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## United States Senate

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August 28, 2015

The Honorable Dr. Stephen Ostroff, M.D.  
Acting Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff,

As the Food and Drug Administration (FDA) moves forward with its rulemaking process to implement the Food Safety Modernization Act (FSMA), we write to highlight the importance of making the rules practical for all sizes and types of farms and facilities. It is especially important that the rules do not place an undue regulatory burden on small farms and producers.

Specifically, FSMA includes language that prevents the FDA from requiring farms to obtain third party audits, intended to avoid placing additional costs and pressures on small farms. The proposed Preventive Controls rule, however, may require any farm selling produce that is usually consumed raw to a manufacturing facility to have an onsite audit to verify that the farmer is complying with the Produce Rule. Third party audits have been shown to create an undue burden on small farms across the country, costing anywhere from \$700 to \$14,000 a year. These audits also pose significant administrative challenges.

We appreciate the FDA's continued commitment to protect food safety. The passage of the law represents an important step towards increasing our confidence in the safety of our food supply. It also strengthens the FDA's commitment to prevention. As the FDA moves forward with the implementation of the FSMA, we want to ensure that rules reflect the statutory language and our intent when we crafted the statute.

Thank you for your attention to this matter.

Sincerely,



Michael F. Bennet  
U.S. Senator