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January 26, 2004

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

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

Re: Docket No. 00P-0685 Advanced Notice Of Proposed Rulemaking. Milk And Cream Products And Yogurt Products; Petition To Revoke Standards For Yogurt And To Amend Standards For Yogurt And Cultured Milk

Gentlemen:

These comments are submitted on behalf of Kraft Foods North America, Inc. (Kraft) in response to the Advanced Notice of Proposed Rulemaking to revoke the standards for nonfat yogurt and lowfat yogurt and to amend the standards for yogurt and cultured milk as published in the July 3, 2003 Federal Register (68 FR 39873). As a major manufacturer of yogurt and yogurt products under the BREYERS and JELL-O trademarks, Kraft is an interested party in the subject matter of the ANPR.

In these comments, Kraft will address the issues specifically raised by the agency in the advanced notice of proposed rulemaking Section III, paragraphs 1 through 14 and will refer as appropriate to the additional issues raised by the agency in its subsequent discussion numbered 1 through 5. Kraft's comments are based on the historical context of the existing standards that we view as being relatively flexible with regards to ingredients and composition. This flexibility has contributed in large part to the success and popularity of these nutritious dairy products by allowing the development of a variety of yogurt products appealing to people of all ages

The provisions of the current yogurt standards, taking into account the stayed provisions set out in 47 Fed Reg 41519 (Sept. 21, 1982), can be summarized in relevant part as follows:

- Basic ingredients include both fresh and reconstituted cream, milk, and skim or partially skimmed milk ingredients that may be combined with any other safe and suitable optional milk-derived ingredients. The use of the optional dairy ingredients is limited only by the requirement in paragraph (d) that the ratio of protein to total non fat milk solids and the protein efficiency ratio of all protein present not be decreased as a result of the addition of the paragraph (d) optional dairy ingredients. Under the current standards, both the basic (paragraph c) dairy ingredients and the optional dairy ingredients are added prior to culturing.

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- Yogurt must use the characterizing lactic acid producing bacterial cultures *Lactobacillus bulcaricus* and *Streptococcus thermophilus*; however, other cultures may be used in addition.

- Yogurt must contain not less than 8.25% milk solids not fat before the addition of bulky flavors.

- There is no current minimum lactic acid content requirement.

- Yogurt may be heat treated after culturing to extend shelf life. If heat-treated, yogurt must be labeled "heat treated after culturing" as part of the name of the food.

- Optional nondairy ingredients are limited to nutritive sweeteners, flavoring ingredients, color, stabilizers and preservatives. Non- nutritive sweeteners may be used if declared as part of the identity of the food, e.g., "Yogurt with Aspartame."
- Low fat yogurt must include a statement of percent milk fat as part of the name.

In the Final Rule adopting the current standards, a number of the provisions of the standards were stayed pending outcome of a hearing; however, a hearing was never conducted. Virtually every domestically produced yogurt utilizes ingredients by virtue of the stayed provisions including preservatives, reconstituted basic dairy ingredients and other milk derived ingredients such as Whey Protein Concentrate (WPC).

The following comments are responsive to the topics specifically requested by the agency.

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

Comment: Kraft agrees that it is appropriate to revoke the standards for nonfat and low-fat yogurt and to combine the three existing yogurt standards into a single standard for yogurt. Kraft also agrees that it is appropriate that use of the terms nonfat and lowfat on yogurts should be based on the total fat content of the products consistent with the provisions of NLEA. Kraft does not agree with the nomenclature provisions of the draft standard proposed by the National Yogurt Association that would mandate that yogurt that meets the NLEA definition of low fat or nonfat include those terms as part of the name of the product.

