DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

AUG 25 2000

Stuart M. Pope
Patton Boggs, LLP
2550 M Street, NW
Washington, DC 20037-1350

Re: Docket No. 00P-0685

Dear Mr. Pope:

This letter is in response to your citizen petition, dated and filed February 18, 2000, requesting that the Food and Drug Administration (FDA) revoke the yogurt standards of identity in 21 CFR 131.200, 131.203, and 131.206 and replace them with the single yogurt standard of identity described in your petition. You also requested that the FDA amend the cultured milk standard of identity in 21 CFR 131.112 to conform with the new yogurt standard. This letter is also to acknowledge the August 9, 2000, letter from Robert L. Garfield to Janice Oliver thanking us for meeting with the National Yogurt Association to discuss the petition cited above.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other Agency priorities and the limited availability of resources. However, we recognize the importance of reinventing food standards in a manner that both protects the interest of consumers and provides manufacturers reasonable flexibility in using innovative techniques to produce foods governed by a standard of identity. Consequently, we are reviewing our entire approach on how to best address the issue of food standards. We are currently working with the Food Safety and Inspection Service of the United States Department of Agriculture to propose guiding principles on how to revise standards. As we continue to develop our policy, we will consider how to most appropriately address your petition in FDA's overall strategy to reinvent food standards.

Moreover, the Center for Food Safety and Applied Nutrition (CFSAN) is establishing program priorities for fiscal year (FY) 2001. As part of its annual planning, budgeting, and resource allocation process, CFSAN is reviewing its programs to set priorities and establish work product expectations. We will consider your request to reinvent the

00P-0685

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standard of identity for yogurt in conjunction with our overall strategy as we identify candidates for our Program Priorities for FY 2001.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,

Virginia L. Wilkening

for Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

cc:
HFA-305
HFS-1 (Levitt)
HFS-3 (Oliver)
HFS-4 (Lake)
HFS-24 (Brock)
HFS-800 (Lewis, Thomas)
HFS-820 (Satchell)
HFS-822 (June, Carey)

R/D:HFS-822:LCarey:7/27/00:202-205-9558:69648
Revised:HFS-822:LCarey:8/01/00
Init:HFS-822:GJune:8/01/00/202-205-4168
Revised:HFS-822:LCarey:8/17/00
HFS-822:LCarey:8/22/00
Init:HFS-822:GJune:8/22/00
HFS-820:FSatchell:8/24/00:202-205-4168

National
Yogurt
Association

August 9, 2000

Ms. Janice F. Oliver, HFS-003
Deputy Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Dear Janice:

The members and staff of the National Yogurt Association (NYA), thank you and your staff for taking time to discuss the status of the Institute's petition to revise the yogurt standard of identity. The yogurt industry stands behind this petition. It will replace the current fragmented standard with one that clarifies yogurt as a food that contains live and active cultures, while recognizing the role of current and future technologies. The proposed standard will establish a clear and consistent standard that will benefit consumers.

NYA understands the significance of priorities. We are resolute in our determination that substantive and appropriate petitions, such as the Institute's proposal, should not be overlooked. NYA appreciates that FDA does associate some importance to the citizen petition process, and like the Agency the Institute believes it is important to clarify and simplify current regulations.

I was very pleased to hear that you will consider publishing NYA's petition for comment. While NYA's ultimate goal is to revise and update the standard, publication of the petition in the *Federal Register* for comment is a noteworthy step.

NYA looks forward to working with FDA, in any manner that is deemed appropriate, to pursue publication and implementation of the petition. NYA appreciated the opportunity to present its views on the petition to revise that standard of identity for yogurt, and will be happy to provide the Agency with any information it will need.

Sincerely,

Robert L. Garfield
Vice President
Regulatory and Technical Affairs

Live & Active Cultures

2000 CORPORATE RIDGE, SUITE 1000, McLEAN, VA 22102, USA TELEPHONE (703) 821-0770 FAX (703) 821-135

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 18, 2000

Stuart M. Pope
Patton Boggs, LLP
2550 M Street, NW
Washington, DC 20037-1350

Dear Mr. Pope:

Your petition, on behalf of the National Yogurt Association, requesting the Food and Drug Administration to amend the cultured milk standard of identity in accordance with the proposed yogurt standard of identity, was received by this office on 02/18/00. It was assigned docket number 00P-0685/CP 1 and it was filed on 02/18/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler
Dockets Management Branch

00P-0685 ACK 1

Citizen's Petition

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20857

4297 '00 FEB 18 P2:20

The undersigned submits this petition, on behalf of the National Yogurt Association, under sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act,[1] and section 10.30 of the Food and Drug Administration's ("FDA's") procedural regulations.[2] The undersigned requests that FDA promulgate a regulation establishing a modernized standard of identity for yogurt to replace the existing yogurt standards of identity, and making conforming amendments to the existing cultured milk standard of identity.

I. Action Requested

Petitioners request the revocation of the yogurt standards of identity at 21 C.F.R. §§ 131.200, 131.203, and 131.206, and the replacement of these standards with the proposed standard of identity at Appendix 1. Petitioner also requests amendments, as set forth in Appendix 2, to conform the cultured milk standard of identity at 21 C.F.R. § 131.112 to the proposed yogurt standard.[3]

II. Statement of Grounds

A. Introduction

The current standards of identity for yogurt consist of three standards for yogurt,[4] lowfat yogurt,[5] and nonfat yogurt,[6] that differ only in milkfat content. Since finalizing the yogurt standards and staying many provisions,[7] FDA has not held hearings on the stayed provisions, nor indicated plans to conduct hearings. The existence of stayed provisions creates multiple gaps in the standard, for which no guidelines exist. In addition, industry practices and FDA policies often differ from, or are not explicit in, the standards. Thus, on

[1] 21 U.S.C. §§ 341 and 371(e).
[2] 21 C.F.R. § 10.30 (all subsequent section references are to 21 C.F.R. unless otherwise indicated).
[3] Petitioner notes that this petition is intended to affect only yogurt products as addressed in the provisions noted, and is not intended to address so-called "frozen yogurt" products.
[4] § 131.200.
[5] § 131.203.
[6] § 131.206.
[7] See 47 Fed. Reg. 41519 (September 21, 1982).

