



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

April 29, 2009

The Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Submitted electronically to <http://www.fda.gov/dockets/ecomments>

Re: Docket No. FDA-2000-P-0126 Milk and Cream Products and Yogurt Products;
Petition to Revoke Standards for Lowfat Yogurts and Nonfat Yogurt and to Amend the
Standards for Yogurt and Cultured Milk. (Proposed Rule)

Dear Sir/Madam:

The International Dairy Foods Association (IDFA) and one of its constituent organizations, the Milk Industry Foundation (MIF) appreciate the opportunity to provide comments to the Proposed Rule to revise the standards of identity for yogurt. The MIF represents 105 member companies that process, distribute and market approximately eighty-five percent of U.S. fluid milk, yogurts, cottage cheese, sour cream, soft cheeses, eggnog, creams, dairy dressing and dips, as well as bottled water, juices and juice drinks.

IDFA strongly supports the Food and Drug Administration's (FDA) actions to move forward with updating the existing Federal standards of identity for yogurt by publishing a Proposed Rule in the *Federal Register* on January 15, 2009 (Docket No. FDA-2000-P-0126). Existing standards for nonfat yogurt, lowfat yogurt and yogurt are outdated and need revision to reflect and accommodate new technology for food ingredients and processing methods as well as current consumer preferences. IDFA has worked with our members that represent the yogurt industry to formulate consensus on the numerous proposed amendments to the standard for yogurt and we are pleased to transmit those positions to you today.

IDFA continues to support the fundamental concepts requested by the National Yogurt Association's petition to establish a new yogurt standard to replace the three existing and fragmented standards for yogurt, lowfat yogurt and nonfat yogurt. The MIF believes it is in the best interest of both yogurt manufacturers and consumers for FDA to modernize these standards to reflect food labeling changes that were enacted with the Nutrition Labeling and Education Act (NLEA) of 1990, as well as to codify provisions in the

standard for the use of optional dairy ingredients that were stayed by FDA in 1982. Revising the yogurt standards is important to allow manufacturers flexibility with technology advances, industry practices and consumer preferences.

Listed below are IDFA's responses to the proposed amendments to the yogurt standards:

a. Milkfat and milk solids not fat content of yogurt.

IDFA supports FDA's proposed requirements 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. The concept of having a single standard for yogurt is consistent with other dairy standards such as milk, cottage cheese and ice cream. Product nomenclature depicting a specific fat level of the yogurt would utilize the Nutrition Labeling Education Act (NLEA) nutrient content claims. NLEA food labeling allows for products that have less than 3 grams of fat per reference amount commonly consumed (RACC) to be labeled as "low fat" and yogurt with less than 0.5 grams of fat per RACC to be named "non fat" "fat free" or other permitted nutrient claim synonyms. The yogurt industry realizes that this change will cause reformulation and relabeling of some products currently existing in the market that meet the existing standard of identity for "low fat yogurt" (0.5 - 2 % milk fat before addition of bulky flavoring) that do not qualify to use the "low fat" nutrient content claim (less than 3 grams of fat per 8 ounce serving/ 225g = .0133 or less than 1.33% milk fat).

IDFA believes that it is important for FDA to clarify the reference food that will be used to determine the relative nutrient content claim "reduced fat yogurt" For other foods the reference food for relative claims is a similar food in same product category, which may be based on either; a current data base, the average of top national brands, an appropriate market leader, a competitors product, or the manufacturer's own brand. However, the yogurt proposal states that the fat level of regular yogurt will be measured prior to the addition of bulky flavorings, which after addition could lower the fat level of the final product to 3.25%. Therefore, IDFA requests that the reduced fat claim be based off either existing products in the marketplace in which the average fat would be not less than 3.25% or if an appropriate marketplace product is not available, be based off of a plain yogurt which is 3.25% fat. Plain yogurt is also know as the "white mass portion" of the final yogurt which includes the "basic dairy ingredients" and "optional dairy ingredients" and may include "other optional ingredients" such as stabilizers, emulsifiers and sweeteners which have been fermented together.