The impetus for a single standard is in part motivated by the agency's desire to ensure that defined nutrient content claims such as lowfat and nonfat are applied to yogurt in a manner consistent with the provisions of NLEA. In 1996, a number of dairy standards reflecting lower fat versions of full fat dairy products were revoked, the assumption being that the lower fat products could continue to be produced and labeled consistent with the provisions of section 130.10. However, in each category, the full fat version of the product was, if not the dominant, at least a significant portion of the category. Therefore,

the standards for the full fat versions were retained with defined minimum milkfat levels as characterizing requirements.

The situation with yogurt is significantly different. Full fat yogurt as defined in the current yogurt standard (21CFR 131.200) constitutes an insignificant portion of the domestic yogurt market. Even in 1977, when FDA first proposed definitions for yogurt and low fat yogurt, the commissioner expressed the concern "that there may not be an appreciable amount of 'yogurt' (i.e., containing 3.25% percent or more milkfat) sold in the marketplace today" to justify a full fat standard.[1] The preamble stated, "If an appreciable amount of 'yogurt' is not being sold, then a final regulation will be published in which the product defined in the proposed standard of identity for 'lowfat yogurt' will be renamed yogurt...".[2] Twenty years later, Stuart Pape, counsel for the petitioner, National Yogurt Association, in a letter to the agency regarding the final rule revoking the standards of identity for low fat dairy products other than yogurt, commented that lowfat and nonfat yogurts constituted 99% or more of all yogurts sold. Mr. Pape's observation that "lowfat and nonfat yogurt products are, in essence, all that is on the market" is substantially true today.[3]

Therefore, to accurately reflect the products produced and marketed in the US, "yogurt" should be defined with a minimum milk solids not fat content of 8.25%, but with no minimum total fat or milkfat content. There is no consumer interest or benefit and no basis in fact for requiring product labeled simply as "yogurt" to contain any specific level of fat as the petition would seem to require.

Kraft believes that there is no need to address fat nutrient descriptor labeling in the standard itself other than to permit the fat descriptor terms defined in 21 CFR 101.62 (b) (1) and (2) (i.e., nonfat and lowfat) to be used as part of the name of the food. As with any other food with no defined minimum fat content, processors should have the option as to whether and how they want to label the product as nonfat or lowfat. For example, on a specific product, a processor may want to put more or equal emphasis on the product being low calorie, or he may prefer to combine the two claims together as a separate label statement rather than as part of the statement of identity.

In addition, the reference in the nomenclature section of the NYA draft to "reduced fat yogurt" [paragraph (e)(1)(i)] seems to imply that anything that does not qualify for lowfat or nonfat labeling would be named "reduced fat yogurt". We suggest that when a product is already predominantly nonfat or lowfat, that labeling a higher fat product as "reduced fat", would not be appropriate.

2. A minimum of 10(7) CFU/g of live and active characterizing cultures at the time of manufacture of yogurt.

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[1] 46 FR 29919, 29920 (June 10, 1977)
[2] Ibid.
[3] Letter to F. Edward Scarbrough, Ph.D., Director, Office of Food Labeling, Office of Food Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, June 4, 1997.

Kraft does not agree that yogurt must contain live and active cultures to be characterized as 'yogurt", nor does it agree with the petitioner's contention that consumers expect a minimum live and active culture content of 10(6)/g or any other specified amount.

In 1981, after considering the numerous comments filed in response to the 1977 proposal on this issue, FDA rejected the proposition that yogurt must contain "abundant" live and active cultures to be characterized as yogurt.[4] The Agency also concluded that yogurt that has been heat treated after culturing to deactivate or reduce the microbial population in order to extend shelf life is sufficiently distinguished from traditional product by the mandatory label declaration "heat treated after culturing". Subsequently, in considering the objections filed in response to the final rule, FDA again rejected arguments that yogurt required active cultures and that the required labeling was insufficient, concluding that the objectors did not raise an issue of fact warranting a hearing.[5]

While the petitioners assert that consumers "expect" yogurt to contain live and active cultures, they appear to no longer contend that the label statement "heat treated after culturing" is insufficient to inform consumers of the absence of live cultures. In fact, the petition proposed to add the "heat treated after culturing" labeling requirement to the cultured milk standard for cultured milk products that have undergone heat treatment subsequent to culturing. Petitioners must therefore agree that consumers understand the message and can distinguish heat-treated product from product with live and active cultures.[6]

Petitioner has presented no evidence that consumers have any preconceived expectation regarding the bacterial content of yogurt. The fact that most processors that do not heat treat, including Kraft, elect to label their yogurt products as containing "live and active cultures" strongly suggests that many, if not the majority of, consumers would not be aware of this fact absent such a labeling statement.

