CORNUCOPIA
INSTITUTE

**October 22, 2014**

TO: FDA Commissioner Margaret Hamburg
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: Yogurt Standard of Identity

Dear Commissioner Hamburg,

It appears that a number of yogurt and Greek yogurt products are not legally complying with the standard of identity set forth in Sec. 131.200 of FDA regulations governing milk and cream.

We formally request an investigation into the legality of using the following food ingredients in products labeled "yogurt."

- Tricalcium phosphate is added to some yogurt brands to boost the calcium content (some sources also allege that it is added as a preservative). Yet the FDA standard of identity for yogurt does not allow the addition of calcium. It appears the FDA standard does not allow any added nutrients to yogurt other than vitamins A and D.

- Milk protein concentrate (MPC) does not meet the GRAS requirement on the larger FDA list of additives: Everything Added to Food in the United States (EAFUS). This is of concern because MPCs do not necessarily come from Grade A facilities and have no standard of identity. It is not clear whether MPCs meet the standard of identity in yogurt as well.

  What is the current GRAS status of milk protein concentrate? Based on our research, MPC does not appear to have successfully garnered GRAS recognition.

- United States imports of MPCs have doubled in the last five years, mostly coming from New Zealand. This $250 million worth of milk protein is taking over the market share long held by American dairy producers and is driving down the price of domestically produced dairy, squeezing many U.S. dairy farmers out of business.

- Import statistics, over the past 15 years, show that processors are outsourcing their dairy protein needs to foreign producers of cheap MPCs, leaving domestic dairy farmers with excess nonfat dry milk.

- There are no FDA standards for what constitutes Greek yogurt, and the use of MPCs might well constitute deception in terms of consumer expectations regarding the product.

Class-action lawsuits have been brought on behalf of plaintiffs alleging deception in yogurt labeling. (The several following paragraphs draw on this legal analysis, courtesy of Fuerstlaw.) [Actual link removed by request of Fuerstlaw.]

Because many products allegedly do not conform to the standard of identity for yogurt, the products are misbranded in violation of state law and the Federal Food, Drug and Cosmetics Act ("FDCA").

The standard of identity for yogurt, nonfat yogurt and low fat yogurt are defined in 21 C.F.R. 131.200, 21 C.F.R. 131.203 and 21 C.F.R. 131.206, respectively. MPC is not expressly listed or described as a permitted ingredient in the applicable standards of identity for yogurt.

Pursuant to Section 403(g)(1) of the FDCA, a food product is misbranded if: (i) it does not conform with the applicable standard of identity; or (ii) its label does not bear the name of the food specified in the definition and standard. 21 U.S.C. § 343(g). Moreover, courts have held that foods which purport to be standardized products, but contain ingredients not recognized in the standard of identity, are misbranded even if the label accurately describes the product's ingredients. See *Libby, McNeill & Libby v. United States,* 148 F.2d 71 (2d Cir. 1945) (affirming *United States v. 306 Cases Containing Sandford Tomato Catsup With Preservative*, 55 F. Supp. 725 (E.D.N.Y. 1944)).

The use of MPC and the other aforementioned materials as ingredients in these products renders the products misbranded pursuant to the FDCA, 21 U.S.C. § 343, because the products are represented as yogurt for which the standard of identity had been prescribed by regulation and the use of MPC in these products does not conform to the standards.

Significantly, manufacturers whose products are deemed by the FDA to be misbranded are subject to enforcement action. Enforcement actions can include the issuance of Warning Letters, injunctions or criminal penalties, 21 U.S.C §§ 332, 333. Previously, the FDA has warned dairy food product manufacturers that when MPC is not listed as an optional dairy ingredient in products governed by a standard of identity, the use of MPC is not permitted and would render the product misbranded.

