



National Milk Producers Federation

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

Agri-Mark, Inc.
Associated Milk
Producers Inc.
Bongards' Creameries
California Dairies, Inc.
Cayuga Marketing
Cooperative Milk
Producers Association
Dairy Farmers of
America, Inc.
Ellsworth
Cooperative Creamery
FarmFirst Dairy
Cooperative
First District Association
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers
Maryland & Virginia
Milk Producers
Cooperative Association
Michigan Milk
Producers Association
Mount Joy Farmers
Cooperative Association
Northwest Dairy
Association
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.
Tillamook County
Creamery Association
United Dairymen
of Arizona
Upstate Niagara
Cooperative, Inc.

March 8, 2021

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

Re: Docket No. FDA-2020-N-1720

Dear Sir or Madam:

These comments respond to the Food and Drug Administration's (FDA) request for information (RFI) entitled "Labeling of Foods Comprised of or Containing Cultured Seafood Cells," published in the *Federal Register* October 7, 2020. The National Milk Producers Federation, 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 like FDA. NMPF provides a forum through which dairy farmers and their cooperatives formulate policy on national issues that affect milk production and marketing.

NMPF does not attempt to speak for the seafood industry and recognizes the right of that industry to advocate for policies that it sees as beneficial. However, the RFI raises three issues that are potentially of direct concern to the dairy industry. Two are procedural and one arises from the substance of the issues that FDA has put before the public.

FDA should enforce existing standards before creating new ones

We frequently hear that FDA has limited resources that may hamper its ability to enforce certain regulations, notably standards of identity. We further note that whereas FDA has received complaints from NMPF and numerous others about inaccurate and misleading labeling by plant-based imitators of milk and other dairy products – complaints literally spanning decades – and whereas FDA solicited and received comments over two years ago on this subject - the agency has nevertheless taken no action to enforce its clear regulations in this area and has given no indication when it will do so. Therefore, it seems highly questionable whether FDA should undertake the creation of new labeling protocols when the agency chooses not to enforce those already in effect.

FDA should coordinate its policies with USDA

A second issue is the agreement between FDA and the U.S. Department of Agriculture (USDA) with respect to lab-grown food products. The RFI correctly states in a footnote

that “Siluriformes fish” are now subject to provisions of the Federal Meat Inspection Act. Reportedly, USDA is working on an advance notice of proposed rulemaking with respect to its responsibilities under the joint agreement. We believe it is critical for the two agencies to work together on these issues, and we question why FDA acted in advance of USDA’s initiatives, rather than sequencing regulatory actions by the two agencies in close proximity so that the public can understand how proposals by each agency would interact. (To take only the most obvious example: the seafood section of any major grocery store markets products that are USDA-regulated – catfish and other Siluformes species – with FDA regulating everything else. Inconsistent labeling or nomenclature stemming from the two agencies’ rules would leave consumers confused and store operators potentially uncertain about their responsibilities.)

“Cultured” should not be used to describe lab-grown foods

Our third concern is that FDA could unintentionally create a system of nomenclature that would leave consumers confused about the derivation and integrity of nutrient-dense dairy products. NMPF believes such confusion is bound to arise from the misuse of the word “cultured.”

In its request for public comment, FDA repeatedly raises the possibility that lab-grown seafood would be referred to as “cultured seafood” or a similar term. To be sure, FDA states that this and similar phrases are “not intended to establish or suggest nomenclature for labeling purposes,” but the repeated use of “cultured” rather than a more descriptive and easily understood term such as “lab-grown,” “synthetic” or “cell-based” makes it appear that the agency is leaning toward permitting “cultured” as a descriptor when the seafood products in question come onto the market.

By permitting use of the term “cultured” with respect to seafood, FDA would commit a critical mistake akin to misleading the public since the term “cultured” is a longstanding descriptor for several standardized and non-standardized dairy products which are characterized by the presence of probiotic/lactic acid-producing bacteria or fermentation processes resulting from the presence of those bacteria. The term [“cultured dairy” is a recognized food category](#) that is considered to include fluid milks, yogurt, skyr, sour cream, cottage, cream cheese and kefir.

