



National Milk Producers Federation

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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.

February 22, 2021

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

RE: Docket Number FDA-2014-N-0053, Requirements for Additional Traceability Records for Certain Foods

Dear Sir/Madam:

The National Milk Producers Federation (NMPF) is pleased to submit the following comments on the Food and Drug Administration's (FDA) Requirements for Additional Traceability Records for Certain Foods. 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.

Sadly, NMPF is disappointed with this proposed rule and believes it is a major step backward from where we were heading over a decade ago. FDA should withdraw this proposed rule, recalibrate, and issue an appropriate proposed rule. Our concerns are addressed below.

HIGH-RISK AND HIGH CONSEQUENCE ARE NOT THE SAME

The Food Safety Modernization Act (FSMA) established the criteria for the designation of high-risk foods for "Enhancing tracking and tracing of food and recordkeeping." Those criteria are below:

(2) DESIGNATION OF HIGH-RISK FOODS.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and thereafter as the Secretary determines necessary, the Secretary shall designate high-risk foods for which the additional recordkeeping requirements described in paragraph

(1) are appropriate and necessary to protect the public health. Each such designation shall be based on—

- (i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;
- (ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
- (iii) the point in the manufacturing process of the food where contamination is most likely to occur;
- (iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- (v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- (vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.¹

Importantly, FSMA does not direct FDA to consider the percent of the population that consumes a particular food. If FDA considers this criterion, and particularly if FDA does not weight other factors properly, popular foods are more likely to be considered high-risk even if those foods are subject to preventive controls and processing steps that make the foods safe and they have not been associated with significant foodborne illness outbreaks. FSMA’s direction for FDA to consider the “likelihood that consuming a particular food will result in foodborne illness due to contamination” does not mean that FDA should consider consumption rates. If anything, this factor speaks more to the sanitary or unsanitary conditions where the product is made or handled and the routine interplay between the food handler/consumer and the particular properties of a given food (e.g., is the food likely to be subjected to temperature abuse, do handlers/consumers routinely and properly cook the food, etc.).

FDA’s inclusion of consumption data (C6) skews the risk ranking dramatically and returns, at times, absurd results.² Cheese and eggs are important staples of the American diet making consumption high. But high consumption does not mean high risk.

¹ FDA Food Safety Modernization Act. 21 USC 2201 § 204 (2011)

² Center for Food Safety and Applied Nutrition. (2020, August). Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223).

Therefore, it is wrong for cheese and eggs to rise to the top of the high-risk list, which happened with the use of this model. While it is true that a large batch or high consumption of a food could cause a higher consequence illness outbreak event, Congress did not tell FDA to create a model that considers that; they told FDA to identify high-risk foods and they gave FDA six criteria to follow. Further Congress did not grant FDA any leeway or discretion, Congress set down six criteria to follow in making that determination and did not include any statement along the lines of “or other criteria as determined by the Secretary.” NMPF has cautioned FDA in the past that it must follow instructions laid down by Congress to the letter of the law else FDA’s action can amount to rewriting the will of Congress which is legally problematic on many levels. As a result of FDA’s unwarranted tinkering, the commodity risk score for “*Cheese (made from pasteurized milk) soft or soft ripened or semi-soft*”, “*shell eggs*”, “*Cheese (made from pasteurized milk) fresh soft*”, “*Crustaceans*”, “*Cucumbers*”, “*Leafy greens*”, “*Melons*”, “*Ocean finfish*”, “*Vegetables*”, “*Nut butters*”, and “*Sprouts*” are all riskier than “*Cheese (made from unpasteurized milk) other than hard*”. In fact, in this model, “*Cheese (made from pasteurized milk) soft or soft ripened or semi-soft*” is ranked at the top of the list, making these cheeses the highest risk foods in the marketplace with “shell eggs” coming in second.³ The category “*Cheese (made from pasteurized milk) soft or soft ripened or semi-soft*” includes many popular cheeses such as mozzarella, cream cheese and cottage cheese and it makes little sense for them to be considered “high-risk.”

NMPF believes that the Center for Disease Control and Prevention (CDC) would take issue with a risk ranking that delivers results as above. In fact, on February 12, 2021, FDA and CDC issued an alert about an outbreak investigation which included the statement “Generally, make sure the Hispanic-style fresh and soft cheeses (like queso fresco) you eat have labels that state, “Made with pasteurized milk.”⁴ That statement is interesting on many levels. First, it is a clear indication that CDC (and in this case, FDA as well) view cheese made with pasteurized milk as safer than cheese made with raw milk. Second, there appears to be a recognition that pasteurization of milk used to make cheese is an effective kill step. Third, there is a clear recognition of the proper nomenclature for cheese products that are a concern, namely, “Hispanic-Style Fresh and Soft Cheeses made from raw milk and other raw milk cheeses.”