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consulting the standards, one cannot discern which provisions FDA currently enforces for manufacturing yogurt.

The incomplete and unclear yogurt standards defeat another purpose of having standards of identity. Inherent in a yogurt standard of identity is the idea that the integrity of the term "yogurt" must be maintained. This concept is crucial to consumers associating the term "yogurt" with a specific food product and its particular characteristics.[7] Under the current yogurt standards however, a consumer purchasing yogurt for its particular characteristics, such as the health benefits associated with live and active cultures, has no assurance that the yogurt contains live and active cultures. The proposed yogurt standard recognizes the defining characteristics of yogurt; the standard establishes that yogurt is the product of fermentation of certain characterizing cultures, and that the finished product contains a significant quantity of these live and active cultures.

Not only do the yogurt standards contain an assortment of effective and stayed provisions, but the standards contain many outdated provisions. Regulatory requirements related to food labeling changed with the implementation of the Nutrition Labeling and Education Act of 1990 ("NLEA").[8] Modernizing the yogurt standard of identity will ensure that aspects of yogurt labeling, such as the use of nutrient content claims, are consistent with the NLEA requirements.

In addition, while the incomplete yogurt standards have remained static, technology has advanced and industry practices have changed. The current yogurt standards do not always allow for manufacturers to implement advances in food technology. Although FDA believes that standards of identity should permit standardized food manufacturers to take advantage of advances in food technology,[9] and has recognized that food standards impede the food industry if they fail to reflect technological advances,[10] FDA has not updated the standards to allow for effective use of new technology. In addition, although FDA seeks flexibility in food standards,[11] the yogurt standards do not contain enough flexibility to allow for use of new or future technological advances.

Thus, the National Yogurt Association ("NYA") proposes a new yogurt standard of identity to replace the currently existing fragmented standards. The proposed standard would finally complete and fully implement a yogurt standard, while clarifying that yogurt is a food product containing a minimum level of certain live and active cultures. The proposed standard takes into account current industry practices and recognizes the need to allow for use of future technologies. This proposed standard establishes a clear, consistent, modernized, and flexible yogurt standard, that will benefit both industry and consumers.

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[7] See 60 Fed. Reg. 67492, 67494 (December 29, 1995).
[8] Nutrition Labeling and Education Act of 1990, Pub. L. 101-535.
[9] See 60 Fed. Reg. at 67499.
[10] See id.
[11] See id.

B. History of the Yogurt Standard of Identity

The outdated yogurt standards, consisting of a conglomeration of effective and stayed provisions, result from a history of incomplete regulatory action. On January 30, 1981, FDA published a final rule for the three yogurt standards of identity.[12] The standards established definitions for yogurt, lowfat yogurt, and nonfat yogurt, and contained provisions regarding optional dairy ingredients, other optional ingredients, methods of analysis, nomenclature, and label declarations.

On September 21, 1982, FDA published a notice confirming the effective date of the final rule for the three yogurt standards.[13] However, due to objections FDA received requesting hearings on certain provisions of the final rule, FDA amended some provisions, and stayed other provisions pending hearings. FDA stayed provisions relating to the use of reconstituted dairy ingredients, milk-derived ingredients, and preservatives. FDA also stayed provisions on the timing of measuring milkfat percentage, and the minimum acceptable titratable acidity of yogurt. FDA's actions resulted in a mumbled, incoherent standard, that, over seventeen years later, still awaits clarification.

On November 9, 1995, FDA proposed to revoke the standards of identity for several lowfat and nonfat dairy products, including lowfat yogurt and nonfat yogurt.[14] By removing these standards, manufacturers would still be able to name the products in accordance with the general provisions of the NLEA. Thus, manufacturers would be able to use the terms "lowfat yogurt" and "nonfat yogurt," under the regulatory provision permitting nutrient content claims to modify a food's general standard of identity.[15] However, under that provision, a product cannot bear a nutrient content claim unless it is not nutritionally inferior to the standard form.[16] Because lowfat and nonfat yogurts contain less vitamin A than full fat yogurt, under the proposed rule, lowfat and nonfat yogurts would require vitamin A fortification to meet the level of full fat yogurt.

In the final rule, FDA acknowledged that yogurt differs from other dairy products in that existing yogurt standards do not require vitamin fortification, and the yogurt standards already cover nearly the full range of possible fat contents (full fat yogurt, lowfat yogurt, and nonfat yogurt).[17] Because lowfat and nonfat yogurts comprise almost the entire yogurt market, and the yogurt industry has not had to develop or adopt mechanisms for fortification, FDA agreed with industry that the rule would result in significant relabeling, reformulation, and equipment costs for yogurt manufacturers.[18] FDA recognized that the yogurt standards already have effective standards for yogurts that are not full fat and thus,

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[12] 46 Fed. Reg. 9924 (January 30, 1981).
[13] 47 Fed. Reg. at 41519.
[14] 60 Fed. Reg. 56541 (November 9, 1995).
[15] § 130.10.
[16] §130.10(b).
[17] 61 Fed. Reg. 58991, 58999 (November 20, 1996).
[18] Id.

