fair dealing in the interest of consumers by ensuring the overall quality and composition of yogurt that may or may not contain added flavoring ingredients. Therefore, FDA is proposing to require in § 131.200(a) that yogurt have a minimum milkfat content of 3.25 percent and a minimum milk solids not fat content of 8.25 percent before the addition of bulky flavoring ingredients. FDA seeks comment on the need for and appropriateness of the following provisions: (1) A minimum milkfat content of 3.25 percent in yogurt, (2) a minimum milk solids not fat content of 8.25 percent, and (3) the application of these two compositional requirements prior to the addition of bulky flavoring ingredients.

b. *Acidity of yogurt.* FDA stayed those portions of the standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (§§ 131.200(a), 131.203(a), and 131.206(a), respectively) that required a minimum titratable acidity of 0.9 percent. These standards also allow an equivalent potentiometric method to be used to determine acidity (i.e., a pH value) in lieu of the Association of Official Analytical Chemists International (AOAC) titration method that is specified in the standards. FDA stayed these provisions in response to an objection to the January 30, 1981, final rule that the required acidity was too high for some consumers' taste and that 0.75 percent is the common industry practice. The agency stated that until such time as this issue is resolved, yogurt, lowfat yogurt, and nonfat yogurt will not be required to meet the 0.9 percent minimum level of titratable acidity (47 FR 41519 at 41522).

NYA requested that yogurt contain a minimum titratable acidity of 0.7 percent prior to the addition of optional ingredients and stated that this level reflects the lower end of titratable acidity commonly used by industry today. This lower acidity level is also supported by comments in response to the

ANPRM. NYA also requested that the yogurt standard specify the acidity requirement as a determination of pH rather than titratable acidity because measuring pH reflects current industry practice and is a more accurate and convenient method than measuring titratable acidity. NYA recommended a maximum pH of 4.6. FDA believes that allowing a minimum titratable acidity of 0.7 percent or an equivalent maximum pH of 4.6 is appropriate as it reflects current industry practice and better meets some consumers' taste preferences. FDA believes that providing for the measurement of acidity in yogurt as a determination of its pH as well as its titratable acidity will introduce flexibility in the yogurt standard. FDA recognizes that each method may pose certain challenges in its application to yogurt. For example, the addition of flavors and colors may interfere with the precise determination of the colorimetric endpoint of titration. By providing for both pH and titratable acidity measurements, the standard gives manufacturers the flexibility to choose a method that best suits their product.

With respect to the application of this acidity requirement, NYA requested that the acidity requirement should apply prior to the addition of any permitted optional ingredients, including dairy ingredients added for technical or functional purposes, microbial cultures, sweeteners, and flavoring ingredients. The stayed provisions that required a minimum titratable acidity would have applied prior to the addition of bulky flavors only. FDA believes that the addition of bulky flavoring ingredients such as fruits and fruit preparations may significantly impact the acidity of the resultant flavored yogurt. Therefore, to ensure the overall quality and sensory characteristics of the finished flavored yogurt, the acidity requirement should apply to the yogurt portion prior to the addition of bulky flavoring ingredients. FDA does not

believe that it is appropriate to exclude the other permitted optional ingredients such as safe and suitable cultures and optional dairy ingredients from the point at which acidity is measured, as these ingredients can be important contributors to the culturing process and acidity development of yogurt. In addition, applying the acidity requirement prior to the addition of bulky flavoring ingredients only is consistent with the Codex Standard, which applies the compositional criteria in the case of flavored fermented milks to the fermented milk part only.

For these reasons, FDA tentatively concludes that a minimum titratable acidity of yogurt of 0.7 percent or a maximum pH of 4.6 is appropriate. FDA also tentatively concludes that applying the acidity requirement to yogurt prior to the addition of bulky flavoring ingredients promotes honesty and fair dealing in the interest of consumers by ensuring the overall quality and sensory characteristics of yogurt. Therefore, FDA is proposing to revise § 131.200(a) to require that, before the addition of bulky flavors, yogurts have either a minimum titratable acidity of 0.7 percent or a maximum pH of 4.6. FDA is interested in comments on the appropriateness of the proposed level and measurement of acidity. In the proposed yogurt standard, FDA has also reformatted this paragraph to be clear, simple, and easy to use by both manufacturers and FDA officials that enforce compliance with the standards.

c. Live and active cultures in yogurt. The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (§§ 131.200, 131.203, and 131.206, respectively) do not require the presence of a specific amount of live and active cultures in yogurt, lowfat yogurt, or nonfat yogurt. NYA recommended that FDA revise the yogurt standards to require a specified amount of live and active cultures and that heat treatment should not be permitted after culturing

because it destroys the live and active cultures in yogurt. NYA submitted data obtained from consumer surveys to support its argument that consumers expect “yogurt” to contain live and active cultures. While the NYA consumer surveys adequately show that consumers believe that yogurt is a healthful food, FDA does not agree that the data submitted support its argument that consumers are generally aware of the presence of live cultures in yogurt or that they expect yogurt to contain live cultures (Ref. 4).

In the absence of convincing data demonstrating that the presence of live and active cultures is a characteristic that consumers expect in yogurt, FDA does not have a basis to require live and active cultures in yogurt at the time of manufacture or at the retail level. Therefore, FDA is not proposing that yogurt must contain a specified amount of live and active cultures.

However, based on the petitioner’s request as well as some comments in response to the ANPRM, there appears to be interest among manufacturers in distinguishing their yogurt products from other yogurt products on the basis of the level of live and active cultures in the food. In the interest of providing a flexible standard that allows for appropriate product diversity and provides for truthful and nonmisleading labeling of yogurt that contains a set amount of live and active cultures, FDA is proposing (1) in § 131.200(a) that yogurt that is not heat-treated may contain a minimum of 10^7 CFU/g of live and active cultures at the time of manufacture of the yogurt with a reasonable expectation that yogurt contains live and active cultures at a level of 10^6 CFU/g at the retail level through the manufacturer’s assigned shelf life of the product and (2) in § 131.200(f)(3) to permit an optional labeling statement such as “contains live and active cultures” or another appropriate descriptor on such yogurt that

is not heat-treated after culturing and that contains the specified amount of live and active cultures.

These levels of live and active cultures are as proposed by the petitioner. The Codex Standard, on the other hand, establishes a minimum amount of microorganisms constituting the starter culture of 10^7 CFU/g of yogurt. FDA seeks comment on the appropriateness of providing for special labeling statements on yogurt products that contain a certain minimum level of live and active cultures and the appropriateness of a minimum level of 10^6 CFU/g throughout the shelf life of the food as the basis for the special labeling statements.

d. *Heat treatment of yogurt after culturing.* The current yogurt standards do permit heat treatment after culturing, provided the phrase “heat-treated after culturing” follows the name of the food in the labeling of these products (§§ 131.200(f)(1)(ii), 131.203(f)(1)(iii), and 131.206(f)(1)(ii), respectively). During the adoption of the yogurt standards, FDA reviewed extensively the question of whether the standards should permit heat treatment of the product after the culturing process. FDA acknowledged in its June 10, 1977, proposal that yogurt is a cultured product containing microorganisms but that in some cases, yogurt is heat-treated after culturing to kill these microorganisms and extend the shelf life of the food (42 FR 29919 at 29920, June 10, 1977). FDA also opined that “except for destroying the microorganisms, these foods retain essentially the same characteristic attributes” of traditional yogurt and, therefore, proposed to preserve the food “yogurt” unqualified in its traditional form that is not heat-treated after culturing and to provide for appropriate labeling “to inform consumers when yogurt has been heat-treated after culturing” (42 FR 29919 at 29920). In response to comments to that proposed

rule, FDA further advised in a final rule that “it is in the best interest of both consumers and international trade to permit heat treatment of yogurts and to require auxiliary labeling to inform consumers that the product has been heat-treated” (46 FR 9924 at 9931).

