DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

August 29, 2014

Peggy Smith
President, American Cheese Society
and
Nora Weiser
Executive Director, American Cheese Society

Dear Ms. Smith and Ms. Weiser:

This letter is intended to provide the American Cheese Society (ACS) with an update on what has been done with respect to non-toxigenic Escherichia coli (*E. coli*) in raw milk cheese. FDA officials met with the American Cheese Society's board during ACS's 2014 Annual Conference in Sacramento, California on July 29-30, 2014. ACS invited FDA to the conference in order to share significant concerns of its membership with FDA, to exchange information, and to engage in important dialogue of mutual importance.

Among several topics discussed during the meeting, ACS expressed its concern about FDA's standard for non-toxigenic (*E. coli*) in raw milk cheese. ACS asked FDA to re-examine its policy for non-toxigenic *E. coli* in raw milk cheese outlined in the final Compliance Policy Guide, Section 527.300 Diary Products – Microbial Contaminants and Alkaline Phosphatase Activity published in December 2010 (hereafter, the 2010 CPG). ACS also shared concern about the commercial flow of Roquefort cheese from facilities in France that FDA recently subjected to a process known as detention without physical examination (DWPE) under Import Alert 12-10 (http://www.accessdata.fda.gov/cms_ia/importalert_9.html) due to non-toxigenic *E. coli* test results.

As we shared during the industry stakeholder conference call in December 2013, the FDA began a food sampling pilot aimed at aligning with the goals of the Food Safety Modernization Act (FSMA), which mandates a risk-informed and preventive approach to food safety. Through this pilot, we are learning more about how often select foods, such as 60-day aged raw milk cheese, become contaminated with foodborne pathogens, and what patterns, if any, may help predict potential contamination in the future. Upon completion, the FDA will have collected and analyzed 1600 samples, to produce a statistically significant data set to help identify potential vulnerabilities and inform the agency's decision making by identifying short-term and long-term next steps. During this pilot process, the agency has been closely monitoring the product collections and analysis and stakeholder feedback in an effort to gather lessons learned and make course corrections, if necessary, to meet the goals of the pilot.

One such course correction is the adjustment of the current testing for non-toxigenic *E. coli* in raw milk cheese and the applied criteria for considering regulatory action to our findings. The 2010 CPG specifies a threshold that dairy products may be considered adulterated within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth when *E. coli* is found at levels greater than 10 MPN per gram in two or more subsamples or greater than 100 MPN per gram in one or more subsamples. To clarify the underpinning of the criteria, FDA is using a three-class attribute sampling plan for examination of non-toxigenic *E. coli* in aged raw milk cheese. The criteria that FDA is using to assess microbial presence of non-toxigenic *E. coli* in raw milk cheese is n=5, c=2, m=10 MPN/g, M=100 MPN/g. Upon re-examining the basis for the non-toxigenic *E. coli* in cheese compliance policy, the sampling and testing instructions in the FY 2014-2015 Surveillance Sampling Program pilot assignment, and the Compliance Program for Domestic and Imported Cheese Products , FDA determined that adjustments to testing and regulatory action information were necessary. Specifically, FDA had been testing ten (10) subsamples per sampled product for non-toxigenic *E. coli* rather than five (5) subsamples using the three-class attributes. FDA also found that, in some instance, a miss-application of the "c" value occurred - a value that denotes a certain number that, although not desirable, can be accepted. FDA issued updated instructions to its field laboratories to limit testing for non-toxigenic *E. coli* in raw milk cheese to solely five (5) subsamples and regulatory information that lots exceeding 10 MPN/g and less than 100 MPN/g in **three or more subsamples** of the five examined are not acceptable; **not two or more subsamples** as presented in 2010 CPG. Changes to FDA's Compliance Program Guidance for Domestic and Imported Cheese Products are underway to reflect this adjustment. Further, FDA will carefully consider the information on non-toxigenic *E. coli* levels in raw milk cheese which ACS indicated that it will share with us, as discussed in the meeting. Also, it is important to note that FDA is still collecting ten (10) subsamples as those are necessary for the pathogen testing for *Salmonella* spp., *Listeria monocytogenes* and *E. coli* O157:H7 that FDA is conducting under the assignment.

FDA officials also recently met with the French Directorate General for Food (DGAL) concerning nine (9) aged, raw milk cheese facilities in France subjected to DWPE related to non-toxigenic *E. coli* findings. The parties shared information of mutual interest under existing confidentiality agreements between the regulatory authorities. Five facilities are no longer subject to DWPE due to the adjusted regulatory criteria being applied as previously described. Likewise, a facility in Italy is also removed from DWPE for same.
We are developing a new webpage to share assignment data with interested external stakeholders. That is not ready yet. However, we want to share interim results of our raw milk cheese testing under the on-going assignment to further our transparency with ACS, particularly given the intense industry concern expressed about non-toxigenic *E. coli* in raw milk cheese. As described above, our goal is to collect 1600 samples of raw milk cheese under the assignment. The most recent tally from mid-August indicates that FDA reached 885 samples collected. These samples comprise raw milk cheeses coming from Austria, Belgium, Bulgaria, Canada, Cyprus, Denmark, France, Germany, Ireland, Italy, Mexico, Netherlands, Nicaragua, Poland, Portugal, Spain, Swaziland, Switzerland, United Kingdom, and the U.S. Five samples isolated *Salmonella* spp. or *Listeria monocytogenes* (two samples and three samples respectively). These stemmed from imported cheese and FDA subjected the involved facilities to DWPE. No products have been found contaminated with *E. coli*

O157:H7. At this stage of the assignment, these test results represent a pathogen contamination rate of less than 1%. With the adjustments to testing and regulatory action criteria discussed previously, approximately 95% of the raw milk cheese examined thus far meet the n=5, c=2, m=10 MPN/g, M=100 MPN/g criteria.

We recognize that FDA is not rolling back the levels for non-toxigenic *E. coli* in aged raw milk cheese at this time to those presented in the draft 2009 CPG. Given the results shared above and the adjustments made, we believe it premature to do so. ACS committed to providing comment(s) and further industry information to the 2010 CPG through the docket as stakeholder comments on guidance are always open.

We look forward to building upon our mutual goal of safe food, particularly including continued safe production of cheese using traditional methods. The initial results above reflect commitment of U.S. cheese producers and international cheese producers to making safe cheese for consumers.

Sincerely,

William A. Correll Jr -S

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