Additionally, IDFA believes that the change in the language from "bulky flavors" (as used in the current yogurt standard) to "bulky flavorings ingredients" should not be interpreted in a manner that changes the current yogurt industry's understanding of this term. IDFA recommends that FDA either retain the term "bulky flavors" as used in the existing yogurt standards, or clarify that the change to using the term "bulky flavoring ingredients" does not alter the industry's understanding of the definition "bulky flavors." IDFA would welcome the opportunity to meet with the Agency to share the industry's views on the current use of bulky flavors.

As FDA noted, this approach will require low fat and nonfat yogurt to now be fortified with vitamin A, to restore nutrients lost with the removal of fat so the lower fat products are not nutritionally inferior to the full fat reference product. It is important to note that fortification of vitamin A to lower fat yogurt will have a significant economic impact resulting not only for the need for additional vitamin fortification equipment, but also the cost of relabeling for all low fat and nonfat types of yogurt to declare vitamin A in the ingredient declaration of the foods. IDFA noticed that FDA acknowledged that this change would potentially result in significant relabeling, reformulation, and equipment costs to manufacturers. However the analysis of economic impact appears to only include the costs of vitamin fortification equipment and fails to account for the majority of labeling that will need to be changed.

The yogurt category is dominated by sales of lower fat versions of yogurt. Retail supermarket sales data from Information Resources Inc in 2008 found that 93% (1420 million pounds) of branded spoonable yogurt sold was low fat or fat free yogurt, and only 6.6% (100 million pounds) was regular fat yogurt. Total spoonable yogurt sales (including both branded and private label) volume grew 17.3% from 1,625 million pounds in 2003 to 1,900 million pounds in 2008. Furthermore the growth in yogurt sales is attributed to increased sales of lower fat versions of low fat and fat free yogurt. Data for branded spoonable yogurts showed that the 2008 sales volume of regular fat yogurt declined by 35 % from 2007, while sales of fat-free varieties of yogurt increased by 17.4 % from 2007.

As sales of low fat yogurt account for more than 90% of total yogurt sales, IDFA is requesting that FDA provide a two year implementation date for these label changes that is consistent with the Uniform Compliance date for label changes. This timetable will provide sufficient time for processors to deplete existing packaging inventory, reformulate products to the new fat levels, install fortification equipment, make the necessary label changes.

b. Acidity of yogurt.

IDFA agrees with FDA that both minimum titratable acidity and maximum pH are appropriate acidity measurements for yogurt. IDFA's earlier comments recommended titratable acidity, however we now recognize that pH is a valuable analytical tool once other ingredients are added to the yogurt. Ingredients added to yogurt such as fruits and flavorings imparting colors to the food can interfere with detecting the visual color change endpoint used in titratable acidity measurement. IDFA believes that a minimum titratable acidity of 0.7 % is too high for some yogurt products that use novel flavorings like chocolate or delicate fruit flavors that can be overshadowed by tart, acidic yogurt. We recommend that the new standard set a level not less than 0.6% titratable acidity in the "white mass portion" (see definitions of white mass and bulky flavoring ingredients above).

The slight reduction in the required level of titratable acidity from not less than 0.7% to 0.6% is necessary to produce yogurt products that meet consumer expectations of a

delicate creamy and tart yogurt taste which is not too acidic or sour and does not need to have higher levels of added sweeteners to counteract the acidity. Establishing the level at 0.6% titratable acidity will also align the U.S. standards with the Codex Standard of Fermented Milk.

IDFA also believes that the requirement of a maximum pH of 4.6 needs to be specific to the amount of elapsed time since filling the yogurt in the final package. This is requested in light of modifications made to the Pasteurized Milk Ordinance at the 2005 National Conference on Interstate Milk Shipments (NCIMS) that specified the time and temperature of yogurt during cooling based on an initial pH of 4.8 or below at filling and with a pH of 4.6 or below within 24 hours of filling. It is clear from pathogen challenge study data reviewed by FDA related to the NCIMS that yogurt is safe when the product is 4.6 or lower within 24 hours of filling.