NYA’s consumer survey data do not support the argument that heat treatment following culturing is inconsistent with consumer expectations of a food named “yogurt.” FDA has no evidence nor is it aware of any information that suggests that the name “yogurt,” when appropriately qualified by the phrase “heat-treated after culturing,” is misleading to consumers in that they believe this food to be “yogurt” that is not heat-treated after culturing. Therefore, FDA is not persuaded that heat treatment after culturing should be prohibited by the yogurt standard. Accordingly, FDA is retaining in § 131.200(a) the provision that permits heat treatment of yogurt after culturing to extend the shelf life of the food.

A review of the data that NYA submitted to support its assertion of consumer expectations of live and active cultures as a characteristic of yogurt also provides some information about consumers’ understanding of the term “heat-treated after culturing.” Although the surveys had several methodological limitations, the data suggest that consumers do not fully understand the meaning of the term “heat-treated after culturing” on yogurt products (Ref. 4). However, no further information or reasons for this finding can be ascertained; for example, it is possible that consumers do not relate the heat treatment statement to its impact on specific attributes of the food. If consumers generally do not expect “yogurt” to contain live and active cultures, as suggested by NYA’s survey data, it is likely that they do not associate the descriptor “heat-treated after culturing” with its effect on live

and active cultures in the food. With the exception of these initial data, FDA does not have factual information or data that would lead us to conclude at this time that “heat-treated after culturing” is not an appropriate accompanying statement for yogurt that is heat-treated after culturing. “Heat-treated after culturing” is a truthful statement that accurately and adequately describes the basic identity of the food. Further, FDA provided for the use of this phrase since the time the yogurt standards were adopted in 1981 and some manufacturers appear to be using this descriptor in the labeling of their products. Most consumer comments that FDA received at the time of adoption of these standards expressed approval of the labeling statement “heat-treated after culturing” to differentiate between heat-treated and non-heat-treated yogurts (46 FR 9924 at 9931). FDA did not receive any consumer comments in response to the ANPRM that expressed a lack of understanding or other concerns with this descriptor in the labeling of yogurts. Therefore, FDA is maintaining the current descriptor “heat-treated after culturing” to accompany the name of the food for yogurt that undergoes heat treatment after the culturing process. However, to enhance consumer understanding of this phrase, provide more meaningful information about the impact of the heat treatment on specific attributes of the food, and distinguish these products from traditional yogurt, FDA advises that manufacturers may consider using additional truthful and nonmisleading statements, such as “does not contain live and active cultures,” in the labeling of their heat-treated yogurt products.

e. Use of reconstituted milk forms as basic dairy ingredients. The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (§§ 131.200, 131.203, and 131.206, respectively) do not provide for the use of reconstituted dairy ingredients as basic dairy ingredients in their manufacture. FDA stayed

those portions of §§ 131.200(a), 131.203(a), and 131.206(a)) insofar as they exclude the use of reconstituted dairy ingredients as basic ingredients in the manufacture of yogurts in response to an objection to the January 30, 1981, final rule that yogurt manufacturers in Florida and the Southeastern States will be adversely affected because the fluid milk supplies in these States are often insufficient for use in yogurt manufacture (47 FR 41519 at 41521). FDA also stated that until such time as this issue is resolved, the use of reconstituted dairy ingredients as basic ingredients in the manufacture of yogurt, lowfat yogurt, or nonfat yogurt will not be the basis for regulatory action (47 FR 41519 at 41521).

According to NYA, manufacturers have routinely used reconstituted dairy ingredients in the manufacture of yogurts. Comments in response to the ANPRM also stated that reconstituted dairy ingredients are currently used as basic ingredients in the manufacture of yogurts and recommended that FDA adopt a modernized yogurt standard that permits this typical industry practice. FDA is not aware of any data or other information that would suggest that the use of reconstituted forms of permitted dairy ingredients, i.e., cream, milk, partially skimmed milk, and skim milk, has an adverse effect on yogurt quality or safety. Moreover, FDA's standards currently permit the use of reconstituted forms of dairy ingredients as basic ingredients in the manufacture of other standardized dairy foods, such as cheeses and related cheese products, ice cream, and frozen custard. Seeing no technical or safety concerns, FDA tentatively concludes that it is appropriate to permit reconstituted forms of cream, milk, partially skimmed milk, and skim milk as basic ingredients in the manufacture of yogurt and its lower fat versions. Therefore, FDA is proposing to revise § 131.200 to permit reconstituted forms of cream, milk,

partially skimmed milk, and skim milk as basic ingredients by (1) redesignating current § 131.200(c) as proposed § 131.200(b), (2) renaming the heading of newly proposed § 131.200(b) as “Basic dairy ingredients” instead of “Optional dairy ingredients” because the proposed new nomenclature better describes the proposed provision, and (3) revising newly proposed § 131.200(b) to include the reconstituted versions of the dairy ingredients permitted in current § 131.200(c). FDA seeks comment on the need for and appropriateness of this proposed provision.

f. Use of safe and suitable milk-derived ingredients as optional dairy ingredients. Stayed portions of the standards of identity for yogurt, lowfat yogurt, and nonfat yogurt listed the optional milk-derived ingredients (i.e., concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, and whey modified by partial or complete removal of lactose and/or minerals) that can be used for the purpose of increasing the nonfat solids content of these foods above the minimum required 8.25 percent, provided the ratio of protein to total nonfat solids of the food and the protein efficiency ratio of all protein present is not decreased as a result of adding these optional ingredients (§§ 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1); redesignated as §§ 131.200(d)(1), 131.203(d)(1), and 131.206(d)(1)). FDA stayed these provisions in response to objections to the January 30, 1981, final rule that these provisions preclude the use of other safe, nutritional, and functional milk-derived ingredients and that there appears to be no rational factual basis for the omission of traditional ingredients such as partially delactosed skim milk, partially hydrolyzed whey, and other safe and suitable ingredients (47 FR 41519).

NYA stated that manufacturers currently use a variety of safe and suitable milk-derived ingredients for the purpose of increasing the nonfat solids content of yogurts. FDA is not aware of any data or other information that would suggest that expanding the current list of optional milk-derived ingredients to permit the use of any safe and suitable milk-derived ingredient, under the conditions stated in the current standard to maintain the nutritional quality of yogurt, would have an adverse effect on the overall quality or safety of yogurt. FDA believes that it is appropriate to incorporate technological flexibility into standards so long as the basic nature and essential characteristics of the food are not adversely affected. Therefore, FDA is proposing to permit the optional use of any safe and suitable milk-derived ingredient as an optional dairy ingredient in the manufacture of yogurt to increase the nonfat solids content of the food above the minimum required 8.25 percent, provided the ratio of protein to total nonfat solids of the food and the protein efficiency ratio of protein present in the food are not decreased as a result of the use of such ingredients. Specifically, FDA is proposing, in new § 131.200(c), “Optional dairy ingredients,” to permit other safe and suitable milk-derived ingredients to be used to increase the nonfat solids content of the food, provided the ratio of protein to total nonfat solids of the food and the protein efficiency ratio of protein present in the food are not decreased as a result of the use of such ingredients. FDA seeks comment on the need for and appropriateness of this proposed provision.

g. Use of safe and suitable cultures in addition to the characterizing bacterial cultures. The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (§§ 131.200, 131.203, and 131.206, respectively) do not prohibit the use of bacterial cultures in addition to the two characterizing lactic

acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. However, the standards do not explicitly state that other bacterial cultures are permitted. NYA requested that FDA revise the yogurt standard to clearly permit the use of other safe and suitable bacterial cultures in addition to the characterizing bacterial cultures. FDA tentatively concludes that explicitly providing for the use of other optional bacterial cultures will enhance the clarity of the yogurt standard. Therefore, FDA is proposing to clarify in new § 131.200(d)(1) that optional safe and suitable cultures may be used only in addition to the required characterizing bacterial cultures specified in the standard.

h. *Use of sweeteners.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt currently provide for the optional use of certain nutritive carbohydrate sweeteners, specifically: Sugar (beet or cane), invert sugar, brown sugar, refiner's syrup, molasses (other than blackstrap), high fructose corn syrup, fructose, fructose syrup, maltose, maltose syrup, dried maltose syrup, malt extract, dried malt extract, malt syrup, dried malt syrup, honey, maple sugar, and any of the sweeteners listed in 21 CFR part 168, except table syrup (§§ 131.200(d)(2), 131.203(d)(2), and 131.206(d)(2), respectively, as redesignated in the September 21, 1982 final rule (47 FR 41519)). The term "sweetened" must accompany the name of yogurt, lowfat yogurt, and nonfat yogurt that is sweetened without the addition of characterizing flavor with any one or more of these permitted sweeteners (§§ 131.200(f)(1)(i), 131.203(f)(1)(ii), and 131.206(f)(1)(i), respectively, as redesignated in the September 21, 1982, final rule (47 FR 41519)).