FDA deferred action on its proposal to revoke the lowfat and nonfat yogurt standards. FDA has not reached a final decision to revoke the lowfat and nonfat yogurt standards.

C. Proposed Yogurt Standard of Identity

1. One Yogurt Standard/Conforming Changes to Cultured Milk Standard

For centuries, yogurt has been characterized by its live and active cultures.[19] Consumers identify yogurt with live and active cultures and expect that when they purchase yogurt, it will contain a significant amount of these cultures. Thus, a minimum live and active cultures content is crucial to the yogurt standard of identity promoting honest and fair dealing in the interest of consumers.

Currently, the yogurt standards do not contain a minimum level requirement for live and active cultures. As a result, products that do not contain live and active cultures can bear the yogurt identity and potentially mislead consumers about the product's defining characteristics and properties. Thus, a viable and meaningful yogurt standard must require a minimum level of live and active cultures.

NYA's proposed standard characterizes yogurt as containing at least 10^7 CFU/g active cultures *Lactobacillus delbrueckii* subspecies *bulgaricus* and *Streptococcus thermophilus* at the time of manufacture. This requirement reflects an appropriate minimum level of live and active cultures to characterize the yogurt. By requiring at least 10^7 CFU/g at the time of manufacture, the requirement provides a method for regulators, as well as manufacturers, to determine compliance.

However, it is most important to ensure that consumers consume a product with a significant amount of live and active cultures. Therefore, the proposed standard recommends that manufacturers have ensured by appropriate means that, under proper conditions of distribution and storage, their yogurt will contain at least 10^6 CFU/g of these live and active cultures through the manufacturer's designated code life for the product.[20] Manufacturers can establish such a process by testing the amount of live and active cultures after the yogurt is held for the amount of time expected to precede consumption, and under the conditions that should be maintained during proper distribution and storage. Such a process would demonstrate that the yogurt is expected to have at least 10^6 CFU/g at the anticipated time of consumption.

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[19] Joseph A. Kurmann, Jeremija Lj. Rasic, and Manfred Kroger, *Encyclopedia of Fermented Fresh Milk Products: An International Inventory of Fermented Milk, Cream, Buttermilk, Whey, and Related Products*, New York, New York: 1992, at 310 (stating that the "microorganisms in the final product must be viable and abundant").

[20] For example, if the yogurt bears a use date, the yogurt must be expected to contain 10^6 CFU/g live and active cultures at the use date. If the yogurt bears a sell-by date, the yogurt must be expected to contain 10^6 CFU/g live and active cultures by the end of the period after the sell-by date during which the manufacturer expects consumption.

NYA notes that although manufacturers may establish that their yogurt products should contain 10^6 CFU/g live and active cultures at the time of consumption, the 10^6 CFU/g level at time of consumption is not a legal requirement. NYA recognizes that standards of identity govern the formulation and characteristics of products to be introduced into commerce. Once products enter the stream of commerce, products are subject to different conditions of distribution and storage that are not within the manufacturer's control. Therefore, NYA proposes that manufacturers may test their yogurt products to demonstrate that, assuming proper distribution and storage, the products would have 10^6 CFU/g of the particular live and active cultures at consumption. However, the standard for enforcement purposes would be 10^7 CFU/g of the particular live and active cultures at the time of manufacture.

Dairy standards must remain flexible enough to give consumers as much product choice as possible. Thus, yogurt-like products (products which resemble yogurt but which do not contain the required level of the characterizing live and active cultures) should have an alternate standard of identity. Under this proposal, if the food otherwise meets the yogurt standard of identity but does not contain the two characterizing cultures at the required levels, then the food qualifies for the cultured milk standard of identity[21] as amended by the proposal.[22] The proposal renames the standard "cultured milk/fermented milk" and permits manufacturers of these products to identify the product as either "cultured milk" or "fermented milk." The use of "fermented milk" reflects the evolving international nomenclature for this type of product and gives manufacturers an additional option in naming their product. Because these products will bear a different identity than yogurt, consumers will not incorrectly believe that the products contain a significant amount of live and active cultures.

The proposed amendments to the cultured milk standard retain most of the standard's current requirements. The standard permits any characterizing microbial cultures, so long as they are declared as part of the product name. Following the existing standard, the proposed standard also permits non-characterizing microbial cultures added for the purpose of producing aroma or flavor. The proposed standard retains the 0.5% titratable acidity requirement and permits the common ingredients butterfat, salt, and citric acid. However, it adopts the proposed yogurt standard's nomenclature provisions based on total fat, to establish two parallel standards that are consistent with the NLEA and that avoid consumer confusion.

2. Acidity – pH 4.6 or lower

When FDA first proposed the yogurt standards, FDA proposed a requirement of 0.5% minimum titratable acidity expressed as lactic acid.[23] A comment on the proposed rule

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[21] § 131.112.
[22] See Appendix 2.
[23] 42 Fed. Reg. 29919, 29920 (June 10, 1977).

stated that ordinarily, yogurt titratable acidity equals 1.0-1.5%.[24] Thus, the comment suggested a required minimum of 0.9%. FDA agreed and finalized the rule at 0.9%. However, FDA received an objection to the final rule, contending that some consumers find 0.9% too tart, and that 0.75% more closely reflects industry practice.[25] FDA stayed the requirement pending a hearing and thus, despite the 0.9% minimum appearing in the standard,[26] there is no extant titratable acidity requirement.

