# Congress of the United States
## Washington, DC 20515

November 22, 2013

The Honorable Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We appreciate the Food and Drug Administration's (FDA) efforts to implement the Food Safety Modernization Act (FSMA) and the agency's willingness to seek input and guidance from producers and processors, which is of great value to our constituents. We are confident that the rulemaking process for the proposed Produce Safety Rule and the Preventive Controls Rule (Docket Nos. FDA-2011-N-0920 and FDA-2011-N-0921) will bolster the overall process of the law's implementation.

Despite your agency's efforts to engage with stakeholders during the rulemaking process, we remain concerned about the ambiguity surrounding many aspects of these proposed rules. In order to improve the law's implementation, we are writing to request that the FDA propose and submit second proposed rules for public comment before issuing the final rules.

After hearing many reservations from our farmers and businesses, we are concerned that the rules as currently proposed, and the heavy cost of complying with them, will force some producers and processors to shutter their operations. Food producers and processors in our states are concerned with a number of issues, including:

- The testing frequency required for certain agricultural waters;
- Restrictions placed on the usage of biological soil amendments;
- Compliance issues at mixed-use facilities;
- New requirements that conflict with existing conservation and environmental standards and practices of the U.S. Department of Agriculture;
- The limiting definitions used in the rule for "farm," "small business" and "very small business"; and
- The lack of consideration of the complexity of various farm ownership entities.

We believe the rules as currently proposed would result in a multitude of unintended consequences that would be severely detrimental to national, regional and local agriculture. By seeking additional input through second proposed rules for public comment before final rules, we believe that producers' concerns can be addressed and unintended consequences can be greatly mitigated.

We appreciate your consideration of this request and look forward to your response.

Sincerely,

Jeanne Shaheen
U.S. Senator

Joe Courtney
Member of Congress

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