NYA requested that FDA revise the current yogurt standards to permit "safe and suitable sweeteners" without specifying a list, as is permitted for

ice cream (21 CFR 135.110(a)(1)), with the sweetener being declared in the ingredient statement of the food so that non-nutritive sweeteners may be used in yogurt without a specific declaration of its presence in the name of the food. NYA argued that under current regulations, manufacturers are able to use non-nutritive sweeteners in yogurt that is modified to be eligible to bear a nutrient content claim, for example, “reduced calorie yogurt,” without a specific declaration of the presence of the non-nutritive sweetener in the name of the food. Consumer comments to the ANPRM strongly opposed this NYA recommendation and requested that the presence of non-nutritive sweeteners be declared in the name of the food.

The regulatory framework governing the naming of standardized foods that do not fully comply with the relevant standards of identity changed with the passage of the NLEA in 1990 and the subsequent establishment of the agency’s requirements for foods named by use of a nutrient content claim and a standardized term (§ 130.10). Specifically, § 130.10(d) permits the addition of safe and suitable ingredients to a standardized food modified to be eligible to bear defined nutrient content claims when these ingredients are needed to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristic to the standardized food even though these ingredients are not specifically permitted by an individual food standard.

In addition, these non-nutritive sweeteners must only be declared by their common or usual names in the ingredient statement as required by § 101.4(a) (21 CFR 101.4(a)), as their presence in the standardized food is not required to be declared within the name of the food. Therefore, for example, a product named “light sweetened yogurt” or “reduced calorie sweetened yogurt” may contain non-nutritive sweeteners to add sweetness to the product so that it

is not inferior in its sweetness property compared to its standardized counterpart, sweetened yogurt. The provisions of § 130.10 do not require these yogurt products to declare the presence of such non-nutritive sweeteners within the name of these foods. The same is true for other standardized foods modified under § 130.10; for example, “light ice cream” and “reduced calorie sweet chocolate.”

There are, however, certain exceptions where the regulatory framework governing the naming of standardized foods that do not fully comply with the relevant standards of identity was not changed by NLEA or the establishment of § 130.10. For example, a few artificially sweetened foods are governed by standards of identity that establish the phrase “artificially sweetened” as a part of the statement of identity of these foods (for example, “artificially sweetened canned pears” (see 21 CFR 145.176)). FDA may consider appropriate actions in the future to bring these particular standardized foods in conformity with NLEA. With the exception of these standardized artificially sweetened foods, foods that are made using non-nutritive sweeteners are not required to declare the presence of the non-nutritive sweetener within the name of the food. Per the ingredient labeling requirements of § 101.4(a), the non-nutritive sweetener is declared by its common or usual name in the ingredient statement of the food. Where special labeling requirements are necessary for the safe use of a non-nutritive sweetener, the conditions for including this information on the label and how and where this information is to be presented on the label are established in the relevant food additive regulation(s). For example, labels of foods that contain aspartame are required to bear the statement “PHENYLKETONURICS: CONTAINS PHENYLALANINE” either on the principal display panel or on the information panel, in accordance with 21

CFR 172.804. This regulation also requires that the statement shall appear prominently and conspicuously in contrast to other printed matter on the label. Any new sweetening ingredients developed and permitted for use in foods in the future will be required to be labeled in accordance with similar new labeling or other requirements necessary for the safe use of the sweetener.

FDA recognizes that there is considerable interest in the special labeling requirements for artificial sweeteners when used in foods in general. Over the years, FDA has been asked to require the disclosure of artificial sweeteners on the principal display panel in addition to the ingredient list. The agency considers the safety of artificial sweeteners as part of the food additive review process and has and will continue to establish special labeling or packaging requirements where necessary for the safe use of these ingredients. FDA does not object to manufacturers voluntarily declaring on the principal display panel that the product is artificially sweetened nor does the agency object to truthful and nonmisleading statements to inform consumers of yogurt that is made using non-nutritive sweeteners.

For these reasons, FDA tentatively concludes that providing for the use of any safe and suitable sweetening ingredients, in lieu of the current allowance for certain nutritive carbohydrate sweeteners, introduces flexibility in the manufacture of yogurt without adversely affecting the basic nature and essential characteristics of yogurt. Therefore, FDA is proposing (1) in § 131.200(d)(2) to provide for the use of any safe and suitable sweeteners in yogurt and (2) to revise § 131.200(f)(1)(i) accordingly to replace the term “nutritive carbohydrate sweetener” with “sweetener(s)”. Consumers would be informed of the presence of the sweetening ingredient through its declaration by its common or usual name in the ingredient statement of the yogurt.

However, FDA tentatively concludes that there is no basis to require the declaration of a non-nutritive sweetener, when used, as part of the name of yogurt. FDA specifically seeks comment on the appropriateness of this tentative decision. Comments that address FDA's tentative decision should include sound scientific and factual data or information that supports the positions presented in the comments.

i. *Use of stabilizers and emulsifiers.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt provide for the use of stabilizers but do not provide for the use of emulsifiers (§§ 131.200(d)(5), 131.203(d)(5), and 131.206(d)(5), respectively). NYA stated that permitting the use of emulsifiers in addition to stabilizers would provide more opportunities for product development and innovation in the yogurt industry. A few comments in response to the ANPRM supported the use of emulsifiers along with the use of stabilizers, which are currently permitted by the standards. FDA does not have any safety or quality concerns with the use of emulsifiers in yogurt, provided that they are used within good manufacturing practice, where there is a need for the ingredient, and within any limitations specified by relevant FDA food additive or generally recognized as safe substance regulations. For these reasons, FDA has tentatively concluded that providing for the use of emulsifiers in addition to stabilizers permits flexibility in the manufacture of yogurt without adversely affecting the basic nature or essential characteristics of yogurt. Therefore, FDA is proposing to revise § 131.200(d)(5) to permit the use of safe and suitable emulsifiers in addition to the current allowance for the use of stabilizers as optional ingredients in the manufacture of yogurt.

j. *Use of preservatives.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (§§ 131.200, 131.203, and 131.206, respectively) do

not list preservatives as permitted ingredients in the manufacture of yogurt, lowfat yogurt, or nonfat yogurt. FDA stayed those portions of §§ 131.200(c), 131.203(c), and 131.206(c) (redesignated as §§ 131.200(d), 131.203(d), and 131.206(d), respectively) insofar as they exclude the addition of preservatives in response to objections to the January 30, 1981, final rule that preservatives such as potassium sorbate and sorbic acid should be permitted to prohibit the growth of yeasts and molds and to extend the shelf life of the foods (47 FR 41519). FDA stated that until this issue is resolved, the appropriate use of preservatives in these foods would not be the basis for regulatory action (47 FR 41519 at 41522). While NYA stated that the use of preservatives will provide flexibility in the manufacture of yogurt and comments from industry supported their use, stating that preservatives help maintain the product's integrity through shipping and storage, at least one consumer group and some consumers opposed their use, citing product quality concerns. However, these comments did not provide any data to support their position. Nor does FDA have any data that indicate that appropriate use of preservatives, particularly in the case of yogurts that are heat-treated after culturing to have an extended shelf life, has an adverse effect on the quality or characteristics of yogurt. In addition, the Codex Standard permits the use of preservatives in the fermented milks that are heat-treated after fermentation. For these reasons, FDA has tentatively concluded that providing for the optional and appropriate use of preservatives permits flexibility in the manufacture of yogurt without adversely affecting the basic nature or essential characteristics of yogurt. Therefore, FDA is proposing in § 131.200(d)(6) to permit the use of safe and suitable preservatives as optional ingredients in the manufacture of yogurt. FDA seeks comment on the need for and appropriateness of this proposed provision.

