



National Milk Producers Federation

2107 Wilson Blvd., Suite 600, Arlington, VA 22201 | (703) 243-6111 | www.nmpf.org

September 25, 2018

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

Re: Docket No. FDA–2018–N–2155, Foods Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments

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 pleased to offer its views in response to FDA’s request for comments on foods produced using animal cell culture technologies. The use of animal cell culture technologies to manufacture meat, poultry and seafood products that resemble their traditional naturally-raised counterparts matters to our members because these rapidly-evolving technologies also impact dairy foods. Specifically, our industry is potentially affected by the use of genetically modified yeast to produce proteins that share chemical identity with milk proteins. Just as laboratories can now make synthetic meat, they will soon be able to manufacture synthetic “milk protein”-based compounds without dairy animals.

When it comes to products manufactured from cell culture technology, FDA has claimed jurisdiction over such products, touting its extensive expertise and scientific experience. While NMPF agrees that FDA has significant experience, experience alone is insufficient, and we would argue that another important quality be considered: FDA’s willingness and ability to enforce its own existing standards of identity. If FDA doesn’t enforce its rules, it should not take on new responsibilities. A rule without enforcement is no rule at all, it is chaos.

The U.S. dairy industry is very familiar with man-made products designed to mimic traditional milk and dairy foods. For decades, manufacturers have been making fake milk and other imitation dairy beverages and using the names of standardized products on the labels. You’ve heard of them before: “soy milk,” “almond milk,” “soy cheese,” and “rice yogurt,” among others. What began as a clever marketing tactic has led to the rampant abuse of standardized dairy terms. But most importantly, it has led to consumer confusion over the nutritional composition of these products and whether they can replace traditional milk in a healthy diet. They cannot.

Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards’ Creameries
Cooperative Milk Producers Association
Cortland Bulk Milk Producers Cooperative
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 Dairyman’s Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Assoc.
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto County Cooperative Milk Producers’ Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative Creamery, Inc.
Swiss Valley Farms
Tillamook County Creamery Association
United Dairyman of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

Over the last 40 years, NMPF and the dairy industry have made repeated requests for FDA to take enforcement action against these misbranded products. Each time, FDA has brushed off our request by claiming the issue is not an agency priority. In fact, NMPF requested that FDA take action as long ago as 1979 when it filed two petitions with FDA calling for the revocation of 21 C.F.R. § 101.3(e) and the withdrawal of the proposed standards of identity for cheese substitutes. At the same time, NMPF sought enforcement action from the FDA against producers of cheese substitutes for misbranding. FDA responded, **“that budgetary constraints had forced it to set investigative and enforcement priorities and that it had assigned its lowest priorities to food economics and food standards.”**¹ Recently, however, FDA Commissioner Scott Gottlieb stated that:

“Ensuring that food is safe and truthfully labeled is one of our fundamental responsibilities at the U.S. Food and Drug Administration. Consumers deserve accurate information about the food they eat and how it can affect their health and nutrition. That’s why Congress entrusted FDA to serve as the nation’s expert on food safety and labeling and to craft predictable, uniform federal requirements on matters within our jurisdiction.”²

In addition, Commissioner Gottlieb pointed out this summer that children are suffering from diseases such as kwashiorkor and rickets because the improper use of dairy terminology on plant-based imitation dairy products conveyed a nutrition benefit that was sorely lacking.³

“One area that needs greater clarity – and which has been the subject of much discussion of late – is the wide variety of plant-based foods that are being positioned in the marketplace as substitutes for standardized dairy products. Many of these plant-based foods use traditional dairy terms (e.g., milk, yogurt, cheese) in the name of the product. For instance, we’ve seen a proliferation of products made from soy, almond or rice calling themselves milk. However, these alternative products are not the food that has been standardized under the name “milk” and which has been known to the American public as “milk” long before the 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act) was established. In addition, some of these products can vary widely in their nutritional content – for instance in relation to inherent protein or in added vitamin content – when compared to traditional milk.

¹ National Milk Producers v. Harris, 653 F.2d 339 (8th Cir. 1981)

² FDA Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA’s support for exempting coffee from California’s cancer warning law, August 29, 2018

³ Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency’s standards of identity for dairy products, July 26, 2018

We intend to look at these differences in relation to potential public health consequences. There are reports that indicate this issue needs examination. For example, case reports show that feeding rice-based beverages to young children resulted in a disease called kwashiorkor, a form of severe protein malnutrition. There has also been a case report of a toddler being diagnosed with rickets, a disease caused by vitamin D deficiency, after parents used a soy-based alternative to cow's milk. Because these dairy alternative products are often popularly referred to as "milk," we intend to look at whether parents may erroneously assume that plant-based beverages' nutritional contents are similar to those of cow's milk, despite the fact that some of these products contain only a fraction of the protein or other nutrients found in cow's milk."

So, for 40 years FDA has ignored its fundamental responsibilities that Congress entrusted to it and as a result, we now have an "anything goes" attitude in the marketplace. Instead of enforcing the law, FDA turned a blind eye toward the mislabeling of too many food products, and children allegedly got sick as a result.

If the development of a regulatory framework continues to linger and enforcement is selective for cultured meat, just like it is for milk, we will see abuse by manufacturers, further consumer confusion, and a lack of fairness in the marketplace. Just as imitation milk should not be called milk without being prefaced with the word imitation, so-called lab-grown meat does not seem to be "meat" in the sense that most Americans understand that term. For that reason, and given FDA's long history of intentionally neglecting its fundamental responsibilities, perhaps it would best for USDA to regulate foods produced using animal cell culture technology.

If FDA does have the relevant experience and is willing to enforce the rules [emphasis on "only if"] it puts forth relevant to cultured meat, the fundamental question arises: Are these meat and poultry products which should be subject to USDA regulations, or are they properly regulated under FDA's authority? While it is clear that fake meat made from plant proteins should be regulated by FDA, cultured meat is another issue. Unfortunately, as was seen and heard at the public meeting, the facts are not fully yet in evidence and they absolutely must be in order to make an informed and transparent decision. If the cultured meat manufacturers are correct in their assertion that the product is truly "meat" (something we doubt), NMPF opines that jurisdiction should be with USDA. If it is something other than traditional meat, then FDA's jurisdiction is likely proper.

Further, if it isn't meat, it should not utilize meat nomenclature – regardless if it is plant-based or cultured -- unless it is abundantly clear what the product is by its name. Perhaps "synthetic beef," "artificial hot dogs" or "cultured imitation meat product" would be fitting. In any case, neither FDA, nor USDA should allow these products into the marketplace under any name until they are fully analyzed and understood, especially with respect to food safety. Perhaps FDA and USDA should work together

now, in a cooperative fashion, to figure out exactly what these products are and what they are not and ultimately assign jurisdiction in a manner consistent with existing law.

We conclude with a plea to the agency: America's dairy farmers again call for a commitment from FDA to enforce standards of identity and labeling regulations for dairy products. It is 40 years past time to resolve this problem.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen". The signature is fluid and cursive, with a prominent initial "C" and a long, sweeping underline.

Clay Detlefsen
Senior Vice President, Environmental and
Regulatory Affairs & Staff Counsel

Attachment