FDA Warning Letters notify recipients and the public that the FDA believes that a particular firm has violated federal law. Thus, given the bad publicity that these letters generate, it is advantageous for firms to correct possible violations as quickly as

possible. The recipients of Warning Letters typically have 15 days to address the issues presented by the Warning Letter and to develop specific corrective actions. Failure to do so may put the recipient in jeopardy of facing product seizures or formal legal action by the FDA.

Notably, on December 10, 2012, Judge Susan Richard Nelson of the U.S. District Court in Minnesota dismissed the General Mills Yoplait Greek yogurt lawsuit. In the ruling, Judge Nelson invoked the doctrine of primary jurisdiction, concluding that the FDA was best suited to handle the dispute. Under the doctrine of primary jurisdiction, a court has discretion to retain jurisdiction or stay litigation and refer issues that fall within the special competence of an administrative agency to that agency for its decision. See *Access Telecomms. v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998). Courts generally apply the doctrine to promote uniformity and consistency within the particular field of regulation. Here, the Court determined that the underlying issue is whether MPC is a proper, permitted ingredient in yogurt as governed by the standard of identity for yogurt, and the resolution of this question falls squarely within the competence and expertise of the FDA, pursuant to the authority granted to the Agency by Congress. See 21 U.S.C. §§ 301, et seq.

We respectfully ask you to expeditiously investigate the merits of our complaint and to conclusively determine whether or not these materials are legally being used in the manufacture of products labeled as yogurt.

Sincerely yours,

Will Fantle
Research Director
The Cornucopia Institute

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2014]
[CITE: 21CFR131.200]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

PART 131 -- MILK AND CREAM

Subpart B--Requirements for Specific Standardized Milk and Cream

Sec. 131.200 Yogurt.

(a) *Description.* Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of current good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) 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 this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(e) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) 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."

(2) Milk solids not fat content--Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I--Official Final Action," under the heading "Total Solids."

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

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

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

(i) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavor.

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

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

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

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the

label as required by the applicable sections of parts 101 and 130 of this chapter.

[46 FR 9939, Jan. 30, 1981, as amended at 47 FR 11825, Mar. 19, 1982; 47 FR 41524, Sept. 21, 1982; 48 FR 24869, June 3, 1983; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

References:

Code of Federal Regulations (CFR) Title 21. 131.200-Yogurt. Accessed July 2014 at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=131.200

Government Accountability Office. "Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk." March 2001

Harmonized Tariff Schedule of the United States. 2009 at Chapter 4, Note 13

Durant, John. Commercial Ruling Division of MPC for United States International Trade Commission Rulings And Harmonized Tariff Schedule. Ruling made on April 5, 2002 at CAL-2 RR:CR:GC 965396ptl.

USDA, Foreign Agriculture Service, trade database available at www.fas.usda.gov/ustrade

Government Accountability Office. "Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk." March 2001.

United States Food and Drug Administration. "FY 2009 Congressional Justification." February 5, 2008 at Foods 21.

United States Food and Drug Administration, database of GRAS available at http://www.foodsafety.gov/~rdb/opa-gras.html

Center for Food Safety and Applied Nutrition, Food and Drug Administration. Notices. "GRAS Notice No. GRN 000167." September 29, 2005.

United States Food and Drug Administration, database of GRAS available at http://www.foodsafety.gov/~rdb/opa-gras.html

United States Food and Drug Administration, database of EAFUS available at http://www.cfsan.fda.gov/~dms/eafus.html

Government Accountability Office. "Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk." March 2001.

Government Accountability Office. "Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk." March 2001.

USDA, Foreign Agriculture Service, trade database available at www.fas.usda.gov/ustrade

USDA, Foreign Agriculture Service, trade database available at www.fas.usda.gov/ustrade

Martin, Andrew. "As recession deepens, so does surplus." *New York Times*. January 1, 2009.

Fuerst Ittleman David & Joseph Law blog. 2013. Class action lawsuits attack yogurt products for nonconformance with standards of identity. Accessed 2014 at http://www.fuerstlaw.com/wp/index.php/03/class-action-lawsuitsattack-yogurt-products/