NYA proposes a minimum of 0.7% titratable acidity expressed as lactic acid, prior to the addition of optional ingredients.[27] This level reflects the lower end of titratable acidity levels found in common industry practice, but permits higher levels. [28] The proposal does not permit an acidity level as low as 0.5%, as FDA originally proposed, because industry does not use such low levels since those products would not bear yogurt's characteristic tartness. Under NYA's proposed standards, a yogurt-like product with only 0.5% titratable acidity could qualify as cultured/fermented milk. Thus, the 0.7% minimum level sets the level in yogurt low enough to allow for varying levels, while ensuring maintenance of yogurt's characteristic traits.

The proposed standard does not express the standard in terms of 0.7% titratable acidity however, but as pH of 4.6 or lower. NYA proposes the standard in these terms because measuring pH, rather than titratable acidity, reflects the current industry practice and is a more accurate and convenient method of measuring acidity. Therefore, rather than requiring a minimum titratable acidity of 0.7%, NYA proposes requiring a maximum pH of 4.6.[29]

3. Pre-Culture Homogenization/Pasteurization

The current yogurt standards state that the food *may* be homogenized and *must* be pasteurized or ultra-pasteurized prior to the addition of cultures.[30] Under the standards, flavoring ingredients (bulky or non-bulky) may be added after pasteurization or ultra-pasteurization.[31] Although a manufacturer may add these ingredients after pasteurization, under FDA's regulations, the manufacturer must ensure that precautionary measures prevent ingredients added after culturing from contaminating the yogurt and rendering the product adulterated.[32]

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[24] 46 Fed. Reg. at 9931.
[25] 47 Fed. Reg. at 41522.
[26] § 131.200(a), § 131.203(a), § 131.206(a).
[27] Appendix 1, § 131.200(a).
[28] A survey conducted by the National Yogurt Association (attached) indicates that of 44 regional and national brands, all contained a titratable acidity above 0.7%, with a range of 0.79% to 1.54%.
[29] Industry practice for cultured milk remains the minimum titratable acidity measurement.
[30] § 131.200(a), § 131.203(a), § 131.206(a).
[31] 47 Fed. Reg. at 41522.
[32] Id; 46 Fed. Reg. at 9927.

As with the current standards, NYA's proposed standard permits manufacturers to homogenize, and requires that they pasteurize or ultra-pasteurize, before culturing.[33] For clarification, rather than stating that the food must be pasteurized or ultra-pasteurized, the proposed standard states that the manufacturer must pasteurize or ultra-pasteurize the standard dairy ingredients before culturing. Under NYA's proposed standard, the manufacturer may add optional ingredients after culturing, and need not pasteurize or ultra-pasteurize these ingredients with the standard dairy ingredients. Of course, to avoid creating an adulterated food, all milk-derived and other optional ingredients must comply with general FDA safety requirements.

4. Standard Dairy Ingredients

The 1981 final rule defined yogurt as produced by culturing cream, milk, partially skimmed milk, or skim milk, alone or together.[34] An objection to the final rule asserted that FDA should permit reconstituted dairy ingredients as a basic milk ingredient.[35] The objection explained that because fluid milk supplies are disproportionately low in southern states, the price of yogurt in southern states will inflate if FDA does not allow reconstituted milk. FDA believed that the objector raised a genuine and substantial issue and thus, pending a hearing, stayed the effective date of the provision which would exclude reconstituted ingredients as basic dairy ingredients. Thus, the current standard does not include reconstituted milk as a basic dairy ingredient, but FDA will not enforce against the use of reconstituted dairy ingredients in yogurt.[36]

NYA recognizes the use of reconstituted milk in the southern United States and elsewhere. Therefore, NYA believes the basic dairy ingredients can include reconstituted ingredients without compromising yogurt's integrity.[37] In addition, NYA's proposed standard recognizes current industry practice by permitting whey protein concentrate ("WPC") as a standard dairy ingredient.[38] WPC contributes functionally as a stabilizer, and contributes a higher quality protein than other dairy ingredients. By specifying the protein level in WPC at a minimum of 34%, the protein content and protein quality (protein efficiency ratio) will be protected. In addition, the standard parallels the ice cream standard by permitting whey solids only if the quantity does not exceed 25% of the total required milk-solids-not-fat. Finally, rather than using the current standard's heading "optional dairy ingredients" to describe these ingredients, the proposed standard refers to them as "standard dairy ingredients," to convey more accurately that these dairy ingredients form the requisite basic ingredients for culturing.

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[33] Appendix 1, § 131.200(a).
[34] 46 Fed. Reg. at 9939.
[35] 47 Fed. Reg. at 41521.
[36] § 131.200(c), § 131.203(c), § 131.206(c).
[37] Appendix 1, § 131.200(b).
[38] Id.

5. Optional Milk-Derived Ingredients

FDA's 1977 proposed rule permitted any "milk-derived ingredients" to increase the milk-solids-not-fat percentage above the required 8.25%.[39] Addition of these ingredients cannot decrease the yogurt's ratio of protein to total milk-solids-not-fat solids, nor the protein efficiency ratio of all proteins present.[40] In the final rule, FDA designated a list of acceptable milk-derived ingredients derived from those traditionally used. The list includes concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulines or whey modified by partial or complete removal of lactose and/or minerals.[41]

Objections to the final rule claimed that replacing "milk-derived ingredients" with a specific list did not promote honesty and fair dealing in the interest of consumers.[42] Use of the list did not permit use of safe, nutritional, and functional milk-derived ingredients, including traditional ingredients such as partially delactosed skim milk, partially hydrolyzed whey, partially hydrolyzed skim milk, low sodium milks, casein, and caseinates.[43] FDA agreed that the objections raised a genuine and substantial issue of fact and thus, pending a hearing, stayed the portions of the provision that restricted the kinds of safe and suitable milk-derived ingredients used as optional ingredients to increase the milk-solids-not-fat content. Thus, although the current standard specifies a list of permissible optional dairy ingredients to raise the milk-solids-not-fat content,[44] manufacturers may use any safe and suitable milk-derived ingredients for this purpose.