Based on the comments provided above, IDFA proposes that section 131.200(a) be modified to require that yogurts have a minimum titratable acidity of not less than 0.6 percent expressed as lactic acid, measured in the white mass of the yogurt or a maximum pH of 4.6 or lower within 24 hour after filling, measured on the finished product.

c. Live and active cultures in yogurt

IDFA believes that the growing popularity of yogurt is based on consumer awareness that it is a healthy and nutritious food providing a good source of calcium and protein. The characterizing lactic cultures of yogurt *Lactobacillus delbrueckii* subspecies *bulgaricus* and *Streptococcus thermophilus*, which impart the delicate acidic flavor and creamy thick texture during the fermentation of the inherent lactose in the milk ingredients, also have an added benefit in lowering the lactose content of the final food. Consumers now associate the benefits of consuming yogurt with live and active cultures in the food. IDFA and our members agree that live and active cultures are an essential characteristic of yogurt that consumers expect. IDFA members are now in agreement that the proposed standard for yogurt should be revised, consistent with the NYA Citizen Petition, to require all yogurts to contain a minimum level of live and active cultures 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 product's shelf life.

In addition, 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. IDFA asserts that only the requirement for yogurt to contain a minimum level of live and active cultures 10^7 colony-forming units per gram (CFU/g) at the time of manufacture should be applied as regulatory enforcement of adherence to the standard.

IDFA members would like to express their concerns with accuracy and repeatability of testing methods used for enumeration of yogurt cultures. Testing conducted by industry and at outside laboratories has found variation between different testing methods and lack of repeatability between duplicate samples. IDFA recommends that for accuracy and

repeatability the International Standard IOS 7889/ IDF 177 Yogurt - Enumeration of Characteristic microorganisms - colony count technique at 37 C method be used to determine the level of live and active cultures rather than the aerobic plate count. Additionally, enumeration of yogurt cultures for regulatory enforcement purposes should be conducted on samples collected from the manufacturing facility and tested within 24 hours to ensure integrity of the sample and provide for a uniform time of analysis.

Additionally, IDFA recommends clarification by FDA that a proposed change to require a minimum of 10^7 CFU/g live and active characterizing cultures, will not be applied to non-standard products that use yogurt as an ingredient such as "frozen yogurt," "yogurt coated cereals" or "dried yogurt powders." IDFA believes that these foods, which do not meet the standard of identity for yogurt, but use yogurt as an ingredient should be able to continue using the appropriately descriptive term "yogurt" as part of the food's statement of identity on the label. We feel that it is critical for FDA to address this matter in the preamble of the final rule.

d. Heat treatment of yogurt after culturing

Based on IDFA's position that yogurt must contain a specific level of live and active cultures, the revised yogurt standards no longer need to maintain the current labeling descriptor "heat-treated after culturing" for yogurt that undergoes heat treatment after the culturing process. Heat-treated yogurt products which do not contain live and active cultures should be prohibited from being labeled "yogurt" and such products should be labeled with some other descriptive or fanciful name. Furthermore, IDFA believes that consumers may not understand the current mandatory label statement "heat-treated after culturing." If FDA nonetheless continues to permit heat-treated products to be labeled "yogurt," IDFA recommends that FDA require such products to be labeled with the phrase "does not contain live and active cultures" in close proximity to the name of the food on the principal display panel.

e. Use of reconstituted milk forms as basic dairy ingredients

IDFA members support FDA's proposal to revise Sec. 131.200 to permit reconstituted forms of cream, milk, partially skimmed milk, and skim milk as basic ingredients and rename the heading "basic dairy ingredients" instead of "optional dairy ingredients." As discussed in 1981, fluid milks supplies may be disproportionately low in southern states and other regions and could inflate the price of yogurt in that area if reconstituted milk ingredients were excluded. This issue is still relevant today. These dairy ingredients both in liquid, dry and reconstituted forms have been used historically during the stayed provision to produce safe and high quality yogurt products.

f. Use of safe and suitable milk-derived ingredients as optional dairy ingredients

