



National Milk Producers Federation

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November 12, 2019

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

Re: Docket No. FDA-2018-N-2381- Horizontal Approaches to Food Standards of Identity Modernization

Dear Sir/Madam:

The National Milk Producers Federation (NMPF), established in 1916 and based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies.

NMPF is supportive of FDA modernizing the standards of identity. We believe that in considering changes to standards of identity, two principles should guide FDA. First, in no case should standards be changed solely for economic reasons in order to permit food companies to lower their production costs. Second, the provisions of individual standards should only be changed where there is a consensus among affected industries, including both manufacturers and the suppliers of major ingredients, that the change is warranted and that consumers will not be misled by such action.

Standards of identity, under the Federal Food, Drug and Cosmetic Act, are to be established whenever they will "promote honesty and fair dealing in the interest of consumers." This statutory principal is potentially consistent with "developing healthier products," but the emphasis in the law is on how consumers are treated: The standards exist to ensure that commerce is conducted honestly and that transactions between buyers and sellers are fair.

NMPF has long been a supporter and defender of the standards of identity. Standards of identity are central to consumers' perception of products, ensuring the product has the ingredients and nutrition they expect. Unfortunately, not everyone follows the rules. For example, most plant-based companies chose to wrongfully label their products with dairy terms partly because of the "health halo" surrounding dairy products. This mislabeling practice has in fact led to malnutrition among consumers due to the assumption that the mislabeled plant-based products have the same nutritional value as actual dairy products. Both the American Academy of

Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
California Dairies, Inc.
Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Ellsworth Cooperative Creamery
FarmFirst Dairy Cooperative
First District Assoc.
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers
Maryland & Virginia Milk Producers Cooperative Association
Michigan Milk Producers Association
Mid-West Dairymen's Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Assoc.
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative Creamery, Inc.
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.

Pediatrics and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition filed comments with FDA expressing their concerns about an increase in child malnutrition cases because of consumers being misled by their assumptions regarding nutrition and plant-based products labeled as “milk.” Former FDA Commissioner Scott Gottlieb expressed a similar concern.

FDA needs to end its failure to enforce standards, regardless of whether FDA has announced it as exercising enforcement discretion or not, with respect to plant-based foods and ensure that everyone follows the rules. The enforcement failure risks making standards of identity meaningless. For the past 40 years, NMPF has urged FDA to enforce the standards of identity to prevent imitation products from being able to use dairy terms. However, even with NMPF filing a Citizen Petition and the closing of two dockets, FDA has yet to do anything. With the standards that are currently in place not even being enforced, we wonder what is the benefit of utilizing resources to create horizontal standards other than to allow companies to get away with that they have already been doing?

Horizontal Standards are Unnecessary

Creating horizontal standards is also for the most part unnecessary. Innovation has continued to happen in the food industry without changing the standards of identity. For example, the yogurt category has continued to expand, while there are only standards of identity for yogurt, low fat yogurt and nonfat yogurt. Greek, Icelandic, French, and others have continued to enter the yogurt category while all still meeting the standard of identity. This is because the standard sets the minimum for a product to be called “yogurt” but does not limit innovation.

An even more common example of innovation is in the frozen foods category -- “frozen dairy desserts” that have been showing up in the freezer case next to the ice cream. While they are a dairy product, frozen dairy desserts don’t meet the standard of identity for ice cream due to differences in either their fat content or type, nonfat content, weight or overrun amount. Not meeting the standard of identity doesn’t prevent these products from reaching the market, though; the manufacturers simply created a new name for their product, as many companies have done when they have a new product which doesn’t meet the standards already set.

We know innovation is a key part of maintaining competitiveness within the food industry. However, NMPF doesn’t believe that horizontal standards which apply to all standards of identity is the best way to modernize them. Horizontal standards could open the door for unexpected consequences and sadly, lower the quality of food, which is the opposite of what we should want for the consumers. And this is something that is already happening- food companies deceive consumers every day

with products like “frozen dairy dessert” which look exactly like containers of ice cream and which are commingled in the freezer case next to and with real ice cream products. Creating these horizontal standards could just allow companies to cheapen their products under the guise of innovation legally.

Examples of where horizontal standards may fail

1. One of the proposed changes is eliminating the requirements or minimums in current standards for salt, sugar, oil and fat. One example given is the removal of milkfat requirements. Doing this would mean that for dairy products, companies could substitute vegetable fats to cheapen their products, and would no longer have to maintain the requirement of milkfat. If milkfat requirements are eliminated, no longer could consumers be assured that when they bought ice cream or butter, they were getting what they paid for. Furthermore, substituting vegetable fat for milkfat has no nutritional benefits as the saturated fat in dairy has been found to have little to no correlation with total mortality or the with the risk of heart disease in adults.
2. Giving manufacturers the flexibility to add or substitute safe and suitable ingredients also raises many red flags as this could ultimately just lead to cheaper products, not necessarily healthier products. Going back to the example above of milkfat being replaced by vegetable fat in ice cream, this substitution can already be done; the final product is just called mellorine, not ice cream.
3. While NMPF agrees that some alternate manufacturing processes to produce standardized foods may be helpful, such as being able to use microfiltered milk in cheesemaking, there is also risk involved with this. Giving manufacturers too much flexibility could lead to cheaper, more processed products. For example, the ice cream standard at 21 CFR 135.110, requires the final product to weigh no less than 4.5 pounds per gallon. Being flexible and not requiring the minimum weight of 4.5 pounds would allow more air to be mixed into the ice cream which is in essence giving the consumer less ice cream in the container and more air.
4. Congress set the standard for butter in 1923 which reads as follows: “That for the purposes of the Food and Drug Act of June 30, 1906 (Thirty-Fourth Statutes at Large, page 768), “butter” shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.” FDA cannot change that standard. FDA cannot override Congress or re-write a Congressional Act. To do so would violate the Constitutional principle of separation of powers. In fact, NMPF believes that FDA is violating the law by not enforcing the butter standard of identity. As the courts said in a recent ruling in the American

Academy of Pediatrics v. FDA, "... if the agency's decision [enforcement discretion] is tantamount to amending or revoking a rule, then it amounts to substantive rulemaking subject to the APA's constraints and generally reviewable by the courts." "Thus, when the FDA takes action to the contrary of the FDCA, through the ultra vires action, the FDA exceeds the authority granted by Congress and its action cannot stand¹." NMPF asserts that FDA's use of "enforcement discretion" with plant-based imitators is ultra vires.

Based on these examples, NMPF believes that creating horizontal standards across all 290 standards of identity runs a high risk for many unintended consequences. We are supportive of the idea of modernizing standards but believe there is a better way. For instance, instead of applying a horizontal standard to all standards, create a horizontal standard which applies to only the dairy standards, or another subgroup of foods such as cheese or yogurt. This eliminates the need to update every standard but allows the impacted industry to work with you in a transparent manner on the horizontal standard while preventing the horizontal standards from being manipulated for company gain.

As stated above, NMPF is supportive of modernizing the standards of identity as we understand that some changes may be needed. But we also recognize that creating horizontal standards of identity could lead to more negative outcomes than positive and urge FDA to proceed with caution.

Sincerely,



Clay Detlefsen, Esq.
Senior Vice President and Staff Counsel

¹ AAP v. FDA - Case # PWG 18-883