In light of these common labeling practices, and in the absence of any evidence of consumer confusion regarding the presence or absence of live and active cultures in yogurts marketed today, there appears to be no need to now insert a minimum live culture requirement in the standard. The agency might consider whether there is a need for a minimum count requirement for products that are voluntarily labeled as containing live and active cultures, but since the standard itself does not require the statement, it would be more appropriate to address that issue in a compliance policy guide if the agency has information that consumers are being misled. However, Kraft is not aware of this being an issue in the yogurt industry, and the petition does not assert that yogurts are being misrepresented as containing abundant live and active cultures when they do not.

Even if one were to assume that the standard should designate a minimum level of active culture, a contention that the agency has rejected twice in the past, no criteria has been suggested to evaluate whether 10(6) /g is the appropriate level. The petitioner seems to be basing the figure on consumer expectation of "abundant " cultures, but presents

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[4] 46 FR 9924, 9931 (Jan. 30, 1981)
[5] 47 FR 41519, 41920-21 (Sept. 21, 1982)
[6] Kraft does not agree with the proposal to add the statement to the cultured milk standard, but does agree that the statement does communicate the absence of active cultures

no evidence, either historical or scientific, that either consumers or experts consider that number to be appropriate or even if it approximates the live and active culture content of yogurts produced and sold today.

It is particularly difficult to perceive how adding a minimum live and active culture requirement to the standard will add "flexibility to allow for use of new or future technological advances".[7] It would appear instead to be a major limitation to the development of both new technologies and new products.

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

Among the goals expressed in the petition is to promote flexibility, recognizing that "technology has advanced and industry practices have changed". The petition also states, "the yogurt standards do not contain enough flexibility to allow for use of new or future technological advances." However, in seeming contradiction to this statement, the petition not only seeks to impose the culture requirement discussed in 2 above, but also to specify a minimum acidity level. Although the current standard specifies a minimum acidity of 0.9% expressed as titratible acidity (TA), that provision was stayed. Therefore, the yogurt standards have never contained an enforceable minimum TA level. The petition cites a potential range of TA levels from 0.5% as originally proposed by the FDA, up to 1.5%, suggesting that 0.7% would be an appropriate minimum.[8] The range of acidity levels clearly suggests that yogurts do in fact vary considerably in tartness reflecting a wide range of consumer preferences. This is further supported by the fact that yogurt has achieved enormous popularity and has expanded into new forms and flavors under a standard that imposed no minimum acid level.

There is no reason to believe that either the industry or consumers would now be benefited by a standardization of this particular characteristic through the imposition of a minimum level where none has existed. While we agree that yogurt is in fact characterized by a tartness derived from the acid content, consumer preferences vary considerably as to the preferred degree of tartness. A number of new yogurts are being introduced in liquid and gelled forms with unique flavors that may appeal particularly to children that are not compatible with higher acidity levels. Therefore, while there is no demonstrated need for the imposition of a minimum titratible acidity level in the standard, if the agency elects to now adopt such a level, Kraft suggests that it be no higher than 0.5% as originally proposed in 1977.[9]

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

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

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[7] Petition, page 2

[8] Petitioner proposes to measure acidity as pH rather than TA, but suggests a maximum pH of 4.6% that Kraft believes more closely equates to .9%TA and not .7% as suggested in the petition.

