DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740-3835

MEMORANDUM OF MEETING

Date: February 11, 2016

Place: Center for Food Safety and Applied Nutrition, FDA, College Park, MD

External Participants:

Nora Weiser, Executive Director, American Cheese Society (ACS)
Dick Roe, President, American Cheese Society
Lynn Giacomini Stray, Owner and COO, Point Reyes Farmstead Cheese (CA)
Andy Hatch, Owner, Uplands Cheese Company (WI)
Gianaclis Caldwell, Owner, Pholia Farm Creamery and Dairy (OR)
Jeremy Little, Owner, Sweet Grass Dairy (GA)
Mateo Kehler, Founder, Jasper Hill Farms (VT)
Marieke Penterman, Owner, Holland's Family Cheese (WI)
Jeremy Stephenson, Cheese Director, Spring Brook Farm and Farms for City Kids (VT)

FDA Participants:

Michael Taylor, Deputy Commissioner for Foods, Office of Foods and Veterinary Medicine (OFVM)
Susan Mayne, Director, Center for Food Safety and Applied Nutrition (CFSAN)
Kari Barrett, Public Engagement, OFVM
Monica Storozyszyn, Special Assistant to the Deputy Commissioner, OFVM
Ted Elkin, Deputy Director for Regulation, CFSAN
Nega Beru, Director, Office of Food Safety (OFS), CFSAN
Bill Correll, Director, Office of Compliance, CFSAN
Caitlin Boon, Senior Advisor, Office of the Center Director, CFSAN
John Sheehan, Director, Division of Dairy, Egg and Meat Products Safety, OFS, CFSAN
Bill Jones, Deputy Director, Office of Food Safety, CFSAN
Mickey Parish, Senior Science Advisor (A), CFSAN

SUBJECT: Meeting with the American Cheese Society to discuss FDA's non-toxigenic *E. coli* standard

Mr. Taylor and Dr. Mayne provided introductory remarks for FDA, stressing FDA's interest in having a dialogue with ACS on the challenges their members face with FDA standards and the steps they take to ensure cheese safety in their operations. It was noted that both ACS and FDA share the same goals of having safe food, and Dr. Mayne noted that ACS could help to play a leadership role in educating their full membership about safe production practices. Dr. Mayne also mentioned that she has been learning more about the science of cheese safety and how non-toxigenic *E. coli* has been used as an indicator of both sanitation and process control. FDA reiterated the commitment to

pause non-toxigenic *E. coli* testing while the agency reexamines the non-toxigenic *E. coli* standard under the new FSMA preventive controls framework.

Ms. Weiser provided introductory remarks for ACS, stressing the importance of valuing cheesemakers that maintain safety, monitor and document their processing conditions, and take corrective actions as needed. Ms. Weiser also listed over twenty industry groups that support ACS in its efforts to preserve traditional cheesemaking practices and to work with FDA to address regulatory barriers.

The meeting continued with presentations from seven cheesemakers from various parts of the country. Each provided the history of their operations, supplied information on the types and volumes of cheese they produce, and mentioned the importance of raw milk cheese and traditional practices to the growth of their businesses. Each also discussed the importance of food safety for their operations, and some provided more specific information on the processing procedures, testing protocols, documentation procedures, and outside audits they use to ensure the safety of their products. Several also mentioned the interactions that they have had with FDA and state inspectors. Presenters noted concerns about uncertainties in the regulatory environment impacting business plans and the need for increased transparency from FDA on testing data and plans for regulatory changes. Regulatory uncertainty concerns voiced included the non-toxigenic *E. coli* standard, use of wooden boards, and the 60-day aging policy for raw-milk cheeses. Presenters also noted that while certain elements of FDA's raw milk cheese regulations were concerning to the artisanal cheese industry, FDA's new FSMA regulations made sense.

Following cheesemaker presentations, a more in-depth discussion was held on the non-toxigenic *E. coli* standard. Some cheesemakers mentioned that they have been discarding product because they are unable to meet the standard under some conditions. For example, while a large majority of product does meet the current non-toxigenic *E. coli* standard, this is not the case in some instances for certain styles of cheeses, and some cheesemakers urged that style should be taken into account in future standard development. Cheesemakers also voiced that they are concerned about a lack of correlation between the presence of non-toxigenic *E. coli* and the presence of pathogens. During this discussion, both FDA and cheesemakers expressed the need for the sharing of industry and regulatory data on the presence of non-toxigenic *E. coli* in cheese. FDA also emphasized a need for more industry information about what controls are currently used to ensure cheese safety more broadly. ACS leadership discussed an upcoming cheese survey they plan to conduct, which may provide useful information, and there was also discussion on sharing FDA data from recent sampling assignments. Having further dialogue on existing data and current industry practices was seen as being potentially helpful to ensuring that FDA and industry actions encourage cheesemaking using modern preventive controls.

The meeting ended with a commitment to hold a follow-up technical meeting to further discuss the science of making cheese safely and appropriate metrics for ensuring safety, particularly under the framework of modern preventive controls. ACS members expressed an interest in including a wide variety of stakeholders in future technical discussions. FDA also committed to seeking outside scientific support in this area as needed. The meeting ended cordially.

Caitlin Boon