

# SOYFOODS

ASSOCIATION OF AMERICA

STANDARDS COMMITTEE

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U.S. Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, Maryland 20857

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CITIZEN PETITION

The undersigned submits this petition under sections 403(i)(1) and 701(a) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 343(i)(1) and 371(a), and 21 C.F.R. § 10.30 and Part 102, to request the Commissioner of Food and Drugs to issue a "common or usual name regulation" in Part 102 of the U.S. Food and Drug Administration ("FDA") regulations to recognize the term "soymilk" as the established common or usual name to be used in labels and other labeling to identify a beverage of this nature (together with other refinements as described more fully below in this petition).

A. ACTION REQUESTED

The undersigned requests the Commissioner to issue a new regulation, to be included in Part 102 of the FDA's regulations, "Common or Usual Name for Nonstandardized Foods," Subpart B, "Requirements for Specific Nonstandardized Foods," to read as follows:

§ 102. Soymilk

(a) The common or usual name of the liquid food that is obtained as a result of combining aqueous-extracted whole soybean solids and water, or, as a result of combining other edible-quality soy protein solids, soybean oil, and water, is "soymilk."

(b) Heat treatment is applied to inactivate trypsin inhibitors and to ensure safety by adequate pasteurization.

(c) Vegetable oils, sweeteners, salt, seasonings, and/or other functional or flavoring ingredients may be added to soymilk.

(d) A product labeled without modification as "soymilk" shall contain not less than 3.0% soy protein, not less than 1.0% soybean fat, and not less than 7.0% total solids.

(e) A product labeled as a "soymilk drink" shall be a beverage that does not meet the requirements of paragraph (d) but that contains not less than 1.5% soy protein, not less than 0.5% soybean fat, and not less than 3.9% total solids.

(f) A product labeled as a "soymilk powder" shall be obtained by removal of water from liquid soymilk, or by the blending of edible-quality soy protein and soybean oil powders. Soymilk powder shall contain not less than 38.0% soy protein, not less than 13.0% soy fat, and not less than 90% total solids.

(g) "Soymilk concentrate" is the product obtained by modifying the level of water in soymilk so that the product shall contain not less than 6.0% soy protein, not less than 2.0% soy fat, and not less than 14.0% total solids.

#### B. STATEMENT OF GROUNDS

The Soyfoods Association of America believes there is a need for FDA to recognize and establish by regulation standard terminology for soymilk products sold in the United States today.<sup>1/</sup>

The present American-English terms "soymilk," "soy milk," and "soybean milk" have all been used to describe the liquid food derived from the cooking and processing of whole soybeans with water.

The earliest known use of the present word "soymilk," spelled as one word, was by Dr. Harry W. Miller and Dr. C. Jean

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<sup>1/</sup> A list of the members of the Board of Directors of the Soyfoods Association of America and of the Soymilk Standard Committee of the Association as of January 1, 1997 is enclosed. Attachment A.

Wen in 1936. It appears in a scientific journal article titled, "Experimental Nutrition Studies of Soymilk in Human Nutrition."<sup>2/</sup>

In 1947, the American Soybean Association ("ASA"), then located in Hudson, Iowa, published the first edition of its Soybean Blue Book. This directory of soy products and processors listed seven companies in the United States as "manufacturers and handlers" under the category of "soy milk."<sup>3/</sup> Later, beginning in 1980, the ASA's Soya Bluebook (updated title) described such products as "soymilk," in one word, or as "soy milk," in two words, under the broader category heading of "soy beverages."<sup>4/</sup>

The United States Department of Agriculture ("USDA") in the 1963 edition of its Agriculture Handbook No. 8 (approved for reprinting in 1975), provided compositional characteristics of "soybean milk," in both fluid and powder form. The fluid "soybean milk" listed contained 3.4% protein, 1.5% fat, 2.2% total carbohydrates and 0.5% ash.<sup>5/</sup>

In addition, in its "Home and Garden Bulletin No. 208," printed in 1977, the USDA listed the nutritive values of various soyfood products including "soymilk." Then in 1986, as part of its program to revise Agriculture Handbook No. 8, USDA published the Agriculture Handbook No. 8-16 -- Composition of Foods: Legumes and Legume Products. This USDA publication discusses the commercial production of "soy milk" in the United States.<sup>6/</sup> A page of nutritional information under the title "SOY MILK, Fluid"

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- 2/ Chinese Medical Journal, 50:450-459 (1936). Copy enclosed. Attachment B.
  - 3/ Soybean Blue Book, 1947. American Soybean Association, Hudson, Iowa, page 72. Copy enclosed. Attachment C.
  - 4/ Soya Bluebook, 1980. American Soybean Association, St. Louis, Missouri, pages 50-51. Copy enclosed. Attachment D.
  - 5/ Agriculture Handbook No. 8 -- Composition of Foods: Raw, Processed, Prepared. Revised December 1963, approved for reprinting October 1975. USDA, Washington, D.C., pages 58-59. Copy enclosed. Attachment E.
  - 6/ Agriculture Handbook No. 8-16 -- Composition of Foods: Legumes and Legume Products. Revised December 1986. USDA, Washington, D.C., page 9. Copy enclosed. Attachment F.

