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

January 27, 2004

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

Re: Docket No. 00P-0685 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. (advanced notice of proposed rulemaking)

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 Advance Notice of Proposed Rulemaking 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 Agency's actions to move forward with updating the existing Federal standards of identity for yogurt with their publishing of an Advanced Notice of Proposed Rulemaking in the *Federal Register* on July 3, 2003 (Docket No. 00P-0685). The existing standards for nonfat yogurt, lowfat yogurt and yogurt are outdated and need revision to reflect and accommodate new technology for food ingredients and processing methods as well as current consumer preferences.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 in the yogurt industry to formulate consensus on the numerous proposed amendments to the standard for yogurt. IDFA will abstain from providing comments on certain amendments to specific aspects for the proposed standards where a consensus position was not developed.

00P-0685 C15

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IDFA supports the fundamental concepts requested by the National Yogurt Association's (NYA) petition to establish one new yogurt standard to replace the current three standards for yogurt, lowfat yogurt and nonfat yogurt. IDFA believes it is in the best interest of both yogurt manufacturers and consumers for the FDA to modernize these standards to reflect food labeling changes that were enacted with the Nutrition Labeling and Education Act (NLEA) of 1990. IDFA also supports codifying the provisions in the standard of the use of optional dairy ingredients that were stayed by FDA in 1982. IDFA is supportive for the proposed change to allow for the use of safe and suitable milk-derived ingredients for technical and functional purposes rather than the current prescriptive listing of dairy ingredients. Revising the yogurt standards is important to allow manufacturers flexibility to utilize technology advances, incorporate industry practices, and respond to consumer preferences.

Listed below are IDFA's responses to the specific provisions set forth in the petition:

1. A single standard of identity for yogurt, which includes provisions for low fat and nonfat yogurts.

IDFA supports the concept of having a single standard for yogurt, which is consistent with other dairy standards for 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." The yogurt industry realizes that this change will cause reformulation or relabeling of some products currently existing in the market that could meet the current standard of identity for "low fat yogurt" (0.5 - 2 % milk fat before addition of bulky flavoring) but 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). However, there is agreement by MIF members that aligning the yogurt standards with other foods is needed to eliminate consumer confusion about the fat levels for yogurt that currently differ from other foods.

2. A minimum of 10^7 colony forming units per gram (CFU/g) of live and active characterizing cultures at the time of manufacture of yogurt.

IDFA members were not able reach consensus on whether the standards of identity should be changed to require a minimum level of live and active characterizing yogurt cultures at the time of manufacture. Therefore, no comment will be presented on this matter.

However, IDFA does have a question related to this requirement. How would the NYA's proposed change to require a minimum of 10^7 CFU/g live and active characterizing

cultures at the time of manufacture, be applied to products that use yogurt as an ingredient such as "frozen yogurt," "yogurt cereal bars," "yogurt smoothies" or "dried yogurt powders?" It is hoped that FDA will address this matter when responding to NYA's petition.

3. An acidity of pH 4.6 or lower, rather than the current requirement of titratable acidity expressed as lactic acid in yogurt.

It is recommended that the yogurt standard retain the current method of titratable acidity (TA) as the primary analytical method since TA is not impacted by varying buffering capacity in the yogurt (due to differences in milk solids). Because of differences in buffering capacity across different yogurt formulas, a given titratable acidity will result in different pH values for different yogurt samples. Additionally, titratable acidity is officially recognized by the Standard Methods for Examination of Dairy Products as valuable for measuring the extent of growth of acid producing bacteria in dairy products. Therefore, IDFA recommends that titratable acidity be specified as the primary method for analysis of acid content in yogurt. IDFA supports the use of pH as an in-process, secondary method for measurement of yogurt acidity provided that appropriate calibration to the primary method is performed for a given formula.