Specifically, FDA seeks comment on (1) whether it is appropriate to permit the use of safe and suitable preservatives in the manufacture of yogurt and (2) whether such provision should limit the use of preservatives in only those yogurts that are heat-treated after culturing, consistent with the Codex Standard.

k. *Use of optional milk-derived ingredients after pasteurization and culturing.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt require the other optional dairy ingredients, when used, to be included in the culturing process and do not provide for the use of optional milk-derived ingredients after pasteurization (§§ 131.200(a), 131.203(a), and 131.206 (a), respectively). NYA requested that FDA revise the yogurt standards to allow the use of optional milk-derived ingredients after the pasteurization and culturing steps in the manufacture of yogurt. Comments to the ANPRM both supported and opposed the NYA recommendation. Some of the opposing comments expressed safety concerns with adding milk-derived ingredients after pasteurization. The agency is not persuaded by NYA's argument, nor did NYA submit any convincing evidence that could overcome the agency's and some of the comments' concern about the safety issues that would arise with the use of milk-derived ingredients after pasteurization of the yogurt mix. FDA is also not convinced of the need for, nor is it aware of, the advantages provided by the use of milk-derived ingredients after the culturing process. Therefore, FDA is not proposing to provide for the use of optional milk-derived ingredients following pasteurization and culturing processes as requested by NYA.

l. *Use of whey protein concentrate as a basic ingredient.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt do not allow

the use of whey protein concentrate as a basic ingredient (§§ 131.200(c), 131.203(c), and 131.206(c), respectively). NYA requested that FDA revise the yogurt standards to allow the use of whey protein concentrate as a basic ingredient. NYA asserted that the inclusion of whey protein concentrate in yogurt products is standard industry practice and should be included in the yogurt standards. NYA also mistakenly believes that the stayed provisions of §§ 131.200(d), 131.203(d), and 131.206(d) would have permitted its inclusion. Comments to the ANPRM both favored and opposed permitting the inclusion of whey protein concentrate in yogurt products. The comments that favored permitting its use in yogurt products cited their function as stabilizers while those opposed questioned the need for its inclusion.

FDA clarifies that the 1982 stayed provisions include paragraph (d)(1) of the current yogurt standard (§ 131.200), which limits the use of optional milk-derived ingredients to the ones specifically listed under that paragraph. The list of basic milk ingredients in paragraph (c) of the current yogurt standard was not among the provisions that were stayed and, therefore, the current standard makes no allowance for the use of whey protein concentrate as a basic ingredient in yogurt. FDA agrees with the comments that question the need for allowing the use of whey protein concentrate as a basic ingredient in yogurt. FDA believes that use of whey protein concentrate as a basic ingredient in yogurt is not consistent with the basic nature of yogurt. This is consistent with the agency's recent tentative decision not to permit milk protein concentrates as a basic ingredient in standardized cheese (which is noted in a recent proposal to permit fluid ultrafiltered milk in standardized cheeses and related cheese products; 70 FR 60751, October 19, 2005). Some comments that supported this provision cited the function of whey protein concentrates as

stabilizers. FDA notes that the agency does not object to the use of safe and suitable stabilizers in yogurt and the current standard provides for the use of stabilizers as an optional ingredient in yogurt. FDA has no evidence at this time to support the amendment of the list of permitted basic ingredients in yogurt to include whey protein concentrate. Therefore, FDA is not proposing to provide for the use of whey protein concentrate as a basic ingredient in yogurt as requested by NYA.

m. *Percent dairy ingredients.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (§§ 131.200, 131.203, and 131.206, respectively) do not require a minimum of 51 percent of dairy ingredients in these foods. NYA requested that FDA revise the yogurt standards to include this requirement to ensure that the predominant ingredients in yogurt are from dairy sources. One trade association supported the inclusion of this requirement while a few other comments questioned the appropriateness of the 51 percent requirement. Comments that opposed this requirement expressed concern that under such a requirement, yogurts could contain up to 49 percent non-dairy ingredients. FDA is not convinced that there is a need to require a minimum amount of dairy ingredients to ensure that dairy ingredients are the primary ingredients of yogurt. The yogurt standard currently requires that the basic ingredients of yogurt be either milk or certain milk-derived ingredients and that yogurt must contain a specified minimum amount of milk solids not fat. FDA tentatively concludes that these provisions adequately ensure that appropriate amounts of dairy ingredients are used in the manufacture of yogurt. Therefore, FDA is not proposing to require a minimum amount of dairy ingredients in yogurt as requested by NYA.

n. *Use of any safe and suitable ingredient that serves a nutritional or functional purpose.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (§§ 131.200, 131.203, and 131.206, respectively) do not permit the optional use of any safe and suitable ingredient for a nutritional or functional purpose. NYA requested that FDA revise the yogurt standards to allow for such safe and suitable ingredients so that there would be enough flexibility in the standards to permit the use of novel ingredients as they are developed in the future. Comments to the ANPRM both favored and opposed the NYA recommendation. The comments that supported NYA's recommended provision stated that it would allow for future advances in ingredient technology while other comments that opposed this provision stated that it could lead to the use of inferior quality ingredients.

FDA recognizes the need for food standards to permit flexibility in food technology, so long as that technology does not alter the basic nature or essential characteristics of the food (68 FR 39873 at 39875). However, FDA does not believe that there is a need for a broad provision to permit any safe and suitable ingredient for a nutritional or functional purpose as recommended by NYA. The existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose. Under the provisions of § 130.10, standardized foods may be modified to contain nutrients not specifically permitted by the relevant standard of identity and to make an expressed nutrient content claim defined by FDA regulation.

As for the use of ingredients for a functional purpose, the proposed yogurt standard provides for the use of specific functional categories of ingredients such as emulsifiers and stabilizers. FDA tentatively concludes that a provision that broadly permits any safe and suitable ingredient for functional purposes

is not necessary and the lack of comments in response to its request in the ANPRM on the need for any functional categories of ingredients in addition to the ones that NYA proposed supports the agency's tentative conclusion. As explained earlier in this section of the document, FDA is proposing to provide for the use of specific functional ingredient categories such as emulsifiers and stabilizers and will consider future requests made under 21 CFR 10.30 for amendments for ingredient categories that are not included in the proposed yogurt standard. However, FDA is not persuaded at this time that a provision that broadly permits any safe and suitable ingredient for a technical purpose is needed in addition to the proposed specific functional ingredient categories. Therefore, FDA is not proposing to permit any safe and suitable ingredient for a nutritional or functional purpose in yogurt as requested by NYA.

o. Methods of analysis. The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt list the methods of analysis for milkfat content, total solids content, and titratable acidity that are from the "Official Methods of Analysis of AOAC International," 13th Ed. (1980) (§§ 131.200(e), 131.203(e), and 131.206(e), respectively). FDA is proposing to revise § 131.200(e) to update these methods to incorporate by reference the "Official Methods of Analysis of AOAC International," 18th Ed. (2005). In addition, FDA is proposing that the pH of yogurt, when used to determine the acidity of yogurt, be determined using the method described in § 114.90(a) (21 CFR 114.90(a)). Finally, FDA is proposing that the live and active cultures content of yogurt be determined using the aerobic plate count methods described in Chapter 3 of FDA's Bacteriological Analytical Manual, January 2001 Edition. FDA seeks comment on the appropriateness of the proposed methods and any alternate methods

that should be considered in lieu of or in addition to the methods proposed in § 131.200(e).

p. *Vitamins and minerals as optional ingredients.* The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt provide for optional fortification of these foods with vitamins A and D (§§ 131.200(b), 131.203(b), and 131.206(b), respectively). If vitamins A and/or D are added for this purpose, the standards require these vitamins to be present in amounts of 2,000 International Units (IU) of vitamin A and/or 400 IU of vitamin D per quart (or 946 milliliters) of the food. In addition, in §§ 131.200(f)(1)(iii), 131.203(f)(1)(iv), and 131.206(f)(1)(iii), the standards require the phrase “vitamin A” or “vitamin A added,” or “vitamin D” or “vitamin D added,” or “vitamins A and D added,” as appropriate, to accompany the name of the food.

