

MEMORANDUM

From: Joseph A. Levitt
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Date: October 3, 2018

Re: FDA Issues Request for Information Regarding Use of Names of Dairy Foods in the Labeling of Plant-Based Products

The Food and Drug Administration (“FDA” or “the agency”) recently issued a request for information (RFI) on the use of the names of dairy foods in the labeling of plant-based products. ^{1/} This action arose from the agency’s Nutrition Innovation Strategy, one tenet of which is a focus on modernizing food standards. During Commissioner Gottlieb’s remarks at the Nutrition Innovation Strategy public meeting, he stated that requests for the agency to take a closer look at the dairy standards of identity is one of many reasons why FDA is interested in modernizing the food standards, and that this would be the first area in which FDA is going to have an active public process for reviewing the standards and how consumers understand the use of terms like “milk” on both animal-derived and plant-based products. ^{2/} This RFI aims to gather information on how consumers use plant-based products and how consumers understand the use of dairy terms, such as “milk,” or “yogurt” when they appear on the labels of plant-based products, as well as the nutritional attributes of these products and how these products can help consumers meet the recommendations in the *Dietary Guidelines for Americans*.

The RFI requests comments, as well as data and other evidence, on many issues, grouped into five general categories with specific questions in each category. FDA requests that comments reference the question by letter and number to associate responses with specific questions. Below is the full list of questions on which FDA is seeking information:

A. The Current Market Conditions and Labeling Costs of Plant-Based Products

1. How many different types of plant-based products that are manufactured to resemble dairy foods such as, for example, milk, cultured milk, yogurt, and cheese, are on the market? Please provide any data or evidence to support your answer.

^{1/} Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, 83 Fed. Reg. 49103 (Sept. 28, 2018).

^{2/} Remarks by Dr. Gottlieb at the Public Meeting on FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy, July 26, 2018, *available at* <https://www.fda.gov/NewsEvents/Speeches/ucm614842.htm>.

2. What percentage of each subclass (e.g., soy or almond) of plant-based products is marketed as a substitute for its dairy counterpart (e.g., milk, cultured milk, yogurt, or cheese)? What percentages of each subclass of plant-based products are marketed with names that include the name of a dairy food (e.g., “milk”) versus names that include another term (e.g., “beverage” or “drink”)? Please provide any data or evidence to support your answer.
3. What are the costs associated with label changes? How often are labels revised?
4. How are plant-based products displayed in stores? For example, are they sold in grocery stores next to or mixed with their dairy counterparts or are they sold in areas of the store that are separate or distinct from the areas where their dairy counterparts are sold? Does the packaging or display of these plant-based products affect consumers' perception or expectation about the nutritional properties or performance of these products?

B. Consumer Understanding, Perception, Purchase, and Consumption of Plant-Based Products, Particularly Those Manufactured to Resemble Dairy Foods Such as, for Example, Milk, Cultured Milk, Yogurt, and Cheese

1. Why do consumers purchase and consume these types of plant-based products? How do they use these products? Specifically, do consumers purchase these plant-based products for use as substitutes for their dairy counterparts, or do consumers purchase these plant-based products for distinct uses? If consumers use these plant-based products as substitutes for dairy foods (for example plant-based beverages as alternatives to milk), what are their reasons? Do consumers think they are healthier, and if so, why? Are consumers purchasing these plant-based products because they may be allergic to dairy or are lactose-intolerant? Are consumers purchasing these plant-based products for reasons related to their personal consumption habits, such as a vegan diet? If consumers do not use these plant-based products as substitutes for dairy foods, what are their reasons for choosing these products? (For example, do these products provide unique taste, flavor, or texture?) Does consumer purchasing behavior differ if the consumer is purchasing the product for himself/herself as opposed to purchasing the product for a family member? Please provide any data or evidence to support your answer.
2. Do consumers perceive these plant-based products to be more nutritious, as nutritious, or less nutritious than their dairy counterparts? If consumers perceive these plant-based products to be more nutritious or as nutritious as their dairy counterparts, to what extent does this affect their decision to buy plant-based products? Please provide any data or evidence to support your answer.
3. Do consumers perceive or expect these plant-based products to perform in the same manner as their dairy counterparts? For example, milk can be an ingredient in preparing other foods. Do consumers expect plant-based beverage products to perform in the same manner as milk when preparing other foods or in recipes that use milk? Please provide any data or evidence to support your answer.
4. How do consumers perceive or understand labeling of these plant-based products? For example, do consumers perceive the labeling as suggesting that these plant-based products are equivalent to or can be substituted for their dairy counterparts? Do consumers perceive

the labeling as suggesting that plant-based products are different or distinct from their dairy counterparts? Please provide any data or evidence to support your answer.

5. We are aware that some plant-based beverage manufacturers use the term “milk” as part of the name of these foods while other manufacturers use terms such as “beverage” or “drink” as part of the name of these foods. Do consumers perceive plant-based beverages to be different if the term “milk” is used instead of “beverage” or “drink”? For example, how do consumers perceive or understand “soy milk” in comparison to “soy-based beverage” or “soy drink”? Please provide any data or evidence to support your answer.

