

Citizen Petition 0486 '03 JAN 31 P1:34

January 27, 2003

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1061, 5630 Fishers Lane
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition, on behalf of Bunker Hill Cheese Co., Inc., under section 401 of the Federal Food Drug and Cosmetic Act and under FDA administrative procedures defined in 21CFR10.30. The undersigned request the FDA to grant an exemption to Section 403 (i) of the FFDCA to the requestor for the use of a common name on future product labeling.

A. Action Requested

Bunker Hill Cheese Co., Inc. requests United States Department of Health and Human Services, CFSAN and the Commissioner of Food and Drugs to grant an exemption of Section 403 (i)(1) to Bunker Hill Cheese Co., Inc. for the application of name "yogurt cheese" as a common or usual name to semi-soft part-skim cheese manufactured using *Lactobacillus bulgaricus* and *Streptococcus thermophilus* live and active cultures characteristic of yogurt as defined under 21CFR131.200. Under the proposal, permission would be granted to include text "Yogurt Cheese" on product labeling applied to the packaged food product and would be printed in text following "Semi-Soft Part-skim" thus comprising a portion of the recognized standard of identity in harmony with 21CFR133.188 (e)(1).

B.1. Statement of Grounds

The current array of cheese standards have not been updated consistent with changes in the cheese industry or the appearance of modern cheese varieties. This is especially true in regards to varieties surfacing with the emergence of the United States specialty cheese market, a market common to Europe for greater than 30 years. The limited breadth of nomenclature approved in current cheese standards do not allow flexibility for assigning common or usual names to modern cheeses.

21CFR101.3(b)(2) stipulates that the statement of identity comprising the principle display panel of a food package shall bear the common or usual name of the food. The limited breadth of current cheese standards do not recognize the term "yogurt cheese" as a common or usual name, therefore use of the name "yogurt cheese" creates misbranding.

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Yogurt cheese is a generally recognized common name in European Union countries. Yogurt cheese is a commonly recognized product in the specialty cheese market throughout Europe with varieties originating in France, Switzerland, and the Balkan region. Yogurt cheese is recognized as a common name in Canada. The Canadian government sets quotas for product imports and has a recognized quota for yogurt cheese which is met in full annually. Yogurt cheese is approved by the Canadian Federal Food Agency as a registered non-EU import cheese. Exclusion of yogurt cheese from the United States would force other countries seeking yogurt cheese to source from EU markets. Failure to recognize yogurt cheese as a unique product identity would result in generic classification and its confusion with other semi-soft part skim cheese products. This would create a disadvantage for U.S. manufacturers in the specialty cheese market against European manufacturers who use the yogurt cheese common name.

Yogurt cheese has been recognized by credible experts in the United States for 30 years. This array of experts includes the government of the United States and world renowned experts in the specialty cheese industry and academia. Frank Kosikowski, Professor of Food Science, Cornell University, described the manufacture of commercial yogurt cheese in his text *Cheese and Fermented Foods*, Brooktondale, N.Y., 1982-1997. The common name "yogurt cheese" is used to describe the product. The United States Department of Agriculture also recognizes "yogurt cheese" as a common name for the product described manufactured using yogurt cultures as performed by Bunker Hill Cheese Co., Inc. from 1999 to present. Yogurt cheese made with the special bacterial starter cultures used in preparing yogurt is described in the Agriculture Handbook (Agriculture Handbook, U.S. Department of Agriculture, *Cheeses of the World*, by The U.S. Department of Agriculture, Dover Publications, Inc., New York, 1972).

"Yogurt Cheese" should be accepted by the Commissioner as a common or usual name for the statement of identity of the commodity because it conforms with the spirit of 21CFR101.18 in that the name "yogurt cheese" bears a common recognition by the public as a standard identifier for the product. The name "yogurt cheese" has been so long and exclusively used by the manufacturer, Bunker Hill Cheese Co., Inc., and their distributors, that it is generally understood by the consumer to mean the said product.

Yogurt cheese has been commercially produced by Bunker Hill Cheese Co., Inc. for 30 years beginning in 1972. Yogurt cheese was initially made with yogurt as culture. Yogurt used for culture starter was produced in an enclosed make vat by inoculation of pasteurized milk with *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, live active cultures characteristic of yogurt. The inoculation was performed by inserting a single can of frozen Redi-Set culture into the vat of milk at the correct temperature. The set would ferment and build acidity for 12 to 14 hours yielding a titrateable acidity greater than 0.90 and resulting in yogurt as defined by 21CFR131.200. A 10 to 15 gallon portion of the yogurt was transferred to the make vat as a starter culture for yogurt cheese manufacture. This was the general practice from 1972 to 1999. Other types of semi-soft part-skim cheeses are produced by the subjection of milk to non-yogurt harmless lactic acid producing bacteria. Yogurt cheese is cultured from uniquely different sets of

harmless lactic acid producing bacteria just as those used in yogurt, hence the name *Yogurt Cheese*.