IDFA fundamentally supports the use of all types of safe and suitable milk derived ingredients in yogurts such as whey protein, milk protein concentrates, caseinates, milk fractions, and lactalbumins as basic milk ingredients contributing to the minimum required 8.25% nonfat solids. However, we realize the use of these ingredients can be accomplished using FDA's existing framework of regulations that permits flexibility for the use of ingredients that are needed to achieve a nutrient content claim or when such

ingredient serves a function as an emulsifier or stabilizer in the food. As a result IDFA is neutral on the proposed definition that limits the use of other safe and suitable milk-derived ingredients as "optional dairy ingredients" used to increase the nonfat solids content of the food.

g. Use of safe and suitable cultures in addition to the characterizing bacterial cultures

FDA's proposal to explicitly state that use of other optional safe and suitable bacterial cultures for yogurt is provided for in the standards is strongly supported by IDFA. The continued growth of the yogurt category is in part due to additional probiotic cultures that are added to compliment the characterizing yogurt cultures. This change will provide clarity to the standard.

h. Use of sweeteners

IDFA welcomed FDA's conclusion to provide for the use of any safe and suitable sweetening ingredients, in lieu of the current allowance for certain nutritive carbohydrate sweeteners. We agree that this modification introduces flexibility in the manufacture of yogurt without adversely affecting the basic nature and essential characteristics of yogurt. IDFA fully supports the changes proposed to provide for the use of any safe and suitable sweeteners in yogurt and accordingly to replace the term "nutritive carbohydrate sweetener" with "sweetener(s)". We also agree that consumers will seek information about the type of sweetening ingredients used by reading the ingredient statement for yogurt as they do with other foods. Therefore, there should be no requirement to require declaration of non-nutritive sweeteners, when used as part of the name of the food.

i. Use of safe and suitable emulsifiers in yogurt.

IDFA supports FDA's proposed change to the yogurt standards that would allow for safe and suitable emulsifiers. Emulsifiers are commonly used in dairy products and including provisions for use of emulsifiers in yogurt will allow for more opportunities in product development to formulate products that meet consumer's expectations of a creamy uniform texture.

j. Use of safe and suitable preservatives in yogurt.

IDFA supports permitting the use of safe and suitable preservatives as optional ingredients in the manufacture of yogurt. The industry believes it is necessary and appropriate to permit the use of safe and suitable preservatives in the manufacture of all types of yogurt and the use should not be solely limited to yogurts that are heat-treated after culturing.

k. Use of optional milk-derived ingredients after pasteurization and culturing

IDFA respectfully requests that FDA reconsider its decision not to permit the addition of milk derived ingredients after pasteurization and culturing. IDFA fully supports the NYA proposal that requested milk-derived ingredients should be permitted to be added after culturing if the dairy ingredients are pasteurized and handled in a manner to prevent post-pasteurization contamination. Permitting the use of such pasteurized dairy ingredients after culturing is similar to the practice of adding pasteurized cottage cheese dressing to

cottage cheese curd to produce the cottage cheese. Furthermore IDFA believes that the use of adding pasteurized milk ingredients after pasteurization and culturing will provide for innovation in product formulation without compromising the safety of the final product.

l. Use of whey protein concentrates as a basic ingredient

Initially, IDFA asserted that reconstituted dairy ingredients, whey protein concentrate (WPC) and whey protein isolate (WPI) should be allowed as standard dairy ingredients for yogurt. We continue to believe that the use of WPC or WPI contributes in the formulation of yogurt both functionally as a stabilizer, and nutritionally to provide a higher quality of protein than milk. However, IDFA does not oppose FDA's proposal that limits the use of whey and whey ingredients to "other optional ingredients."

m. Percent dairy ingredients

IDFA agrees with FDA's proposal to not require a minimum of 51 percent dairy ingredients in yogurt. We believe there is no need to ensure a minimum amount of dairy ingredients as the proposed yogurt standard requires the basic ingredients of yogurt to be either milk or certain milk-derived ingredients and that the yogurt must contain a minimum amount milk solids non fat.

n. Use of any safe and suitable ingredient for nutritional or functional purposes

See IDFA comments in section f.