³ Center for Food Safety and Applied Nutrition. (2021, January 12). FSMA proposed rule for Food Traceability.

⁴ Center for Food Safety and Applied Nutrition. (2021, February 12). Listeria monocytogenes outbreak in Hispanic-style CHEESE (Feb 2021).

PASTEURIZATION IS A KILL STEP IN CHEESEMAKING

There is some uncertainty in the industry regarding the use of pasteurized milk in cheesemaking and whether that constitutes a “kill step” under section §1.1355 of the proposed rule. We believe it does. Kelley Jackson, CDC, stated in June 2018 that:

Pasteurization is the process of heating milk to a high enough temperature for a long enough time to kill disease-causing germs, including *Listeria*. Routine pasteurization of milk began in the United States in the 1920s and became widespread by 1950 as a way to reduce contamination and human illness. It worked, leading to a dramatic reduction in both illnesses and outbreaks. **Public health professionals and health care providers consider it one of public health’s most effective food safety interventions ever.**⁵

The confusion exists because certain individuals have asserted that cheese itself is not pasteurized, rather only the milk that goes into the cheese is pasteurized. We think that is shortsighted and is splitting hairs unnecessarily. CDC routinely advocates for the consumption of cheese made from pasteurized milk because those cheeses are generally considered safe and they have expressly stated so:

“Consumers, particularly persons at high risk for listeriosis, are advised to avoid unpasteurized milk and dairy products made from unpasteurized milk. **Soft cheeses made with pasteurized milk, including commercial cottage cheese, cream cheese, and processed mozzarella, are generally considered safe** [emphasis added.] However, some soft cheeses made with pasteurized milk, particularly Latin-style soft cheeses, have been produced in facilities with improper processing conditions, resulting in *L. monocytogenes* contamination. Consumers cannot evaluate the conditions under which a cheese was made on the basis of labeling or other attributes of the product. We advise persons at higher risk for listeriosis (the elderly, persons with immunocompromising conditions, and pregnant women) to carefully consider whether to consume Latin-style and other soft cheeses implicated in previous outbreaks.”⁶

⁵ Jackson, K. A., Gould, L. H., Hunter, J. C., Kucerova, Z., & Jackson, B. (2018). Listeriosis outbreaks associated with Soft Cheeses, United STATES, 1998–20141. *Emerging Infectious Diseases*, 24(6), 1116-1118. doi:10.3201/eid2406.171051

⁶ Jackson, K. A. (2018). Listeriosis outbreaks

NMPF is dumbfounded that CDC considers cottage cheese, cream cheese, and processed mozzarella cheese as “generally considered safe” while FDA labels these cheeses as high risk. These cheeses do not belong on the high-risk list, nor do most made with pasteurized milk. That is not to say these cheeses are no-risk because other factors could lead to contamination, but that does not rise to the level of high risk.

Further, a determination by FDA that the use of pasteurized milk in cheesemaking does not equate to a kill step in the finished cheese product would render all of CDC’s and FDA’s advice to consumers about selecting only pasteurized milk and dairy foods made from pasteurized milk meaningless and create considerable consumer confusion. Further, it would contradict FDA’s current advice on **The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk** which is posted on FDA’s website.⁷ FDA’s advice speaks for itself.

Protect Your Family with Wise Food Choices

Most milk and milk products sold commercially in the United States contain pasteurized milk or cream, or the products have been produced in a manner that kills any dangerous bacteria that may be present. But unpasteurized milk and products made from unpasteurized milk are sold and may be harmful to your health. To avoid getting sick from the dangerous bacteria found in raw milk, you should choose your milk and milk products carefully. Follow these guidelines:

Low Risk Choices

- **Pasteurized** milk or cream
- Hard cheeses such as cheddar, and extra hard grating cheeses such as Parmesan
- Soft cheeses, such as Brie, Camembert, blue-veined cheeses, and Mexican-style soft cheeses such as Queso Fresco, Panela, Asadero, and Queso Blanco made from **pasteurized** milk
- Processed cheeses
- Cream, cottage, and Ricotta cheese made from **pasteurized** milk
- Yogurt made from **pasteurized** milk
- Pudding made from **pasteurized** milk
- Ice cream or frozen yogurt made from **pasteurized** milk

⁷ Center for Food Safety and Applied Nutrition. (2018, November 8). Unpasteurized milk can pose a serious health risk.