NYA's proposed yogurt standard recognizes the value of flexibility in the yogurt standard and thus permits any "milk-derived ingredients."[45] Because the proposed standard dairy ingredients include the milk-derived ingredients used to raise the milk-solids-not-fat content, the proposed "optional ingredients" include milk-derived ingredients to enhance technical or functional attributes. This standard takes into account the wide range of milk-derived ingredients available for current use, and allows for use of novel milk-derived ingredients. Thus, manufacturers can take advantage of technological advances without waiting for an amendment to the standard.

NYA's proposed standard also recognizes the importance of dairy ingredients to the yogurt product. The current standard has no requirement for the amount of "white mass," *i.e.,* dairy ingredients, that must appear in a finished yogurt product. Thus, under the current standard, products that contain only small amounts of dairy ingredients can be labeled as "yogurt." NYA proposes to maintain the integrity of "yogurt" as a dairy product by

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[39] 42 Fed. Reg. 29919 (June 10, 1977).
[40] § 131.200(d)(1), § 131.203(d)(1), § 131.206(d)(1).
[41] 46 Fed. Reg. at 9927.
[42] 47 Fed. Reg. at 41519.
[43] Id.
[44] § 131.200(d)(1), § 131.203(d)(1), § 131.206(d)(1).
[45] Appendix 1, § 131.200(c)(1).

requiring that dairy ingredients (including standard dairy ingredients and optional dairy ingredients) comprise a minimum of 51% of the finished yogurt product mass.[46]

6. Optional Bacterial Cultures

Although the current standards permit bacterial cultures in addition to the two characterizing cultures, *Lactobacillus delbrueckii subsp. bulgaricus* and *Streptococcus thermophilus*, the regulation does not explicitly so state.[47] Thus, the proposed standard clearly lists as optional ingredients "optional safe and suitable bacterial cultures, in addition to the characterizing cultures," to clarify that manufacturers may use other bacterial cultures beyond the two characterizing cultures.[48]

7. Sweeteners

The current standards list permissible nutritive carbohydrate sweeteners: sugar(sucrose), beet or cane, invert sugar (in paste or sirup form), brown sugar, refiner's sirup, molasses (other than blackstrap), high fructose corn sirup, fructose, fructose sirup, maltose, maltose sirup, dried maltose sirup, malt extract, dried malt extract, malt sirup, dried malt sirup, honey, maple sugar, or any of the sweeteners listed in Part 168 of FDA's regulations (sweeteners and table sirups), except table sirup. Although FDA included a list because it perceived that consumers preferred a list of ingredients in the standard,[49] consumers do not likely benefit from a standard containing a long list of potential sweeteners that might appear in a yogurt product. Instead, consumers benefit from the declaration in the ingredient list of the sweetener used, as required by the NLEA. Thus, NYA's proposed standard creates additional flexibility in manufacturing by broadly permitting "safe and suitable sweeteners," without specifying a list.

Although the current yogurt standards do not contain a provision permitting nonnutritive sweeteners, in a letter to NYA counsel, FDA stated that under a 1988 FDA policy guidance, a yogurt product may contain aspartame.[50] The product must conform to the yogurt standard before addition of the sweetener, and the product's name must reflect the addition (*e.g.*, by adding "sweetened with aspartame" to the statement of identity on the principal display panel). Alternatively, under NLEA, a yogurt manufacturer can use additional ingredients not provided for in the standard if the nutritionally modified food is not inferior in performance characteristics to the standardized food. [51] Thus, a manufacturer could add a nonnutritive sweetener, such as aspartame or acesulfame potassium, to make

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[46] Appendix 1, § 131.200(a).
[47] 46 Fed. Reg. at 9933.
[48] Appendix 1, § 131.200(c)(2).
[49] 46 Fed. Reg. at 9933.
[50] Letter to Stuart M. Pape, Patton Boggs LLP, from Michelle A. Smith, Ph.D., Food Technologist, Food Standards Branch, Division of Programs and Enforcement Policy, Office of Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, March 3, 1997.
[51] § 130.10.

reduced calorie products named using the nutrient content claim for which the food qualifies, in conjunction with the standardized term (*e.g.*, "reduced calorie yogurt"). The ingredient need not appear on the principal display panel but must appear in the declaration of ingredients along with an asterisked statement indicating that the ingredient is not contained in regular yogurt.

The NYA proposed standard clarifies that yogurt may contain any safe and suitable sweetener.[52] By including nonnutritive sweeteners in the standard, a term such as "sweetened with aspartame" need not appear on the principal display panel, just as with the ice cream standard of identity.[53] However, the nonnutritive sweetener must still appear in the ingredient list and therefore, a consumer desiring to know the ingredients can refer to the ingredient list to determine if the product contains nonnutritive sweeteners.

8. Flavoring, Color, Stabilizers, and Emulsifiers

NYA's proposed standard permits "flavoring ingredients" and "color additives" as optional ingredients,[54] as does the current standard. The current standard also permits "stabilizers," but does not allow for emulsifiers. Emulsifiers are commonly used as fat substitutes, and including them in the standard will allow for more opportunities in product development. Thus, NYA's proposed standard allows manufacturers more flexibility by permitting "stabilizers and emulsifiers."