[9] 42 FR 29919, 29920 (June 10, 1977)

In 1982, objectors to the proposed yogurt standards asserted that it did not promote honesty and fair dealing in the interest of consumers to specifically limit the permitted dairy ingredients to those listed in paragraph (c) in lieu of other safe, nutritious, and functional milk-derived ingredients as originally proposed. In light of these objections, FDA stayed the provision of the standard that restricted the optional milk ingredients to those specifically listed in the standard.[10] The FDA also stayed the provisions of paragraph (a) that would have excluded the use of reconstituted dairy ingredients as the basic ingredients of yogurt. As a result, for the last 20 years, the industry has been operating under a standard that has had no restriction with respect to the use of optional safe and suitable milk-derived ingredients other than the proviso "that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients."[11]

Kraft agrees with the petition to the extent that it supports the optional use of reconstituted dairy ingredients as well as any other safe and suitable milk-derived ingredient thereby reflecting the de facto status of the standards for the last 20 years. However, we oppose limiting the use of safe and suitable milk-derived ingredients as a portion of the basic dairy ingredients added prior to culturing solely to the single ingredient, WPC. This is a new restrictive recipe requirement not factually supported by the petition, the present standard, or common industry practice.

Kraft also disagrees with limiting use of WPC to WPC with 34% protein. Whey protein concentrate is defined in 21 CFR 1979c as containing a minimum protein content of 25%. The current standard provides sufficient assurance that the protein to total milk solids not fat ratio be maintained as well as the protein efficiency ratio of the protein present.

Accordingly, we urge the FDA to revise the proposal to eliminate the specific reference to WPC in paragraph (b), to revise the heading of paragraph (b) to read "Dairy ingredients" and to revise the first sentence of paragraph (b) to read as follows:

> (b) *Dairy ingredients.* Cream, milk.... etc.
> or the reconstituted versions of these dairy ingredients may be used alone or in combination. Other safe and suitable milk-derived ingredients may also be added: *provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients. When one or more of the ingredients specified in this paragraph is used, it shall be included in the culturing process.

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

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[10]47 FR 41519 The excluded ingredients specified in the preamble as examples were: partially delactosed skim milk, partially hydrolyzed whey, partially hydrolyzed skim milk, low sodium milks, casein, and caseinates.

[11]21 CFR 131.200(c)(1)

Kraft agrees that appropriate safe and suitable dairy ingredients may be added to yogurt subsequent to culturing for technical or functional purposes. Therefore, Kraft supports the retention of the safe and suitable dairy ingredient provision in paragraph (c)(1) as well as paragraph (b).

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

In 1982, in responding to one commenter's suggestion that flavoring ingredients be limited to 25% of the finished food, the agency stated that the limitation was unnecessary due to the cost of the flavoring ingredients and the organoleptic properties being self-limiting factors. We agree with that observation. We are not aware of products being sold today under the name "yogurt" that even begin to approach a non dairy content of 50%. FDA should also consider whether establishing a 51% minimum dairy content implies that yogurt may contain up to 49% non dairy ingredients and still be characterized as yogurt. It should also be pointed out that the 51% dairy requirement would not ensure a 51% yogurt mix content unless the dairy ingredients are required to be cultured. Some current products referred to as "Smoothies" that are combinations of yogurt and fluid milk contain in excess of 50% dairy but less than 50% yogurt.

8. **The use of any safe and suitable nutritive or nonnutritive sweeteners in yogurt.**

Kraft agrees that this is a reasonable addition to the yogurt standard. The use of artificial or nonnutritive sweeteners has been a common practice for over a decade for reduced calorie sweetened yogurts.

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

Kraft agrees that safe and suitable emulsifiers should be permitted as well as stabilizers. This could be particularly useful in nonfat products in order to achieve appropriate texture and mouth-feel.

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

By virtue of the stay, industry has been utilizing preservatives, primarily potassium sorbate, in yogurt for the last two decades. This use is in the best interest of consumers in that it extends useful storage life even under the varying conditions found in home refrigerator units.

