



Mr. William Correll  
Director  
Office of Compliance  
CFSA/FDA

September 10, 2014

Dear Mr. Correll,

Thank you for your letter dated August 29, 2014 as well as the Industry Updates issued by FDA on September 4 and 8, 2014. These clarifications and timely adjustments to the field laboratory testing protocols have an immediate and positive impact on ACS cheesemaker members as well as our international counterparts. Per FDA's request at our Sacramento meeting, we have asked that our members submit comments to the 2010 Compliance Policy Guide (CPG), and hope this will allow them to share their thoughts, ask questions, and offer insight into how enforcement of the 2010 CPG impacts their businesses.

We have been asked one question repeatedly by our members and media, and we hope that FDA can shed some light on this so that we may provide industry stakeholders with the most accurate information. We are being asked why the 2009 Draft was initially created, and ultimately, why the changes from that draft to the final 2010 CPG were made. In particular:

Why were the proposed permissible levels for non-toxigenic *E. coli* changed, and the explanatory language regarding raw milk cheeses removed, from the 2009 CPG draft to the 2010 final CPG?

The language of the 2009 Draft was as follows:

“Because of the close association of raw milk with the animal environment, low levels of *Escherichia coli* may be present in raw milk or products made from raw milk, even when properly produced using GMPs. However, the presence of *Escherichia coli* in a cheese and cheese product made from raw milk at a level greater than 100 MPN/g (Most Probable Number per gram) indicates insanitary conditions relating to contact with fecal matter, including poor employee hygiene practices, improperly sanitized utensils and equipment, or contaminated raw materials. The presence of *Escherichia coli* at levels greater than 10 MPN/g in a dairy product, other than a cheese or cheese product made from raw milk, also indicates insanitary conditions. The presence of *Escherichia coli* at levels greater than 10 MPN/g in a dairy product made from pasteurized milk indicates that contamination occurred after pasteurization.”

We have also received a number of inquiries regarding the scientific data and/or correlation between the presence of non-toxicogenic *E. coli* and the incidence of pathogens in cheese overall, and how that data supports the determination of allowable limits. Any information you could provide on this would be greatly beneficial, as without this information we are concerned that public perception will persist in viewing the approach as unjustified.

Thank you for your assistance with this matter. I look forward to hearing more, and hope that your insights will also help guide us as we continue to move forward with our Best Practices Guide for Cheesemakers.

Sincerely,



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