NYA requested that FDA retain this provision for the optional fortification of yogurt with vitamins A and/or D. NYA also requested that the levels of fortification also be retained. However, NYA stated that yogurt is rarely measured by quart and, therefore, listed the minimum amounts of vitamins A and D fortification in terms of yogurt’s reference amount customarily consumed (RACC), i.e., 225 g (21 CFR 101.12). Comments in response to the ANPRM did not specifically address this provision.

In § 101.54(e) (21 CFR 101.54(e)), FDA has established requirements for claims related to the fortification of foods with certain nutrients, including vitamins and minerals. These requirements apply to any food (unless otherwise in conflict with the requirements specified in a standard of identity) that contains added vitamins or minerals for the purpose of making a relative labeling claim such as “fortified” or “added.” According to the provisions of

this regulation, a relative claim such as “fortified” or “added” may be made in the labeling of a food, provided that the food contains at least 10 percent more of the reference daily intake for vitamins and minerals per RACC compared to an appropriate reference food.

This requirement currently applies to yogurts that bear a fortification claim with respect to vitamins or minerals other than vitamins A and D. When yogurt is fortified with vitamins A and D, the requirements for the optional use of these two vitamins specified in the yogurt standard apply. FDA points out that the provision for the optional fortification of yogurt with vitamins A and D was established in 1981 prior to the implementation of the NLEA and the adoption of the certain nutrient content and relative claims regulations, including § 101.54. FDA believes that it is appropriate to apply the provisions of § 101.54(e) to vitamins A and D fortification of yogurt as they currently apply to fortification of yogurt with other vitamins and minerals and as they currently also apply to vitamin and mineral fortification of other foods. FDA also believes that the modernization of the yogurt standard should include bringing the outdated vitamins A and D fortification provisions in conformity with the applicable relative claims provisions and thus ensure consistency in the use of these claims in the labeling of foods. Therefore, FDA is proposing to revoke § 131.200(b), which provides for specific optional amounts of vitamins A and/or D in yogurt, and § 131.200(f)(1)(iii), which provides for special labeling of yogurt that contains vitamins A and D in accordance with § 131.200(b). FDA seeks comment on the need for and appropriateness of this tentative decision. Specifically, FDA seeks comment on (1) whether the agency should retain current § 131.200(b) and, if so, what the legal or scientific

justification for retaining this provision is, and (2) the appropriateness of applying § 101.54(e) to yogurt fortified with vitamins A and/or D.

2. Revocation of the Standards of Identity for Lowfat and Nonfat Yogurts

NYA and most of the comments to the ANPRM requested that FDA establish a single, modernized standard of identity for yogurt that would provide for lower-fat versions of the food rather than the current fragmented standards for yogurt, lowfat yogurt, and nonfat yogurt. NYA and some comments also expressed that providing for lowfat and nonfat yogurts within a single yogurt standard of identity would preclude the need to apply the “nutritional equivalence” requirements of § 130.10 to the lowfat and nonfat yogurts. NYA stated that imposing the nutritional equivalence requirement on lowfat and nonfat yogurt would pose an unnecessary and substantial cost to the yogurt industry.

Establishing a single standard for yogurt and providing for variations of the food within the standard is consistent with the general principles that FDA proposed for modernizing food standards. A single standard would maintain a uniform set of requirements for all yogurt products, whether they are full-fat or lower-fat versions, while providing flexibility and ease of compliance to manufacturers. Therefore, FDA is proposing to revoke the standards of identity for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206). However, rather than establishing separate requirements for “lowfat yogurt” and “nonfat yogurt” within the yogurt standard of identity, FDA is proposing that lower-fat versions of yogurt may be produced under the current provisions of § 130.10.

Section 130.10 sets out requirements for foods that are named by use of an FDA-defined nutrient content claim and a standardized term. In 1993, FDA

established § 130.10, among several other regulations implementing the provisions of the NLEA, to assist consumers in maintaining healthy dietary practices by providing for modified versions of standardized foods that bear descriptive names that are meaningful to consumers. Under the provisions of § 130.10, manufacturers may modify standardized foods to make them eligible to bear a nutrient content claim that is defined by FDA regulation, for example: “reduced fat sour cream,” “light margarine,” or “low fat cheddar cheese.” One of the provisions of this regulation requires that such modified foods be restored in their nutrient content such that the modified food is not nutritionally inferior to the standardized version (see § 130.10(b)).

Following the codification of § 130.10, FDA revoked a number of lowfat and nonfat dairy food standards, including those for lowfat and nonfat milk products and lowfat cheeses, to ensure that the use of nutrient content claims in the labeling of these products would be consistent with the provisions of the NLEA. FDA also proposed to revoke the standards for lowfat and nonfat yogurts; however, based on comments received at that time, FDA delayed final action on its proposal to revoke these standards for 120 days because of the technical difficulties and economic considerations associated with their revocation (61 FR 58991 at 58999). FDA acknowledged that if the standards for lowfat and nonfat yogurts were revoked, modifying the standardized food yogurt to make the nutrient content claims “lowfat” or “nonfat” under the provisions of § 130.10 would require addition of vitamin A to make the product nutritionally equivalent to full-fat yogurt. FDA also acknowledged that such a nutrient addition requirement could potentially result in significant relabeling, reformulation, and equipment costs to manufacturers. FDA advised

of its intention to move to resolve this matter at the end of the 120-day period. However, as FDA noted in the ANPRM, the agency has not resolved this issue.

Many of the comments in response to the ANPRM did not offer any specific comments on this issue. A few, however, recommended that FDA should not apply the provisions of § 130.10 to yogurt. These comments were concerned with over-fortification should FDA require that lowfat and nonfat yogurts be restored to the vitamin A levels found in full-fat yogurt. These comments did not provide any factual information or data to support their stated concern of vitamin A over-fortification.

FDA believes that it is appropriate to apply the provisions of § 130.10 to yogurt as they currently apply to all other standardized foods, including standardized dairy foods. FDA points out that it deferred action on this issue in 1996 to enable the yogurt industry to be better able and equipped to meet the nutritional equivalence requirements of § 130.10. FDA sees no reason to continue to exempt lowfat and nonfat yogurts from the nutritional equivalence requirements that apply to all other standardized foods that make lowfat or nonfat nutrient content claims. Further, FDA received no data nor is it aware of any information to support the concern of over-fortification. Yogurt made with whole milk contains 27 µg retinol activity equivalents (RAE) (a unit measurement of vitamin A) per 100 g compared to 14 µg RAE/100 g in lowfat yogurt and 2 µg RAE/100 g in nonfat yogurt (USDA National Nutrient Database for Standard Reference—Release 19) (Ref. 3). Restoring the levels of vitamin A in lowfat and nonfat yogurts would require adding vitamin A in amounts necessary to increase the level of vitamin A in these foods to about 27 µg RAE/100 g, with reasonable deviations from this level permitted by FDA labeling regulations. According to the Institute of Medicine (IOM), the median intake