IDFA believes that a pH of 4.6 is too low 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 a level not less than 0.7% titratable acidity in the "white mass" before the addition of "optional ingredients" be set for yogurt. The slight reduction of the required level of titratable acidity from not less than 0.9% to 0.7% is needed to produce flavored yogurt product that meets consumer expectations of a delicate creamy and tart yogurt taste which is not too acidic or sour. Also the lower titratable acidity level, which produces a less tart product, may allow for products to be flavored with fewer additional sweeteners thus allowing formulation of healthier, lower sugar and lower calorie products.

4. The use of optional milk-derived ingredients after pasteurization and culturing of yogurt.

IDFA supports the NYA petition recommending that "the food" shall be pasteurized or ultra-pasteruized prior to the addition of the characterizing yogurt bacteria cultures. This will ensure that the standard dairy ingredients used to make yogurt are subject to heat treatment needed for food safety. MIF also supports the proposed change to allow any milk derived ingredients to be used for technical or functional purposes as this change is important to allow for the use new technologies of filtration and fractionation of milk components to be used as functional ingredients in yogurt. These optional ingredients may or may not be included in the pasteurization and culturing process depending on previous processing and the resultant safety of post-pasteurization addition.

5. The use of reconstituted dairy ingredients and WPC as basic dairy ingredients in yogurt, and the specifications related to WPC, when used.

IDFA agrees that reconstituted dairy ingredients and whey protein concentrate (WPC) and whey protein isolate (WPI) should be allowed as standard dairy ingredients for yogurt. As discussed in 1981, fluid milk 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. MIF agrees with the assertion that the basic dairy ingredients can include reconstituted milk ingredients without compromising yogurt's integrity.

In addition, 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. New membrane filtration processing technology allows for the concentration and isolation of whey protein components without excessive heating or chemical addition. As a result, whey proteins are highly valued for their nutritional value, functionality, and taste. Whey proteins are easily digestible, high-quality proteins with significant amounts of the important amino acids leucine, isoleucine, and valine. They are superior in nutritional value to soy protein and casein, providing 14% higher nutritional value.

6. The optional use of any milk derived ingredient that provides a technical or functional purpose in yogurt.

IDFA strongly supports the use of all types of optional milk derived ingredients for technical and functional purposes. Allowance of all types of safe and suitable dairy ingredients will provide for the use of new technologies such as milk protein fractions with specific technical and functional properties. This is important as food and dairy manufacturers are responding to today's obesity epidemic by formulating healthier foods and foods that have specific nutritional and health benefits. One example is that yogurt could be formulated by allowing the use of filtered milk that has water and lactose (milk sugar) removed to lower the sugar content and increase protein.

7. The minimum dairy ingredients content requirement of 51 percent of the total weight of yogurt.

The requirement of having a minimum dairy ingredient requirement of 51% is supported by IDFA. This is consistent with the new revision to the Codex standard for Fermented Milk Products. It is also consistent with consumer expectations that a dairy product such as yogurt would contain milk as the predominant ingredient.

8. The use of any safe and suitable nutritive or non-nutritive sweeteners in yogurt.

The yogurt standards should be updated to allow for the use of any safe and suitable nutritive and non-nutritive sweeteners. This change is important as yogurt should not be restricted from using the many innovative sweetener ingredients that are being developed for specialized purposes to reduce the sugar and calorie content of foods. Additionally, this change to allow yogurt to contain safe and suitable non-nutritive sweeteners will clarify that yogurt labels will not have to include the phrase "sweetened with _____" (the blank filled in with the common and usual name of the sweetener) to the products name in the principal display panel.

9. The use of safe and suitable emulsifiers in yogurt.

IDFA supports the change in the yogurt standards that would allow for safe and suitable emulsifiers. Emulsifiers are commonly used in dairy products and including provisions for the 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.