9. Preservatives

The current yogurt standards do not include preservatives in the list of acceptable optional ingredients. An objection to the 1981 rule asserted that the standard should provide for the use of preservatives such as potassium sorbate and sorbic acid to prohibit growth of yeasts and molds and to extend yogurt's shelf life.[55] Pending a hearing, FDA stayed the optional ingredients provision of the standards insofar as it excluded preservatives. Thus, although the standards do not include preservatives, FDA will not enforce against the appropriate use of preservatives in yogurt. NYA's proposed standard permits safe and suitable preservatives, *i.e.*, chemical and other preservatives, in order to provide flexibility and enable use of technology.[56] The product label must disclose the presence of preservatives in accordance with 21 C.F.R. Part 101.

10. Vitamins and Minerals

The current standards permit fortification. If the fortification is with vitamins A or D, vitamin A must be present at not less than 2,000 IU per quart, and vitamin D must be

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[52] Appendix 1, § 131.200(c)(3).
[53] § 135.110(f)(7).
[54] Appendix 1, § 131.200(c)(4), (5).
[55] 47 Fed. Reg. at 41522.
[56] Appendix 1, § 131.200(c)(7).

present at not less than 400 IU per quart.[57] The phrase "vitamin A (or D)" or "vitamin A (or D) added" must accompany the statement of identity on the principal display panel. NYA's proposed standard maintains these requirements, but lists them in terms more applicable to yogurt.[58] Because yogurt is rarely measured by quart, the minimum quantity of vitamins A and D is listed in terms of yogurt's reference amount customarily consumed. Unlike the current standards, the provision for added vitamins does not stand alone but appropriately appears under the "optional ingredients" section.

11. Nutritional and Functional Ingredients

NYA's proposed standard permits the use of any safe and suitable ingredients that are added to yogurt for nutritional or functional purposes.[59] This provision recognizes that advances are constantly being made in the area of food technology, and thus, it is necessary for the yogurt standard to maintain enough flexibility to permit the use of novel ingredients as they are developed.

12. Methods of Analysis

NYA's proposed standard includes the same method of analysis for milk-solids-not-fat content as the current standard.[60] Because the proposed standard contains the minimum requirement of 10^7 CFU/g live and active yogurt cultures at time of manufacture, the proposed standard provides that active cultures are to be enumerated using the International Dairy Federation procedure set forth at Appendix 3.[61] To measure pH level, the proposed methodology follows the standard set forth at 21 C.F.R. § 114.90(a).[62]

13. Nomenclature

One Standard

The 1981 rule establishes three standards of identity for yogurt, differing in milkfat content only: "yogurt," "lowfat yogurt," and "nonfat yogurt."[63] Although in 1995 FDA proposed to revoke the "lowfat" and "nonfat" standards for dairy products and let manufacturers make claims about fat levels under NLEA's nutrient content claim regulations,[64] FDA delayed final action on the proposal as it pertained to yogurt.[65] FDA realized that requiring yogurt manufacturers to meet the "nutritional equivalence"

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[57] § 131.200(b), § 131.203(b), § 131.206(b).
[58] Appendix 1, § 131.200(c)(8).
[59] Appendix 1, § 131.200(c)(9).
[60] Appendix 1, § 131.200(d)(2).
[61] Appendix 1, § 131.200(d)(1).
[62] Appendix 1, § 131.200(d)(3).
[63] § 131.200, § 131.203, § 131.206.
[64] 60 Fed. Reg. at 56541.
[65] 61 Fed. Reg. at 58991.

requirements,[66] and thus make lowfat and nonfat yogurts nutritionally equivalent to full fat yogurt, would require vitamin A fortification at significant cost to the industry. FDA has taken no further action with regard to yogurts that do not contain full fat content.

NYA recognizes that the names "lowfat yogurt" and "nonfat yogurt" have a long history of use in dairy product nomenclature, and thus, FDA must provide some mechanism for employing these names. However, revoking the lowfat and nonfat yogurt standards would result in a vitamin A fortification requirement that poses an unnecessary, but substantial, cost to the yogurt industry. Therefore, NYA's proposed standard maintains the three yogurt types, full fat "yogurt," "lowfat yogurt," and "nonfat yogurt," so manufacturers can name the products without meeting the "nutritional equivalence" requirement.[67] For simplicity, the proposed standard incorporates the different yogurt types into one standard, with the product name depending on the percent total fat contained in the product.

Fat Content

Under the 1981 rule, before the addition of bulky flavors, "yogurt" contains not less than 3.25 percent milkfat, "lowfat yogurt" contains between 0.5 and 2.0 percent milkfat, and "nonfat yogurt" contains less than 0.5 percent milkfat.[68] Lowfat yogurt must declare the percentage of milkfat in conjunction with the name of the food.[69]

Although NYA's proposed standard prevents yogurt from having to meet the "nutritional equivalence" requirement, the proposed rule does seek to remain as consistent as possible with NLEA provisions.[70] Thus, the proposed standard changes the milkfat percentage standards to total fat per reference amount customarily consumed ("RACC" equals 8 oz.), as used in the NLEA nutrient content claim requirements.[71]

The proposed identities for "lowfat yogurt" and "nonfat yogurt" directly parallel nutrient content claim requirements under NLEA.[72] "Lowfat" products must contain at least 0.5g total fat, but not more than 3.0 g total fat, and "nonfat" products must contain less than 0.5g total fat. The proposed standard does not set a particular total fat level for full fat "yogurt"; yogurt with any level of fat above "lowfat yogurt" is considered "yogurt."[73]

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[66] See § 130.10.
[67] Appendix 1, § 131.200(e).
[68] § 131.200, § 131.203, § 131.206.
[69] § 131.203(f)(1)(i), § 131.206(f)(1)(i).
[70] § 130.10.
[71] § 101.62(b).
[72] Appendix 1, § 131.200(e).
[73] Under the NLEA, manufacturers can label their products "reduced fat" if they satisfy the requirements of § 101.62(b)(4). Therefore, yogurt bearing 25% less fat than an appropriate reference food, and complying with § 101.62(b)(4), could bear the statement of identity "reduced fat yogurt."