of vitamin A ranges from 744 to 811 μg RAE/day for men and 530 to 716 μg RAE/day for women, with about 26 and 34 percent of this vitamin A activity provided by provitamin A carotenoids among men and women, respectively. These median intake levels are well below the IOM-established tolerable upper intake level (UL) for adults of 3,000 μg /day of preformed vitamin A (Ref. 5). According to a USDA report, the vitamin A content per capita per day in the U.S. food supply remained at a relatively constant level over the past two decades, ranging from 1,220 μg RAE in 1980 to 1,260 μg RAE in 2000 (Ref. 6). More specifically, the vitamin A content of the food supply did not change significantly since 1996 (1280 RAE), when FDA deferred action on revoking the lowfat and nonfat yogurt standards because of concerns about industry capability to restore vitamin A levels of yogurt. Moreover, although per capita consumption of all yogurt has steadily increased during this time from 5.9 pounds in 1996 to 8.2 pounds in 2003 (Ref. 7) (these data were not categorized based on fat content of the yogurt), the contribution of yogurt to daily vitamin A intake would not be expected to be altered significantly if the nutritional equivalency requirements of § 130.10 were to apply to lowfat and nonfat yogurts. For example, if all of the 8.2 pounds of yogurt consumed per capita in 2003 were to contain vitamin A levels equivalent to that found in full-fat yogurt, the vitamin A contribution of that amount of yogurt would be about 1,005 μg RAE vitamin A per capita per year or 2.7 μg RAE/day. Considering that the vitamin A content of the food supply is about 1,260 μg RAE per capita per day, the calculated contribution of yogurt (assuming all yogurt has vitamin A at levels found in full-fat yogurt) of about 2.7 μg RAE per capita per day is small. Therefore, subjecting yogurt to the nutritional equivalency provisions

of § 130.10 is not expected to raise the overall vitamin A content of the food supply significantly.

After considering all relevant issues, including the safety concerns related to vitamin A addition, FDA tentatively concludes that the best approach is to revoke the existing lowfat and nonfat yogurt standards and to permit the modification of the standardized food yogurt to bear nutrient content claims, including “low fat” and “nonfat,” under the existing provisions of § 130.10. Further, under this proposal, manufacturers would be able to continue to make yogurt products bearing other nutrient content claims, such as “reduced fat yogurt” or “light yogurt” under the provisions of § 130.10.

Accordingly, for the reasons stated in this section, FDA is proposing to do the following:

(1) Amend the yogurt standard of identity in 21 CFR 131.200 to:

(a) Provide for the use of reconstituted forms of cream, milk, partially skimmed milk, and skim milk as basic dairy ingredients;

(b) Permit the use of any safe and suitable milk-derived ingredients to increase the nonfat solids content, provided such addition does not adversely affect the protein quality or content of the food;

(c) Apply the minimum milkfat content of 3.25 percent and minimum milk solids not fat content of 8.25 percent prior to the addition of bulky flavoring ingredients;

(d) Require an acidity of yogurt of either a titratable acidity of not less than 0.7 percent expressed as lactic acid or a pH of 4.6 or lower;

(e) Permit the use of any safe and suitable cultures in addition to the required characterizing bacterial cultures specified in the standard;

(f) Permit the use of any safe and suitable sweetening ingredients;

(g) Permit the use of any safe and suitable emulsifiers in addition to stabilizers;

(h) Permit the use of any safe and suitable preservatives;

(i) Require yogurt that is not heat-treated and is labeled with the phrase “contains live and active cultures” or other appropriate descriptor to contain live and active cultures of 10^7 CFU/g at the time of manufacture with a reasonable expectation of 10^6 CFU/g throughout the manufacturer’s assigned shelf life of the food;

(j) Revoke the provisions within the standard that permit the addition of vitamins A and D and state the labeling requirements such that these vitamins may be added to yogurt under § 101.54(e);

(k) Update the methods of analysis for milkfat and total solids contents and titratable acidity to incorporate by reference the Official Methods of Analysis of AOAC International 18th Ed. (2005);

(l) Provide that the pH of yogurt, when used to determine the acidity of yogurt, be determined using the method described in § 114.90(a); and

(m) Provide that the live and active cultures content of yogurt be determined using the aerobic plate count methods described in Chapter 3 of FDA’s Bacteriological Analytical Manual, January 2001 Edition and

(2) Revoke the lowfat yogurt and nonfat yogurt standards of identity in §§ 131.203 and 131.206, respectively, such that the standardized food yogurt in proposed § 131.200 could be modified to produce lower-fat versions under the current provisions of § 130.10, which describe the requirements for foods named by use of a nutrient content claim (including “low fat” and “fat free”) and a standardized term (such as “yogurt”).

As explained previously, FDA tentatively concludes that these amendments are appropriate and will promote honesty and fair dealing in the interest of consumers.

Pending issuance of a final rule amending the existing standard of identity for yogurt and revoking the existing lowfat and nonfat yogurt standards of identity, FDA intends to consider the exercise of its enforcement discretion on a case-by-case basis when yogurt products are in compliance with the standard of identity proposed in this proposed rule and when the labeling of such products is not otherwise false or misleading. The act's enforcement provisions commit complete discretion to the Secretary (and by delegation to FDA) to decide how and when they should be exercised (*Heckler v. Chaney*, 470 U.S. 821 at 835 (1985); *Schering Corp. v. Heckler*, 779 F.2d 683 at 685–86 (D.C. Cir. 1985) (stating that the provisions of the act “authorize, but do not compel the FDA to undertake enforcement activity”)). Until the agency issues a final rule amending the current yogurt standard and revoking the current lowfat and nonfat yogurt standards, the agency believes that its exercise of enforcement discretion will help alleviate the confusion that the petitioner contends has resulted due to the existence of the stayed provisions of the current yogurt standards. In addition, the agency believes that its exercise of enforcement discretion will also provide a clear and flexible standard and encourage greater consistency and uniformity in the marketplace for yogurt products, and thereby assist consumers in making informed product choices.

C. NYA's Recommended Amendments to the Standard of Identity for Cultured Milk

NYA requested that FDA revise the current standard of identity for cultured milk (§ 131.112) to (1) provide for the alternate term “fermented

milk;” (2) require a minimum level of total dairy ingredients of 51 percent; (3) permit the use of reconstituted milk and whey protein concentrate as “standard dairy ingredients;” (4) provide for the use of any milk-derived ingredients as “optional dairy ingredients;” (5) permit the use of safe and suitable sweeteners, emulsifiers, and preservatives; and (6) permit the use of any safe and suitable ingredients added for nutritional or functional purpose.

FDA tentatively concludes that NYA did not provide a sufficient basis to amend the cultured milk standard. NYA did not provide a rationale for its proposed amendments to the cultured milk standard other than to simply fit into the standard for “cultured milk” those yogurt products that would not be permitted to be named “yogurt” under NYA’s recommended standard for yogurt. Nor did NYA address, as a number of comments to the ANPRM pointed out, the consumer confusion that might occur from including semisolid yogurt-type products (that would not qualify as “yogurt” under NYA’s recommended yogurt standard) in the cultured milk standard, which has long been associated with fluid cultured milk products.

III. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

We are publishing this proposed rule under the formal rulemaking process. Executive Order 12866 does not require us to analyze the costs and benefits of proposed rules that we publish under this rulemaking process.

B. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule may generate compliance costs for some small firms, the agency believes that this proposed rule would have a significant

economic impact on a substantial number of small entities. FDA requests comment on this issue. The following analysis, in conjunction with the preamble, constitutes the agency's initial regulatory flexibility analysis as required by the Regulatory Flexibility Act.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. As stated previously in this analysis, with this rule the agency intends to amend the yogurt standard and revoke the lowfat and nonfat yogurt standards to promote honesty and fair dealing in the interest of consumers. The proposed amendments are intended to modernize the current yogurt standards to permit flexibility and provide for technological advances in yogurt production, while preserving the basic nature and essential characteristics of yogurt consistent with consumer expectations and thus protecting consumer interest.