o. Methods of analysis

As noted above in section c, IDFA members have concerns with accuracy and repeatability of testing methods used for enumeration of yogurt cultures. Methods such as the "aerobic plate count methods described in Chapter 3 of FDA's Bacteriological Analytical Manual" that are appropriate for the enumeration of aerobic bacteria are not suitable and reliable for detection of characterizing yogurt cultures or the other optional cultures that may be added. Therefore, IDFA recommends using the International Standard IOS 7889/ IDF 177 Yogurt - Enumeration of Characteristic microorganisms - colony count technique at 37 C method to determine the level of live and active cultures rather than the aerobic plate count.

p. Vitamins and minerals as optional ingredients

IDFA understands FDA's proposal to align the optional fortification of vitamin A and D in yogurt with nutrient content claims used for other foods. However, IDFA requests that the provisions for vitamin A and/or vitamin D fortification be retained in terms of the required amounts and the nomenclature section of the current yogurt standards. We request this not be changed based on the long standing practice that permits and defines vitamin A and D fortification in yogurt and all other milk and milk product standards. If voluntary nutrient content claims are made for added minerals or vitamins other than vitamins A and D, such claims would be required to follow the appropriate regulations as they relate to level and labeling requirements.

IDFA asserts that changing the framework for labeling yogurts fortified with vitamin A and/or D to the requirements of relative nutrient content claims would result in additional labeling of comparative statements and quantitative information that is not currently required for milk or other milk products. This change could result in consumer confusion. Flexibility and uniformity can be best achieved if FDA were to consider retaining the current provisions for optional vitamin A and/or D and the specific nomenclature provided in the standard for labeling with a slight modification. We recommend that in the sections for vitamins A and D the amounts should be based on a percentage of the recommended Daily Value rather than a specific level per quart. We also suggest that the yogurt standards be further amended in the section for vitamin D to include the words "not less than" before the level of vitamin D." Those changes will permit adding higher levels of vitamin D if warranted in the future by recommendations of the Institute of Medicine's (IOM) Committee and allow flexibility to align addition of vitamins A and D with any updates of the Daily Values or Recommended Daily Intakes.

Specifically IDFA suggests the following language be used:

(b) Vitamin addition (optional).

(1) If added, vitamin A shall be present in such quantity that the food contains not less than 10% Daily Value per Reference Amount Commonly Consumed (RACC) thereof, within limits of current good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that the food contains not less than 25% Daily Value per Reference Amount Commonly Consumed (RACC) thereof, within limits of current good manufacturing practices

Conclusion:

IDFA and our members that manufacture yogurt agree there is a need for updating the existing yogurt standard to permit the use of new technologies as to ingredients and processing techniques, product development and consumer benefits. In general, IDFA members support the NYA petition which would establish a new yogurt standard to replace the currently existing three fragmented standards for yogurt, lowfat yogurt and nonfat yogurt. The revised standard will reflect food labeling changes that were enacted with the Nutrition Labeling and Education Act (NLEA) of 1990, as well as codify provisions in the standard for the use of optional dairy ingredients that were stayed by FDA in 1982. Modernizing the yogurt standards is important to allow manufacturers flexibility with technology advances and industry practices.

As mentioned in our detailed comments above, IDFA urges the yogurt proposal be revised to require all yogurts to contain a minimum level of live and active cultures 10^7 colony-forming units per gram (CFU/g) at the time of manufacture. Heat-treated yogurt products which do not contain live and active cultures at the required level should be prohibited from being labeled "yogurt" and such products should be labeled with some other descriptive or fanciful name. As a result the revised yogurt standards no longer need to maintain the current labeling descriptor "heat-treated after culturing" for yogurt that undergoes heat treatment after the culturing process.

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We strongly urge FDA to move forward swiftly with publishing a final rule to modernize the standard of identity for yogurt. However due to the financial burdens of label changes, discarding obsolete packaging inventory and installing vitamin fortification equipment required by this new standard, we ask that FDA provide for an appropriate time period for implementation of at least two years. Our staff looks forward to providing the Agency with more detailed and comprehensive information that it may need to act, and answer any questions you have.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Cary Frye". The signature is written in a cursive, flowing style.

Cary Frye
Vice President,
Regulatory Affairs