

Congress of the United States
Washington, DC 20515

December 3, 2015

The Honorable Michael Taylor
Deputy Commissioner for Foods and Veterinary Medicine
Food and Drug Administration
U.S. Department of Health and Human Services

Dear Deputy Commissioner Taylor:

We write to you today with concerns regarding the FDA's new non-toxigenic *E. coli* standard for raw milk cheeses contained in the latest edition of the FDA *Compliance Program Guidance Manual* and *Compliance Policy Guide*. We are concerned that this standard could have a detrimental effect on cheese producers in our districts, and we ask that you carefully consider their feedback and that of the scientific community, and whether there is a commensurate risk and public safety benefit with a more stringent standard.

As you know, cheese production is an important, and growing, component of our nation's value-added agricultural economy. It is an economic driver in rural areas across the country, producing good jobs, internationally-recognized brands, and award-winning cheeses. Though the industry has a storied history, recent partnerships between the private sector, the United States Department of Agriculture Rural Development, and others have helped spur the creation of new businesses and allowed cheese production and innovation to grow at an exceptional rate.

The new FDA standard for non-toxigenic *E. coli* levels in raw milk cheeses threatens to halt the growth of the raw milk cheese industry. As you know, FDA has reduced the amount of allowable non-toxigenic *E. coli* in cheeses from 10,000 most probable number (MPN)/gram in 2009 to 10 MPN/gram under the new standard. While we understand a more stringent standard may be appropriate for cheeses made from pasteurized or heat-treated milk, the application of new *E. coli* standards to raw milk cheeses is inconsistent with internationally-recognized microbiological guidance established by the International Commission on Microbiological Specifications for Foods (ICMSF).

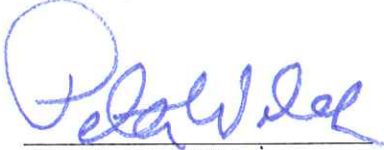
The new standard will severely limit the production of raw milk cheeses across the country. Such a drastic step would only be justified were these cheeses presenting a demonstrable public health risk, which, to date, we have not seen evidence of. Further, we are told by some of the nation's leading food safety scientists that monitoring for nonpathogenic *E. coli* has no value in mitigating the risk of raw milk cheese pathogens of greatest concern.

Given the potential impact of this new standard, we are seeking to better understand its scientific basis. Why did the FDA feel a more stringent *E. coli* standard for raw milk cheese was warranted? What evidence exists to demonstrate that raw milk cheeses produced under current practices place public health at risk? Has the science upon which this standard is based been subject to peer review? Is it appropriate to apply the same standards to raw milk and to pasteurized milk cheeses considering that the fate of pathogenic bacteria and the public health

risks associated with the two classes of cheese are known to be very different? And to what extent did the FDA consult with international organizations and producers who import cheese into the U.S. in proposing this standard?

We support FDA's efforts to ensure the safety of our nation's food supply; however, we share the concern of our constituents that standards must be scientifically based and be imposed on the industry only when necessary to address a known threat to public health. We urge the FDA to carefully balance these concerns and we look forward to your response.

Sincerely,



PETER WELCH
Member of Congress



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U.S. Senator



TONY CARDENAS
Member of Congress



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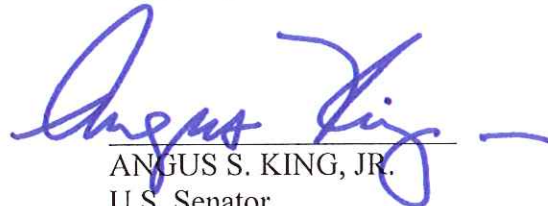
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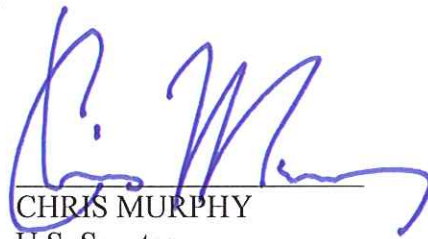
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Member of Congress



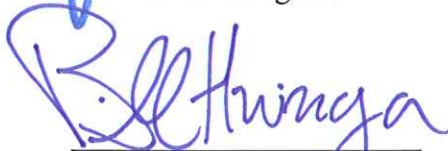
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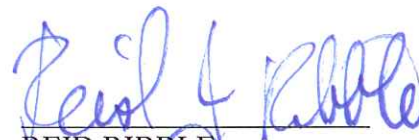
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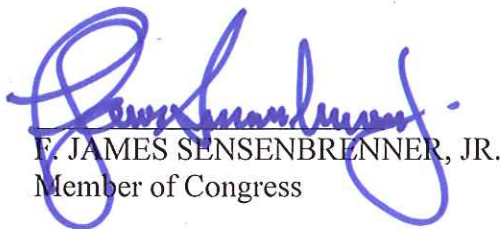
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