Regulatory Options

We considered the following regulatory options:

- (1) Take no action,
- (2) Take the proposed action,
- (3) Take the proposed action except for the acidity requirements,
- (4) Take the proposed action except for applying the nutritional equivalency provisions to lowfat and nonfat yogurt, and
- (5) Take the proposed action except for the minimum live and active cultures requirements for yogurt bearing labeling such as "Contains Live and Active Cultures".

Option One: Take No Action

We can only define costs relative to a baseline. We usually select the option of taking no action as the baseline because it helps readers identify the

costs of actions that change the status quo. By definition, the baseline itself has no costs.

Option Two: Take the Proposed Action

This proposed regulation would affect yogurt manufacturing firms in North American Industry Classification System (NAICS) code 311511, Fluid Milk Manufacturing. The Small Business Administration defines a small business in NAICS code 311511 as a business with 500 or fewer employees. This proposed regulation would not affect firms that manufacture nonstandardized products such as frozen yogurt (NAICS code 311520: Ice Cream and Frozen Dessert Manufacturing) and dried yogurt-style mixes (NAICS code 311514: Dry, Condensed, and Evaporated Dairy Product Manufacturing), or products that contain yogurt as an ingredient (miscellaneous NAICS codes). We request comment on the types of firms that would be affected by this proposed rule.

We searched an online commercial database, D&B Dun's Market Identifiers, for firms in NAICS code 311511 that had the word "yogurt" in the description of the firm's activity and 500 or fewer employees and found 34 firms. We also searched for manufacturing establishments using the same procedure and found 33 manufacturing establishments. We are only interested in firms that actually operate manufacturing establishments, so we estimate that 33 small firms manufacture yogurt.

Our analysis of existing requirements and the proposed requirements suggests that only three provisions of this proposed rule might require some small firms to change their current activity. The other provisions of this proposed rule are either consistent with current requirements or provide additional flexibility to firms beyond that available under current

requirements. For purposes of this analysis, we only associate costs with those proposed provisions that might require some small firms to change their current activity: We do not classify as costs of this proposed rule any voluntary costs that some small firms may undergo because they choose to change their manufacturing practices in ways that would be newly permitted by the proposed regulation. We request comments on the provisions of this proposed rule that might require small firms to change their current activity. The three provisions that we believe might require some small firms to change their current activity are as follows:

- The proposed requirement that yogurt have either a titratable acidity of not less than 0.7 percent expressed as lactic acid or a pH of 4.6 or lower. The requirement that yogurt have a minimum titratable acidity of 0.9 percent was stayed, and yogurts in the current marketplace are not subject to this acidity requirement.
- The proposed application of the nutritional equivalency provisions of § 130.10 to lowfat and nonfat yogurt, which would require firms to fortify their lowfat and nonfat yogurt with vitamin A. Currently, we do not require lowfat and nonfat yogurt to be nutritionally equivalent to regular yogurt.
- The proposed requirement that yogurt bearing optional labeling statements such as “contains live and active cultures” must contain a minimum of 10^7 CFU/g of live and active cultures at the time of manufacture of the yogurt with a reasonable expectation that the yogurt will contain live and active cultures at a level of 10^6 CFU/g through the manufacturer’s assigned shelf life of the product. Currently, we do not require yogurt with labeling such as “contains live and active cultures” to contain any particular minimum level of live and active cultures.

With respect to the requirements relating to acidity, we believe that all or nearly all yogurt currently on the market has a titratable acidity well above the proposed minimum cutoff of 0.7 percent titratable acidity, usually in the range of 1.0 to 1.3, and a pH level well below the proposed maximum level of 4.6, usually in the range of 4.1 to 4.3. Some comments in response to the ANPRM said that the proposed minimum titratable acidity percentage and maximum pH level reflect current industry practice. Nevertheless, some yogurt produced by small manufacturers might not meet one of these acidity requirements. If a yogurt did not meet one of these requirements, then the manufacturer would need to change its manufacturing process to produce yogurt that complies with the acidity requirement. Potential ways to increase the acidity of the product include increasing the amount of yogurt cultures and/or increasing the time and/or temperature of fermentation. We do not have sufficient information to estimate the costs of taking such steps. However, the likelihood that any plants would need to take these steps is very low. Therefore, we estimate that the proposed acidity requirements would generate minimal or no compliance costs.

We previously analyzed the costs associated with applying the nutritional equivalency provisions of § 130.10 to lowfat and nonfat yogurt, which may require some small yogurt manufacturing firms to fortify their lowfat and nonfat yogurt with vitamin A, in a final rule that revoked standards of identity for several low fat and nonfat dairy products (61 FR 58991). In that analysis, we estimated this provision would generate a one-time cost of up to \$52 million. We based that estimate on comments that suggested that 69 percent of yogurt manufacturers at that time produced only standardized yogurt and did not have the necessary vitamin metering equipment to add vitamins to

their product and a comment that said that the necessary equipment would cost \$250,000 per plant. We estimated there were 300 yogurt-producing plants of all sizes in 1996. We also estimated a one-time present value of \$240,000 for the annual cost of adding vitamin A, which is the only vitamin that we assumed manufacturers would need to add to yogurt. We arrived at the total estimate of \$52 million as follows: [(300 yogurt manufacturing plants x 69 percent of plants needing equipment = 207 plants needing equipment) x \$250,000 per plant for equipment] + \$240,000 total present value for obtaining and adding vitamin A (61 FR 58991 at 59001).

FDA experts on the yogurt manufacturing industry believe that the cost for small firms to add vitamins to yogurt would be significantly lower now. Our current estimate is that the total cost to set up the necessary equipment would be no more than \$50,000 per plant. In addition, some small plants may vat pasteurize and add vitamins manually to the batch of yogurt base before pasteurizing and fermenting. These plants would not need to purchase additional equipment. Therefore, we now estimate that equipment costs to add vitamins would be between \$0 and \$50,000 per plant.

As previously stated, we estimated that there are 33 small firms that manufacture yogurt. We do not know how many of these plants produce only yogurt and, therefore, do not already have the equipment necessary to add vitamins. In the absence of other information, we retain the information that we received in 1996 that 69 percent of yogurt-producing plants do not have the necessary equipment. In that case, approximately 23 small yogurt producing plants might need to buy equipment to add vitamins to yogurt. We do not know how many of these plants could add vitamins manually without needing additional equipment. Therefore, we estimate that the total equipment

cost for these 23 plants would be between \$0 and \$1.15 million (23 x \$50,000). These 23 plants represent 11 percent of the 207 yogurt producing plants of all sizes that we estimated in 1996 would need to buy the necessary equipment. If we scale down our previous estimate of the one-time present value of \$240,000 for the annual cost of adding vitamin A by the number of small plants that may need to buy equipment to add vitamins to lowfat or nonfat yogurt, then the one-time present value would be approximately \$27,000. Therefore, our total estimate of the cost to add vitamin A is between \$0 and \$1 million, i.e., [(33 small yogurt manufacturing plants x 69 percent of plants needing equipment = 23 plants needing equipment) x \$50,000 per plant] + [(\$240,000 total present value for obtaining and adding vitamin A for 207 plants operated by firms of all sizes) x (23 plants operated by small firms / 207 plants operated by firms of all sizes)]. We request comments on our estimate of the number of small firms that would need equipment to add vitamins, the cost of this equipment, and the cost of adding vitamin A. We also request comments on whether the proposed rule would require any small firms to add any nutrients other than vitamin A to yogurt.