C. Consumer Understanding Regarding the Basic Nature, Characteristics, and Properties of Plant-Based Products

1. What do consumers believe to be the basic nature, characteristics, or properties of plant-based products manufactured to resemble dairy foods such as, for example, milk, cultured milk, yogurt, and cheese? Is consumer understanding of the basic nature of plant-based products influenced by inclusion of terms such as milk, cultured milk, yogurt, and cheese in the names in the labeling of these products? Do consumers expect plant-based products labeled with such names to have physical characteristics, performance characteristics, or properties of their dairy counterparts? If so, in what ways? Please provide any data or evidence to support your answer.
2. What do consumers believe are the main ingredients of plant-based products? What do consumers understand/think about the different protein sources being used to make these plant-based products? Do they understand that some of these plant-based products contain proteins from more than one plant source (e.g., almond and pea protein)? Are these beliefs or understanding influenced by the inclusion of dairy food names, particularly “milk,” “cultured milk,” “yogurt,” or “cheese,” in the product name? Please provide any data or evidence to support your answer.
3. What is consumers' understanding of the amount or proportion of plant-based ingredient(s) relative to other ingredients in plant-based products? Are consumers aware that other ingredients (e.g., emulsifiers, thickeners, sweeteners, and added nutrients such as vitamins and minerals) are used in the manufacture of these plant-based products? How does the use of these ingredients impact consumer perception of these products? Please provide any data or evidence to support your answer.
4. Do these plant-based products vary in ingredients, even when manufactured using the same type of plant source (e.g., soy or almond)? If so, how? What are consumers' expectations regarding the ingredients of different brands of each subclass (e.g., soy or almond) of plant-based products? What impact, if any, does the compositional variation have on purchase and consumption decisions? Please provide any data or evidence to support your answer.

D. Consumer Understanding of the Nutritional Content of Plant-Based Products and Dairy Foods and the Effect, if Any, on Consumer Purchases and Use

1. Dairy foods, such as milk, cultured milk, yogurt, and cheese, may differ in nutritional content compared to plant-based products manufactured to resemble these dairy foods. What

nutrients, if any, do consumers believe to be provided from dairy foods such as milk, cultured milk, yogurt, and cheese? What nutrients, if any, do consumers believe to be in plant-based products that resemble dairy foods, such as milk, cultured milk, yogurt, and cheese? Do consumers expect certain nutrients to be present in both plant-based products and their dairy counterparts, and, if so, what nutrients do they expect? Do these expectations change depending on the terms included in the names of plant-based products, e.g., “milk,” “beverage,” “drink,” “yogurt,” “yogurt alternative,” “vegan cheddar cheese,” “cheese shreds”? Please provide any data or evidence to support your answer.

2. Do parents and caregivers who purchase these plant-based products for young children or other family members believe that these plant-based products are nutritionally equivalent to their dairy counterparts and can replace them as a food choice? Are expectations of nutritional equivalency a factor in parents' and caregivers' decisions to purchase these plant-based products as part of young children's or other family members' balanced diet? Please provide any data or evidence to support your answer.
3. Do these plant-based products vary in nutrient composition, even when manufactured using the same type of plant ingredients (e.g., soy or almond)? If so, how? What are consumers' expectations regarding the nutrient compositions of different brands of each subclass (e.g., soy or almond) of plant-based products? What impact, if any, does the compositional variation have on purchase and consumption decisions? Please provide any data or evidence to support your answer.
4. We are aware that the United States Department of Agriculture's National Nutrient Database for Standard Reference (USDA Nutrient Database) provides information about the nutritional content of dairy foods as well as some plant-based products that resemble dairy foods (Ref. 2). However, we believe the USDA Nutrient Database may not be a full representation of all the varieties of dairy foods, including milk, cultured milk, yogurt, cheese, and of the plant-based products manufactured to resemble these dairy foods, currently in the United States marketplace. We are interested in any data regarding the nutritional profiles of different dairy foods, such as, for example, milk, modified milk, cultured milk, yogurt, and cheese products, and any data regarding the nutritional profiles of the various plant-based products that resemble dairy foods, including fortified versions of those plant-based products. We are particularly interested in obtaining data that compares the amounts of protein, calcium, vitamin D, and potassium in these plant-based products and their dairy counterparts.
5. How do the protein qualities of plant-based products compare to their dairy counterparts? How does the variation, if any, impact consumer perception, and purchasing and consumption decisions? Please provide any data or evidence to support your answer.

E. The Role of Plant-Based Products and Dairy Foods in Meeting the Recommendations in the *Dietary Guidelines for Americans*

1. Do consumers understand that certain plant-based products might have a nutritional content that is not adequate to place them in the dairy group as described in the Dietary Guidelines? How does this influence their purchasing behavior with respect to plant-based products and dairy foods? Please provide any data or evidence to support your answer.

2. Do consumers who purchase or consume plant-based products instead of dairy foods, such as yogurt or cheese, believe that these plant-based products meet the dairy group recommendation described in the Dietary Guidelines? Please provide any data or evidence to support your answer.

Comments are due to this docket on November 27, 2018. FDA will consider the information submitted in determining the agency's next steps in addressing this product category.

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We will continue to monitor developments related to the use of standardized dairy terms on the label of plant-based foods. Please contact us if you have any questions or if you are interested in submitting comments to the docket.