is provided. The product is described as containing 2.75% protein, 1.91% fat, 1.81% carbohydrates and 0.27% ash.<sup>7/</sup>

Although no compositional standard for soymilk currently exists in Canada, a March 21, 1984 memorandum from the Government of Canada to its regional food specialists states:

At a recent meeting with Agriculture Canada, it was agreed that the term "soymilk" would be the acceptable designation for the aqueous extract of soybeans used in the manufacturing of TOFU. This decision was based on a review of the research literature where the term "soymilk" has been in use for 60 years or more. It can therefore be argued, as in the case of cocoanut milk, that the common name "soymilk" is well established within this particular trade, thus barring any objection from the dairy industry.

The document, after showing a brief flow chart of a "soymilk" processing method, adds:

Please be advised that we will be recommending the use of this name and of its French equivalent "jus de soya" (MAPAQ) for labelling purposes. For the sake of uniformity, we would appreciate your doing likewise.<sup>8/</sup>

According to data searches in SoyaScan, a computerized bibliographic database on soybean products and research maintained by the Soyfoods Center in Lafayette, California, the word "soymilk" was used in the title of English-language periodicals, conference papers, or book chapters, at least nine times during the 1960s, 31 times during the 1970s, and 84 times during the 1980s. In 1983, "soymilk" appeared for the first time

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7/ Agriculture Handbook No. 8-16 -- Composition of Foods: Legumes and Legume Products. Revised December 1986. USDA, Washington, D.C., page 141. Copy enclosed. Attachment G.

8/ Government of Canada Memorandum No. G7138-1, March 21, 1984, to Regional Food Specialists, from Johanne B. Robert-Stolow, Manufactured Food Division, Consumer Products Branch, Hull, Quebec, Canada. Copy enclosed. Attachment H.

in the title of a U.S. Patent (No. 4,409,256, titled "Soymilk Process").<sup>2/</sup>

The Soyfoods Association of America believes that the word "soymilk," written as one word, has come to be widely used, recognized, and accepted to describe this particular type of food, and that this term now should be officially recognized by FDA as the correct name for the product.

FDA regulations recognize that "[a] common or usual name of a food may be established by common usage . . . ,"<sup>10/</sup> and the Soyfoods Association of America believes that, as shown above, through common usage the term "soymilk" has become the correct "common or usual name" of this product. We request FDA to recognize the appropriateness of this usage by issuing a regulation of the type set forth above in section A. of this petition.

In 1996, after several years of broad-ranging consideration, the Soyfoods Association of America adopted a series of voluntary industry standards for "soymilk" products. "Voluntary Standards for the Composition and Labeling of Soymilk in the United States," Soyfoods Association of America (March 1996) ("Soymilk Standards").<sup>11/</sup> The research assembled and the nomenclature practice documented in the course of developing the Soymilk Standards provide the basis for the details of the common or usual name regulation proposed above, details which are drawn directly from the final consensus standards. Accordingly, we enclose a copy of the Soymilk Standards and incorporate them by reference as a part of this petition. Indeed, we believe these Soymilk Standards are themselves a notable new event that

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<sup>2/</sup> Statement dated October 3, 1993, by Bill Shurtleff, Director and Head Librarian, Soyfoods Center, Lafayette, California. Copy enclosed. Attachment I.

<sup>10/</sup> 21 C.F.R. § 102.5(d). We understand that soymilk manufacturers and distributors in the United States may sometimes have been advised in the past by FDA personnel to use the term "soy beverage" or "soy drink" (for which no standard or definition exists) on their packaging or promotional materials. The Soyfoods Association of America believes that, as shown above in this Citizen Petition, those generic terms are not consistent with historical precedents comprising more than 50 years of usage of the term "soymilk," including use of the "soymilk" term by the USDA and the Government of Canada.

<sup>11/</sup> Copy enclosed. Attachment J.

provides additional proof that the term "soymilk" has in fact become established as the term used by both consumers and industry to identify this type of product.

In closing, we note that if, for any reason, FDA would prefer at this time to proceed with a common or usual name regulation that would contain less than all of the text proposed above in section A. of this petition, the Soyfoods Association of America would be agreeable to a proposal that would include only paragraphs (a) and (c), although we believe the enclosed Soymilk Standards provide a reasonable basis for the entire proposal set forth above, and we would prefer the entire proposed text.

C. ENVIRONMENTAL IMPACT

We hereby claim a categorical exclusion from the need to prepare an environmental assessment in support of this citizen petition, pursuant to 21 C.F.R. § 25.24(a)(11), which concerns the establishment by regulation of labeling requirements.

D. ECONOMIC IMPACT

An economic impact assessment is required under FDA's regulations, 21 C.F.R. § 10.30(b)(D), only when requested by the Commissioner following review of a petition. No such request has been made in this case (and we would not expect that one would be needed).

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 the only data and information known to the petitioner that are unfavorable to the petition (see footnote 9).

Respectfully submitted,

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