We do not know how many yogurt products currently have labeling such as “contains live and active cultures” but do not meet the proposed requirements relating to levels of live and active cultures. We estimated the one-time cost of changing all yogurt labels using a computer model developed for that purpose [FDA Labeling Cost Model. Final Report. Revised January 2003. Research Triangle Institute.] The estimated cost was \$9 million to \$21 million. However, some yogurt is produced by firms that are not small businesses. We again searched D&B Dun’s Market Identifiers, for all firms in NAICS code 311511 that had the word “yogurt” in the description of the firm’s

activity and found a total of 46 firms. We estimated earlier that 33 of these are small manufacturing firms. Therefore, approximately 72 percent of the firms manufacturing yogurt are small. We assume that all firms produce roughly the same number of yogurt products so that labeling costs are roughly similar across firms. Under this assumption, the potential labeling costs for small firms are approximately 72 percent of the potential labeling costs for all firms, or \$6 million to \$15 million. We do not know how many yogurt products produced by small firms bear labeling such as “contains live and active cultures.” Therefore, we estimate one-time labeling costs for small firms to be \$0 to \$15 million.

In summary, we estimate the proposed rule would generate costs for small firms of \$0 to \$1 million for installing vitamin metering equipment and adding vitamin A to some lowfat and nonfat yogurt and \$0 to \$15 million to change the labels on some yogurt products that bear labeling such as “contains live and active cultures.” Therefore, we estimate total costs of \$0 million to \$16 million. This amounts to an average cost of approximately \$0 to \$498,000 for each of the 23 small firms that need vitamin metering equipment and \$0 to \$450,000 for each of the 10 small firms that do not.

Option Three: Take the Proposed Action Except For the Acidity Requirements

Eliminating the acidity requirements would eliminate the costs associated with meeting those proposed requirements. In our discussion of Option Two, we estimated those costs to be minimal or zero. Therefore, we estimate total costs under this option to be \$0 million to \$16 million.

Option Four: Take the Proposed Action Except For Applying the Nutritional Equivalency Provisions to Lowfat and Nonfat Yogurt

Eliminating the application of the nutritional equivalency provisions to lowfat and nonfat yogurt would eliminate the costs associated with meeting those proposed requirements. In our discussion of Option Two, we estimated those costs to be \$0 to \$1 million. Therefore, we estimate total costs under this option to be \$0 to \$15 million.

Option Five: Take the Proposed Action Except For the Minimum Live and Active Cultures Requirements for Yogurt Bearing Labeling Such As “Contains Live and Active Cultures”

Eliminating the proposed minimum live and active cultures requirement for yogurt bearing labeling such as “contains live and active cultures” would eliminate the costs associated with meeting that proposed requirement. In our discussion of Option Two, we estimated those costs to be \$0 to \$15 million. Therefore, we estimate total costs under this option to be \$0 to \$1 million.

C. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”

Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the act (21 U.S.C. 343–1(a)) provides that: “* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g). * * *”

This proposed rule, if finalized as proposed, would make changes to the existing standards of identity for yogurt, lowfat yogurt, and nonfat yogurt. Although any final rule would have a preemptive effect in that it would preclude States from issuing any requirements for the standard of identity of yogurt that are not identical to the requirements of the final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(1) of the act displaces both State legislative requirements and State common law duties (*Riegel v. Medtronic*, 128 S. Ct. 999 (2008)). In addition, as with any Federal requirement, if a State law requirement makes compliance with both Federal law and State law impossible, or would frustrate Federal objectives, the State requirement would

be preempted. See *Geier v. American Honda Co.*, 529 U.S. 861 (2000); *English v. General Electric Co.*, 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc.*, 373 U.S. 132, 142–43 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

V. Environmental Impact

The agency has determined under 21 CFR 25.32(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment; therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that the provisions of this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3220).

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Letter to Mr. Stuart M. Pape, Patton, Boggs, & Blow from FDA, November 23, 1988.
2. Codex Standard for Fermented Milks (CODEX STAN 243–2003).
3. U.S. Department of Agriculture, Agricultural Research Service. 2006. USDA National Nutrient Database for Standard Reference, Release 19. Yogurt, plain, whole milk; yogurt, plain, low fat; yogurt, plain, skim milk.
4. Verrill L.A., Memo to file—Consumer research on standards for yogurt submitted by the National Yogurt Association, January 27, 2006.
5. Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. 2000. Pages 82–161. Food and Nutrition Board, Institute of Medicine, National Academy Press, Washington, DC.
6. Gerrior S., Bente L., and Hiza H. 2004. Nutrient Content of the U.S. Food Supply, 1909–2000. Home Economics Research Report No. 56. Table 2. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion.
7. USDA ERS. Food availability spreadsheets. Fluid milk and cream—per capita consumption, pounds. Updated December 21, 2004. Accessed online at: <http://www.ers.usda.gov/Data/FoodConsumption/FoodAvailSpreadsheets.htm> December 28, 2005.

List of Subjects in 21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR part 131 be amended as follows:

PART 131—MILK AND CREAM

1. The authority citation for 21 CFR part 131 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

2. Revise § 131.200 to read as follows:

§ 131.200 Yogurt.

(a) *Description.* Yogurt is the food produced by culturing one or more of the basic dairy ingredients specified in paragraph (b) of this section and any of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*. The ingredients specified in paragraphs (b) and (c) of this section shall be pasteurized or ultra-pasteurized prior to the addition of the characterizing bacterial culture. One or more of the other optional ingredients specified in paragraph (d) of this section may also be added. The food may be homogenized. Yogurt may be heat-treated after culturing to extend the shelf life of the food. Yogurt, before the addition of bulky flavoring ingredients, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has either a titratable acidity of not less than 0.7 percent

expressed as lactic acid or a pH of 4.6 or lower. Yogurt that is not heat-treated after culturing may contain a minimum level of live and active cultures of 10^7 colony-forming units per gram (CFU/g) at the time of manufacture with a reasonable expectation of 10^6 CFU/g through the manufacturer's assigned shelf life of the product.

(b) *Basic dairy ingredients.* Cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of these ingredients may be used alone or in combination.

(c) *Optional dairy ingredients.* Other safe and suitable milk-derived ingredients may be used to increase the nonfat solids content of the food, provided that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(d) *Other optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cultures, in addition to the characterizing bacterial culture specified in paragraph (a) of this section.

(2) Sweeteners.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers and emulsifiers.

(6) Preservatives.

(e) *Methods of analysis.* (1) The following referenced methods of analysis are from the "Official Methods of Analysis of AOAC International," 18th Ed. (2005). They are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, FDA must

publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Also, it is available for inspection at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2163, and is available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877.

(i) Milk solids not fat—Calculated by subtracting the milkfat content from the total solids content using the methods prescribed in section 33.2.45, “AOAC Official Method 990.21 Solids-Not-Fat in Milk by Difference between Total Solids and Fat Contents.”

(ii) Titratable acidity—As determined by the method prescribed in section 33.2.06, “AOAC Official Method 947.05 Acidity of Milk Titrimetric Method.”

(2) pH—As determined by the potentiometric method described in § 114.90(a) of this chapter.

(3) Live and active cultures—As determined by the aerobic plate count methods described in Chapter 3 of FDA’s Bacteriological Analytical Manual, January 2001 Edition. Chapter 3 of FDA’s Bacteriological Analytical Manual, January 2001 Edition, is located at <http://www.cfsan.fda.gov/~ebam/bam-3.html>. The method is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The FDA will request approval to incorporate by reference any updates to this Web site. The FDA will change the date of the Web site in this paragraph with each update. You may obtain a copy from

the Division of Microbiology (HFS-710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html.

(f) *Nomenclature*. The name of the food is “yogurt”. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word “sweetened” if a sweetener is added without the addition of characterizing flavor.

(ii) The parenthetical phrase “(heat-treated after culturing)” shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

(2) The term “homogenized” may appear on the label if the dairy ingredients used are homogenized.

(3) The name of the food may be accompanied by the phrase “contains live and active cultures” or another appropriate descriptor if the food contains the amount of live and active cultures specified in paragraph (a) of this section.

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

§ 131.203 [Removed]

3. Remove § 131.203.

§ 131.206 [Removed]

4. Remove § 131.206.

Dated: January 9, 2009.

Leslye M. Fraser,

*Director, Office of Regulations and Policy, Center for Food Safety and Applied
Nutrition.*

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