The following table sets forth the nomenclature for the various total fat levels:

Name of Product	Total fat per RACC (8 oz. serving)
Yogurt	More than 3.0g
Lowfat yogurt	At least 0.5g, but not more than 3.0g[74]
Nonfat yogurt	Less than 0.5g[75]

Measurement

An objection to the final rule stated, and FDA agreed, that the standards' wording implied that the manufacturer should measure milkfat content after the addition of optional ingredients.[76] The objector argued that this requirement discourages manufacturers from adding optional ingredients to increase the milk-solids-not-fat content, because then the manufacturer must add milkfat also, in order to meet the requirement. The objector requested that FDA change the rule to clarify that manufacturers measure milkfat content after addition of the standard dairy ingredients only. FDA believed that the objection raised a genuine issue of material fact and stayed the provision to the extent that it requires measurement of milkfat after the addition of optional ingredients.

NYA's proposed standard states that manufacturers must measure the finished product's total fat content in determining the product's name. Thus, the standard will more closely resemble the NLEA nutrient content claim requirements, and the claims will provide consumers with more accurate information concerning the product's actual fat content. For example, under the current standards, a yogurt contains less that 0.5g milkfat after culturing, but then has chocolate added, may be considered "nonfat yogurt with chocolate added" if the milkfat content is calculated prior to the addition of the chocolate. Under NYA's proposed standard, if the added chocolate rendered the total fat content of the finished product greater than 0.5g, the product could not claim to be "nonfat yogurt."

14. Declaration of Ingredients

Consistent with the current yogurt standards,[77] the proposed standard requires declaration of each ingredient as required by 21 C.F.R. Parts 101 and 130.[78]

D. Conclusion

The current yogurt standards do not contain a coherent set of provisions that accurately represents FDA's current enforcement policy. Therefore, the standards defeat the

[74] § 101.62(b)(2).
[75] § 101.62(b)(1).
[76] 47 Fed. Reg. at 41521.
[77] § 131.200(g), § 131.203(g), § 131.206(g).
[78] Appendix 1, § 131.200(f).

purpose of preventing consumer fraud by having a statement of identity to which manufacturers and consumers can look to know the ingredients contained in yogurt and the procedures employed to make yogurt. NYA's proposed standard consolidates the three yogurt standards into one comprehensive and clear standard. The proposal addresses cultured milk/fermented milk products also, to ensure that both yogurt and cultured milk/fermented milk products have an identity with characterizing features. The standard incorporates current technologies and industry practice, yet remains flexible enough to allow for use of technological advances. NYA proposes that FDA adopt the proposed yogurt standard and the accompanying cultured milk/fermented milk amendments to finally give the dairy industry accurate and workable guidelines with which to manufacture yogurt, and to ensure that consumers receive yogurt that is a standardized product containing minimum levels of certain live and active cultures.

III. Environmental Impact

Petitioners hereby claim a categorical exclusion from the environmental assessment requirement pursuant to 21 C.F.R. § 25.30(h).

IV. Economic Impact

An economic impact analysis is not required at this time.

V. Certification

The undersigned certifies, that, to the best of the undersigned's knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes favorable and unfavorable representative information relevant to the petition.

Respectfully submitted,

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Doc. 511817

Proposed Standard of Identity

Yogurt

Revise § 131.200 to read as follows:

§ 131.200 Yogurt.

(a) *Description.* **Yogurt** is the food produced by culturing one or more of the standard dairy ingredients specified in paragraph (b) of this section. Yogurt contains at least 10^7 CFU/g active yogurt cultures, at the time of manufacture, of the characterizing lactic acid-producing bacteria, *Lactobacillus delbrueckii subsp. Bulgaricus* and *Streptococcus thermophilus*, and the manufacturer may have records demonstrating that, under proper conditions of distribution and storage, the yogurt will contain at least 10^6 CFU/g live and active cultures through the manufacturer's assigned code life for the product. One or more of the optional ingredients specified in paragraph (c) of this section may also be added. All ingredients used are safe and suitable. Yogurt, before the addition of optional ingredients specified in paragraph (c), contains not less than 8.25 percent milk-solids-not-fat from the standard dairy ingredients specified in paragraph (b), and has a pH of 4.6 or lower. Dairy ingredients comprise at least 51% of the food's overall ingredients by weight. The food may be homogenized and the ingredients specified in paragraph (b) shall be pasteurized or ultra-pasteurized prior to the addition of the characterizing yogurt bacterial cultures.

(b) *Standard dairy ingredients.* Cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of these standard dairy ingredients may be used alone or in combination. Whey protein concentrate, minimum protein concentrate 34% ("WPC"), may be used, if the total quantity of WPC used in this paragraph and paragraph (c) does not result in a quantity of WPC that exceeds 25% of the total milk-solids-not-fat. When one or more of the ingredients specified in this paragraph is used, it shall be included in the culturing process.

(c) *Optional ingredients.* (1) Dairy ingredients. Any milk-derived ingredients used for technical or functional purposes.

(2) Optional safe and suitable cultures, in addition to the characterizing cultures.

(3) Safe and suitable sweeteners.

(4) Flavoring ingredients.

(5) Color additives.

(6) Stabilizers and emulsifiers.

(7) Preservatives.

(8) Vitamins and minerals. (i) If added, vitamin A shall be present in a minimum quantity of 500 International Units per reference amount customarily consumed.

(ii) If added, vitamin D shall be present in a minimum quantity of 100 International Units per reference amount customarily consumed.

(9) Any safe and suitable ingredients added for nutritional or functional purposes.