10. The use of safe and suitable preservatives in yogurt.

IDFA agrees that safe and suitable preservatives should be allowed in yogurt. In addition, we request that antimycotics also be added to the list of optional ingredients to combat yeast and mold, the most common cause of spoilage for cultured dairy foods. In 1981, FDA proposed excluding preservatives for use as optional ingredients in yogurt but, later stayed this provision pending a hearing, which has not yet occurred. Therefore, FDA has not taken enforcement action against the appropriate use of preservatives. However, we believe this change to codify the use of preservatives and antimycotics in yogurt is needed to provide manufacturers with the flexibility to produce yogurt products that meet consumer and retail demand.

11. The use of any safe and suitable ingredient added for a nutritional or functional purpose in yogurt.

The modifications suggested to the yogurt standards to allow for the use of any safe and suitable ingredients for a nutritional or functional purpose is strongly supported by IDFA. As yogurt manufactures strive to compete with other foods to produce healthy and nutritious products, they must have the same flexibility to use novel ingredients. Dairy products such as yogurt already provide consumers nutritious products rich in calcium, protein and 8 essential vitamins and minerals. But, as consumer demand grows for healthful products and foods with specialized nutrients, yogurt should also be able to use vitamins, minerals, and nutraceutical ingredients such as soy, lutine, and omega-3 fatty acids. Additionally, safe and suitable ingredients may be needed for a specific function in the yogurt, such as the incorporation of nitrogen with aeration equipment used to produce

yogurt that has a whipped light texture without the "off" flavors that could occur with whipping the product with air.

12. The use of the descriptor "nonfat" on a yogurt that may contain less than 0.5 g of total fat per RACC (i.e., 225 g for yogurt (21 CFR 101.12)).

As noted in our response to question one, IDFA supports the concept of having a single standard for yogurt and using the descriptor "nonfat" for yogurt that contains less than 0.5 grams of total fat per RACC or 225 gram serving. This approach aligns the yogurt labeling with other foods under the present NLEA requirements for nutrient content claims term. IDFA has in the past petitioned to align all dairy standards of identity with other food labeling requirements. In 1998, changes we made for most dairy products with the exception of yogurt. We continue to urge FDA to complete this task by finalizing the proposed changes to the yogurt standards.

13. The use of the descriptor "low fat" on a yogurt that may contain at least 0.5 g but not more than 3.0 g total fat per RACC.

As noted in our response to question one, IDFA supports the concept of having a single standard for yogurt and using the descriptor "low fat" for yogurt that contains at least 0.5 grams but not more that 3.0 grams of total fat per RACC or 225 gram serving. The yogurt industry realizes that this change will cause reformulation or relabeling of some products currently existing in the market that meet the current standard of identity for "low fat yogurt" (0.5 - 2 % milk fat before addition of bulky flavoring) but 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). However, there is agreement by MIF members that aligning the yogurt standards with other foods is needed to eliminate consumer confusion about the fat levels for yogurt that currently differ from other foods.

14. The need to amend the standard for cultured milk to provide for the alternate term "fermented milk" and to make it consistent with any changes made in the standard for yogurt, and the appropriateness of the proposed amendments to the standard for cultured milk.

IDFA members were not able to reach consensus on this matter and therefore have no comment.

15. The need for any functional ingredients categories in addition to the ones proposed in the petition.

As outlined in our response to question ten, IDFA believes that antimycotics should also be added to the list of optional ingredients as the most common form of spoilage for cultured dairy foods is yeast and mold. Allowing the use of antimycotics as a preservative

in yogurt is needed to provide manufacturers with flexibility to produce yogurt products that meet consumer and retail demands.

16. Comments on the need to amend fermented milk and cultured milk standards in light of consumer experience with these standards.

IDFA does not have any specific information on consumer expectations or experience with the fermented milk and cultured milk standards. However we feel that all of the changes recommended by IDFA will impact only the yogurt standard and will not affect these other dairy standards.