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

Kraft agrees that it is appropriate to incorporate sufficient flexibility within the standard to provide for the future use of novel ingredients, packaging and processes developed through advances in technology that will enable the continued innovation that has made yogurt products so popular with today's consumers. The only functional category not specifically mentioned in the petition that would be useful would be buffering agents in the event that the agency decides to require an increased acidity level.

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

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

Earlier in these comments, Kraft supported establishing a single standard for yogurt with no required minimum fat content. Under a single standard as modified as Kraft has suggested, yogurts that meet the definitions of "low fat" and "nonfat" as established by FDA under NLEA, could at the option of the processor be labeled as "lowfat" or "non fat" or the permitted synonyms either as part of the name or as separate nutrient content descriptors.

It is important to note that under this definition, "yogurt" could not be represented as a "low" or "fat free food" since yogurt is permitted to contain variable levels of fat. In addition, qualification as low or non fat depends on total fat content of the product including any bulky flavoring ingredients and not just on the milkfat content of the white mix. Therefore, qualification of products for the nutrient content descriptors will be determined on a product-by-product basis and may vary by bulky flavor addition even if a common white mix is used as the yogurt base.

FDA has repeated its position in the 1996 deletion of several other low and non fat dairy product standards that if standard yogurt is modified under the provisions of 130.10 to qualify for the nutrient content claims "lowfat" and "nonfat", the products would be required to be fortified with vitamin A to be nutritionally equivalent to standard yogurt. However, if the standard for yogurt has no required minimum fat level, then no modification of "standard" yogurt is required and products labeled as "lowfat" and "nonfat" do not fall under the provisions of 130.10 and do not require fortification.

This result reflects the reality of the yogurt market. The vast majority of yogurt sold in this country has been low and non-fat yogurt; therefore, the vitamin A contribution to the diet has historically been that contributed by the low and non-fat products. This is in contrast to the other dairy products that were the subject of the 1996 revisions in which the full fat versions were the dominant categories and the reduced fat served as true substitutes with a lower Vitamin A content then the dominant full fat variety.

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.

The petitioner seeks to establish an "alternate standard of identity" for "yogurt-like products" i.e., yogurts that do not meet the live and active organism limits requested in the petition.[12] If the agency does not agree to require a specified minimum level of live and active cultures and to prohibit the heat treatment of yogurt after culturing, then the need to address the cultured milk standard is essentially eliminated. Even if limits are established, Kraft does not agree that it would be appropriate to amend the cultured milk

[12]Petition page 5

standard to include products that have never been considered by the industry or the consuming public to be "cultured milk".

Unlike the yogurt standards that under the stay permit the use of reconstituted dairy ingredients as the basic ingredients in the manufacture of yogurt, the cultured milk standard defines products that are made from "fresh" fluid milk ingredients. Therefore, the cultured milks that are familiar to American consumers such as buttermilk, and to a lesser extent, acidophilus cultured milk and kefir cultured milk, are liquid products with fat and solids contents similar to liquid milk. The petition does not address the consumer confusion that might occur from the identification of semisolid yogurt type products with a name that has long been associated with fresh fluid cultured milk products. FDA should reject the suggestion that yogurts no longer qualifying as "yogurt" under an amended standard be labeled as "cultured milk".

Conclusion: Kraft supports the objective of amending the current yogurt standards by combining the current three standards into a single standard with no minimum fat or milkfat content requirement. Kraft also agrees that to the extent that yogurt is described as lowfat or nonfat, those terms should be consistent with the definitions under NLEA. As noted above, Kraft opposes the revisions proposed by the NYA that would require and quantify the presence of live and active cultures, but would support the suggested revisions that would in effect codify the stayed portions of the existing standards and permit the use of safe and suitable functional ingredients.

If you have any questions regarding these comments please contact the undersigned. Thank you for this opportunity to comment.

Respectfully Submitted,
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