(d) *Methods of analysis.*

(1) Enumeration of live and active cultures --- As determined by the method prescribed by the International Dairy Federation.

(2) Milk-solids-not-fat-content --- Calculated using the following methods from the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th Ed. (Copies are available from the Association Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, D.C.). Subtract the milkfat content (as determined by the method prescribed in section 16.059 "Roese-Gottlieb Method (Reference method) (11) --- Official Final Action, under the heading "Fat") from the total milk solids content as determined by the method prescribed in section 16.032, "Method I--- Official Final Action," under the heading "Total Solids."

(3) pH--- As determined under 21 C.F.R. § 114.90(a), "Potentiometric method for the determination of pH."

(e) *Nomenclature.*

(1) If the food contains the amount of live and active *Lactobacillus delbrueckii subsp. Bulgaricus* and *Streptococcus thermophilus* cultures as indicated in paragraph (a), the food is "yogurt," except

(i) if the finished food complies with the requirements of 21 C.F.R. § 101.62(b)(4)(i), and is not "lowfat yogurt" or "nonfat yogurt," then the food must comply with 21 C.F.R. § 101.62(b)(4)(ii), and the name of the food is "reduced fat yogurt."

(ii) if the finished food contains at least 0.5g, but not more than 3.0g, total fat per reference amount customarily consumed, then name of the food is "lowfat yogurt."

(iii) if the finished food contains less than 0.5 percent total fat per reference amount customarily consumed, the name of the food is "nonfat yogurt."

(2) 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.

(3) 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 phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added," as appropriate. The word "vitamin" may be abbreviated "vit."

(f) *Declaration of ingredients.* 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.

Proposed Standard of Identity Amendments

Cultured Milk/Fermented Milk

Revise § 131.112 to read as follows:

§ 131.112 Cultured Milk/Fermented Milk.

(a) *Description.* **Cultured milk** or **fermented milk** is the food produced by culturing one or more of the standard dairy ingredients specified in paragraph (b) of this section with characterizing microbial organisms. One or more of the optional ingredients specified in paragraph (c) of this section may also be added. All ingredients used are safe and suitable. Cultured milk or fermented milk, before the addition of optional ingredients specified in paragraph (c), contains not less than 8.25 percent milk-solids-not-fat from the standard dairy ingredients specified in paragraph (b), and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid, before the addition of bulky flavors. Dairy ingredients comprise at least 51% of the food's overall ingredients by weight. The food may be homogenized and the ingredients specified in paragraph (b) shall be pasteurized or ultra-pasteurized prior to the addition of the microbial cultures.

(b) *Standard dairy ingredients.* Cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of any of these standard dairy ingredients may be used. Whey protein concentrate, minimum protein concentrate 34% ("WPC"), may be used, if the total quantity of WPC used in this paragraph and paragraph (c) does not result in a quantity of WPC that exceeds 25% of the total milk solids not fat. When one or more of the ingredients specified in this paragraph is used, it shall be included in the culturing process.

(c) *Optional ingredients.* (1) Dairy ingredients. Any milk-derived ingredients used for technical or functional purposes.

(2) Aroma- and flavor-producing microbial culture.

(3) Safe and suitable sweeteners.

(4) Flavoring ingredients.

(5) Color additives that do not impart a color simulating that of milkfat or butterfat.

(6) Stabilizers and emulsifiers.

(7) Preservatives.

(8) Vitamins and minerals. (i) If added, vitamin A shall be present in a minimum quantity of 500 International Units per reference amount customarily consumed.

(ii) If added, vitamin D shall be present in a minimum quantity of 100 International Units per reference amount customarily consumed.

(9) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

(10) Salt.

(11) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(12) Any safe and suitable ingredients added for nutritional or functional purposes.

(d) *Methods of analysis.*

(1) Milk-solids-not-fat content --- Calculated using the following methods from the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th Ed. (Copies are available from the Association Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, D.C.). Subtract the milkfat content (as determined by the method prescribed in section 16.059 "Roese-Gottlieb Method (Reference method) (11) --- Official Final Action, under the heading "Fat") from the total milk solids content as determined by the method prescribed in section 16.032, "Method I--- Official Final Action," under the heading "Total Solids."

(2) Titratable acidity---As determined by the method prescribed in section 16.023, "Acidity (2)---Official Final Action," or by an equivalent potentiometric method.

(e) *Nomenclature*

(1)The name of the food is "cultured milk" or "fermented milk," except:

(i) if the finished food complies with the requirements of 21 C.F.R. § 101.62(b)(4)(i), and is not "lowfat fermented milk" or "lowfat cultured milk" or "nonfat fermented milk" or "nonfat cultured milk," then the food must comply with 21 C.F.R. § 101.62(b)(4)(ii), and the name of the food is "reduced fat fermented milk" or "reduced fat cultured milk."

(ii) if the finished food contains at least 0.5g, but not more than 3.0g, total fat per reference amount customarily consumed, then name of the food is "lowfat fermented milk" or "lowfat cultured milk."

(iii) if the finished food contains less than 0.5 percent total fat per reference amount customarily consumed, the name of the food is "nonfat fermented milk" or "nonfat cultured milk."

(2) 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.

(3) The name of the food shall be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., "kefir cultured milk," "acidophilus fermented milk," or when characterizing ingredients such as those in paragraph (c)(2), (9), (10) and (11) of this section and lactic acid-producing organisms are used, the food may be named "cultured buttermilk."

(4) 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 flavoring.

(ii) The phrase "vitamin A or "vitamin A added," or "vitamin D" or "vitamin D added," or "vitamin A and D added," as appropriate. The word "vitamin" may be abbreviated "vit."

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

(f) *Declaration of ingredients.* 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.