17. Comments on the appropriateness of omitting the provisions for labeling declaration of heat treated after culturing.

This matter is closely related to the issue that the yogurt standard requires a minimum of 10^7 CFU/g of live and active characterizing cultures at the time of manufacture of yogurt, and products not meeting the yogurt standard would be covered under the cultured milk standard. IDFA members were not to able reach consensus on whether the standards of identity should be changed to require a minimum level of live and active characterizing yogurt cultures at the time of manufacture. Therefore, no comment will be presented on this matter.

18. Acidity levels and the use of pH rather then acidity.

As presented in IDFA's response to question three, we recommend the acidity requirement be measured only by titratable acidity, not pH. Titratable acidity measurement is more commonly used by the dairy industry than pH. Additionally, titratable acidity is officially recognized by the Standard Methods for Examination of Dairy Products as valuable for measuring the extent of growth of acid producing bacteria in dairy products.

19. Whether the presence of live and active cultures is an essential characteristic of yogurt and, if so in what amounts.

IDFA members were not able to reach consensus on whether the presence of live and active cultures is an essential characteristic of yogurt. Therefore, no comment will be presented on this matter

20. The appropriateness of conducting tests to ensure the presence of live and active cultures thought the assigned shelf life.

IDFA will not provide comments on this matter as it is closely related to the requirement of a minimum level of live and active characterizing yogurt, a subject on which we were unable to reach consensus.

21. Whether the proposed standard of identity would adequately ensure the presence of live and active cultures throughout the shelf life of the product and at the point of purchase or consumption.

IDFA will not provide comments on this matter as it is closely related to the requirement of a minimum level of live and active characterizing yogurt, a subject on which we were unable to reach consensus.

22. Alternative provision that may be needed to fulfill the requirement of live and active cultures present at 10^7 CFU/g.

IDFA has no comment on this matter.

23. Comments on whether the yogurt industry is equipped to meet the nutritional equivalence requirement (130.10) for nonfat and low fat products.

IDFA believes that there are still challenges for the yogurt industry to meet FDA's nutritional equivalence requirement that requires minute amounts of vitamin A to be added to reduced fat products to ensure the food is nutritionally equivalent to a full fat product. There is a risk that improper over fortification of vitamin A could have a significant negative impact on public health and the safety of the finished food. The majority of the yogurt consumed in the US is low fat and nonfat varieties that for the past decade have not included additional amounts of vitamin A to restore the food to the nutritional equivalence of whole milk yogurt. IDFA recommends that yogurt be exempt from the requirements of nutritional equivalence under CFR 21 section 130.10.

24. The appropriateness of continuing to exempt yogurt from the nutritional equivalence requirement, unlike other standardized foods making lowfat and nonfat nutrient content claims.

IDFA agrees that it is appropriate to exempt yogurt from the nutritional equivalence requirements.

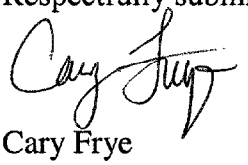
Conclusion:

IDFA and our members that manufacture yogurt agree that there is a need for updating the existing yogurt standard to permit the use of new ingredients and processing techniques, which will foster product development and provide greater benefits to the consumer. In general, IDFA members support the NYA petition which would establish a new yogurt standard to replace the currently existing three fragmented yogurt, lowfat yogurt and nonfat yogurt standards. The revised standard should 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.

We strongly urge FDA to move forward with the proposed rulemaking to modernize the standards of identity for yogurt. Just as IDFA had difficulty reaching consensus on some aspect of the changes, comments that FDA may receive from other organizations and consumers may not fully agree. Due to the formal rule making provisions that exist for dairy standards, this lack of full agreement could induce FDA to require a public hearing. IDFA realizes that a hearing would be a significant burden on FDA's already stretched staff. However, IDFA hopes that FDA will be able to publish those proposed changes in the standards where the industry is in agreement. IDFA feels that it is very important to provide the yogurt industry with a coherent set of provisions that accurately represent FDA's current enforcement policy.

Our staff looks forward to providing the Agency with more detailed and comprehensive information as may be required to act, and to answer any questions you may have.

Respectfully submitted,



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