Growth rate curves and lactic acid production varied with each vat, over time, and according to seasonal climate. The length of time required to produce a vat varied with the amount of time necessary to reach the total lactic acid bacteria load needed to produce curds. Variance resulted in significant variation of end product quality. Advances in science have led to improvements in the manufacture of commercial yogurt cultures. Modern yogurt cheese cultures are grown by the manufacturer and cryogenically frozen in pellet form and filled into hermetically sealed containers. The frozen pellets are a concentrated form of the starter which can be added directly to the make vat and is appropriately named Direct Vat Set culture. In 1999, Bunker Hill Cheese Co., Inc. converted to use of Direct Vat Set for the production of yogurt cheese. No other changes were made. The switch resulted in an improvement to food safety through the elimination of contamination risk caused by yogurt production and transfer steps at the cheese factory. Additional improvements to product quality were netted by the elimination of the yogurt culture inconsistencies mentioned.

In all aspects, the yogurt cheese end product produced from 1999 onward is unchanged from yogurt cheese produced from 1972 to 1999. A safer and more uniform quality product can now be made quicker, however a legal issue with misbranding is created. Exemption is requested to allow BHC to move forward with production of the equivalent product under advanced technology while retaining the recognized name in labeling.

Be it further stated that loss of the distinct recognition of “yogurt cheese” as a standard identifier renders the product labeled only as “Semi-soft Part-skim Cheese” thusly resulting in two distinctly different classifications of product sharing one common name. Use of one name applied to two product types would create confusion for the general public. People in the general public expecting to purchase yogurt cheese may indeed purchase “Semi-soft Part-skim” and those desiring “Semi-soft Part-skim” inadvertently may purchase yogurt cheese without clear distinction between products. Acceptance of “Semi-soft Part-skim Yogurt Cheese” as a common and usual name will eliminate the issue.

The market significance of the name “yogurt cheese” is generally understood by the consumer to connote a particular class, kind, type, or style of food and therefore meets the spirit of conformity as would the name “Swiss Cheese” applied to an emmental style cheese made in the USA outside of Switzerland. By this reasoning, acceptance of “yogurt cheese” as a common or usual name via the granting of the proposed exemption is consistent with the spirit of the regulation as stated in 21CFR101.18 (c)(4).

Given the justification, Bunker Hill Cheese Co., Inc. requests the name “Yogurt Cheese” be granted recognition as a common or usual name for the product meeting the description provided. Use of the common name “Yogurt Cheese” carries global recognition and meets the spirit of 21CFR101.3 and 102.5 in like manner as the common name “Swiss Cheese” meets the spirit of the law for a distinct product despite

manufacture outside of Switzerland. The common name "Yogurt Cheese" meets the spirit of 21CFR101.3 in that it is not intentionally misdescriptive, or misleading of the general public being the name commonly used by the public for such food.

B.2. Conformity Steps

The proposed common name would become a part of the statement of identity and shall be presented in bold type on the principle display panel in a size reasonably related to the most prominently printed matter and shall read in lines parallel to the base of the package in the spirit of 21CFR101.3(d). Under the proposal, labeling compliance to 21CFR101.3(a) will be accomplished by inclusion of the identity label "Semi-soft Part-skim Yogurt Cheese" on the principle display panel of the food package.

B.3. Negative Aspects of Petition Approval

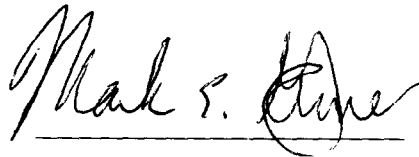
Approval of the petition could cast light on the need for review and update of current cheese standards as defined in 21CFR133. Elimination of enforcement against other current manufacturers of yogurt cheese would conserve FDA resources, but would penalize Bunker Hill Cheese Co., Inc. who has already spent resources on compliance. In the absence of approval, Bunker Hill Cheese Co., Inc. would be forced to file a complaint against other yogurt cheese manufacturers to impose enforcement.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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