More specifically –

- FDA itself uses “cultured” and other forms of the same word in its standards of identity. There is, for example, a standard for “cultured milk” codified at [21 CFR 131.112](#). The standard of identity for “yogurt” at [21 CFR 131.200](#) states that the food is made by “culturing” one or more ingredients “with a characterizing bacterial culture.”

- The term is also used in naming dairy products that depart from a standard of identity. A fermented dairy product that is similar to yogurt but does not meet that food's standard of identity (e.g., because of the use of milk protein concentrate to raise protein and lower sugar content, is [marketed as a "cultured dairy blend."](#) Major retailers such as Kroger [sell products](#) labeled with this term.
- "Cultured" is also used to describe products with an additional manufacturing step involving live bacterial cultures, e.g., ["cultured butter."](#) ["Cultured buttermilk"](#) is manufactured through a different process than that which yielded traditional buttermilk.

Thus, the term "cultured" in dairy products has a meaning that is *not* remotely related to the artificial manufacturing processes involved in lab-grown food products. NMPF is concerned that if FDA encourages or allows the lab-grown food industry to appropriate this terminology, the result will be consumer confusion and a "lose, lose, lose" outcome that will benefit neither consumers, the seafood and dairy industries, nor the agency itself.

Furthermore, for decades the marketplace has served up "imitation crab meat" which is popular and is found in many seafood dishes. Louis Kemp, a major purveyor of imitation crab meat, describes that product as follows:

"Imitation crab, also often referred to as "krab", has been given a bad rap; it isn't fake food at all. It includes portions of real crab meat complemented by a main ingredient – the one that makes it an affordable option to real crab – Wild Alaska Pollock.

Wild Alaska Pollock is added via a malleable seafood paste called Surimi, which gives imitation crab the form, flavor and look of real crab. Currently a \$1 billion industry, surimi has been popular in Asia for over 900 years and is now enjoyed globally in French, Thai, and Japanese cuisines as well as seafood dishes including lobster, shrimp, scallops, and of course, crab."

We note, in our opinion, that the phrase "imitation crab meat" correctly follows FDA's decades-old labeling regulations with respect to its imitation products. We commend the Louis Kemp brand and the Trident Seafoods family of brands for following the rules – like everyone should, especially since the plant-based imitators of a variety of foods have long flaunted, disregarded and ignored FDA's rules with impunity. We further feel it would be inappropriate, unfair and confusing to consumers to allow the word "imitation" to be used on synthetically or laboratory-created artificial foods and to do so could negatively impact an industry that has followed FDA's rules.

We also question whether FDA's repeated use of "cultured" is signaling the synthetic seafood industry that they do not need to follow existing FDA regulations and, once again, remind FDA the Administrative Procedures Act (APA) does not permit FDA to

re-write a rule with guidance, or otherwise, instead of following the established, written and long-established finalized requirements of the APA. As such, NMPF reserves all rights to pursue legal action should FDA choose not to follow the APA.

To be clear, the issue is not that consumers will confuse dairy and seafood. They will not. Rather, the problem is that if the word “cultured” becomes understood to refer to foods derived from synthetic processes not found in nature consumers will think the same word on dairy labels means they have been manufactured similarly or that synthetic seafood products bearing such labeling contain natural cultures that have been in use for centuries – which is clearly not the case.

NMPF urges FDA to make clear – through regulatory action if necessary – that “cultured” is neither accurate nor acceptable as a descriptor for lab-grown products (whether seafood or otherwise). To reiterate—NMPF believes such labeling will either give those products an undeserved halo because consumers think they are made with live bacterial cultures, or – more likely – it will prove detrimental to dairy consumption because consumers will mistakenly think that healthy and natural dairy foods have in fact been derived from cellular technology.

In summary, FDA should reject the use of the word “cultured” in this context, move only in cooperation and coordination with USDA. and before taking any further steps in this area, FDA should enforce standards of identity for dairy and other foods that have been in effect for decades.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen". The signature is stylized and cursive.

Clay Detlefsen, Esq.
Senior Vice President and Staff Counsel