High Risk Choices

- Unpasteurized milk or cream
- Soft cheeses, such as Brie and Camembert, and Mexican-style soft cheeses such as Queso Fresco, Panela, Asadero, and Queso Blanco made from unpasteurized milk
- Yogurt made from unpasteurized milk
- Pudding made from unpasteurized milk
- Ice cream or frozen yogurt made from unpasteurized milk

HISTORICALLY THE PROBLEM HAS BEEN SOFT, SEMI-SOFT AND FRESH HISPANIC CHEESES

In 2011, Congress told FDA to develop a list of high-risk foods which would require additional traceability requirements. At that time, with respect to cheese, the conventional wisdom was that soft Hispanic cheeses made from raw milk and some other raw milk cheeses were to be included. This was supported by CDC. One of the reasons for the focus on Hispanic cheeses was the fact that there were a number of outbreaks associated with these cheeses where they were made in small production facilities operating under unsanitary conditions or in a non-commercial facility, that produced a cheese which became commonly known as “bathtub cheeses.” In unregulated settings, it becomes largely irrelevant whether cheeses are made from pasteurized or raw milk, they are without a doubt absolutely “high-risk.” For reasons unknown in this rulemaking, FDA converted that concern and nomenclature to “cheese, other than hard” which includes pasteurized cream cheese, cottage cheese, ricotta, monterey jack, mozzarella and others that have no basis for being considered high risk. In 2011, everyone knew where the risk was in the cheese category, the phrase “Hispanic-style Cheese” had meaning in both the Hispanic community as well as in non-Hispanic communities.

CDC even issued a guidance infographic, “Check the Cheese, Avoid *Listeria*” which we have attached.⁸ The message CDC hoped to convey was that some types of Hispanic-style soft cheeses carry *Listeria* and that a *Listeria* infection in pregnant women can cause miscarriage, stillbirth, or death of the newborn. In this infographic, CDC also points out that pregnant Hispanic women are about 24 times more likely than the general public to get a *Listeria* infection. CDC was clear and transparent with respect to the cheeses they

⁸ Centers for Disease Control. (n.d.). Check the Cheese, Avoid *Listeria*. Retrieved February 18, 2021, from <https://www.cdc.gov/listeria/pdf/hispanic-pregnant-women-soft-cheese-infographic-508c.pdf>

were concerned about – queso blanco, queso blando, queso cotija, queso panela, queso ranchero and cuajada en terron. Because of their higher risk, CDC emphasized that Hispanic women should avoid cheese made with unpasteurized milk and that soft Hispanic cheeses made in unclean places are still problematic despite pasteurization. CDC’s message was clear and transparent and has undoubtedly helped pregnant Hispanic women maintain healthy pregnancies. FDA’s nomenclature choice for what cheeses are high-risk with respect to this rule is muddy at best and undermines CDC’s public health mission. FDA should return to using that nomenclature that CDC and others at FDA use.

CONCLUSION

NMPF believes that 1) the inclusion of consumption data in the risk ranking model is inconsistent with Congress’s directive, 2) that cheese made from pasteurized milk is food that has been subjected to a kill step and 3) the name/identity of the cheese products on the Traceability Lists should be Hispanic Cheeses (or similar) made from raw milk and other raw milk cheeses.

In addition to the issues we have raised in these comments, NMPF would like to be on the record as concurring with comments provided by our colleagues at the International Dairy Foods Association (IDFA). IDFA commented extensively on a multitude of very important issues facing the dairy and broader food industry which FDA needs to address before moving forward with this rule.

Given the flaws in this proposed rule, NMPF believes this proposal should be withdrawn and a new proposed rule should be proposed that is more consistent with Congress’s mandate and common sense.

Thank you for your consideration.

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

Attachments:

1. FDA Alert: Outbreak Investigation of *Listeria monocytogenes* – Hispanic-style and Soft Cheeses (February 2021)
2. Listeriosis Outbreaks Associated with Soft Cheeses, United States, 1998-2014, *Emerging Infectious Diseases*, Vol. 24, No. 6, June 2018
3. Check the Cheese, Avoid Listeria, CDC Infographic October 1, 2015