United States Senate

WASHINGTON, DC 20510

November 13, 2013

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

Dear Commissioner Hamburg,

We write to offer our comments on the U.S. Food and Drug Administration's (FDA's) proposed Produce and Preventive Controls Rules. Specifically, we seek to clarify the intent of our successful amendment to the Food Security Modernization Act (FSMA) – that rules be properly scaled to small farmers and facilities selling through short supply chains – and insist that FDA make crucial improvements to the rules before they are finalized.

In amending FSMA, we sought to prevent excessive regulations from constraining small farm and food processing operations and instead ensure that FDA focused its limited resources on areas of greater risk to food safety. Small producers selling direct to consumers are less likely to create a public health risk than large production or processing operations. We still believe it is essential to create separate, modified requirements appropriate for small farms and those appropriate for larger farms and processors: one size does not fit all. In creating the qualified exemption for small farms and facilities, we did not remove food safety requirements; rather, we emphasized applying common-sense rules for food safety at small operations that would still allow small, local markets and farms to flourish. We need more small farms and facilities, not fewer, and these proposed rules must not stymie this local economic growth.

In determining whether a farm qualifies for food safety requirements more appropriate for small operations, FDA has left a number of terms inadequately defined or not defined at all. We strongly urge FDA to reconsider the following issues:

- In calculating the gross dollar amount of food sold at a farm or facility, the rules should specify that only food subject to the new regulations ought to count towards the $25,000 *de minimus* exemption in the Produce Rule and for the $500,000 annual gross sales limit for the modified requirements for a farm or facility in both rules. Without a revision clarifying this distinction, diversified farms that primarily raise livestock, dairy, grain, feed, or forage may be forced to follow regulations required of large produce operations for only a small amount of produce grown.
- In defining a very small business in the Preventive Controls Rule, we encourage FDA to use at least the $1 million gross sales limit, since this definition would include all of the farm sales, not simply sales from crops subject to the rules.
- The draft rules do not clarify the definition of a retail food establishment for purposes of direct sales, which was required by FSMA. Sales directly to consumers through community supported agriculture shares, roadside stands, farmers markets, online

farmers markets, online grocery delivery and all other direct-to-consumer channels should be included in the direct sales threshold in the definition of retail food establishment in the final rule.

- A definition or description of material conditions is not presented in the draft rules regarding the FDA's authority to withdraw the qualification for the exemption or alternative set of rules for small farms or facilities. Providing the clarity that FDA would need evidence before initiating withdrawal proceedings is important for guiding farmers in their decisions about how to run their business and transparency.
- The definition of packing and holding in the draft Preventive Controls Rule does not take into account the role that community supported agriculture efforts, farmer cooperatives and other activities play in aggregating fruits or vegetables from a number of small farms for direct sales. This needs to be clarified so that such food hubs and other innovative ways to reach markets do not trigger the rules for large industrial operations.

FDA's proposed process to withdraw a small farm or facility from the less burdensome requirements of the Produce or Preventive Controls Rules is overly severe, unfair, and does not allow recourse for the farmer or owner. We believe that if FDA has evidence of a food safety risk at a qualified exempt entity, it should first employ warning letters and technical assistance as opposed to immediate withdrawal. Unless repeated, egregious, or intentional actions on small farms and facilities are threatening food safety, FDA should not withdraw qualified exempt status. FDA should also outline a reasonable path and timeline for a small farm or facility to address any food safety issues and regain its original qualified status.

Additionally, we have concerns beyond administering our amendment. In the proposed Produce Rule we demand that FDA harmonize provisions on manure and compost with the Department of Agriculture's National Organic Program. The organic standards have been reviewed, field-tested, and accepted by farmers. Setting even more restrictive standards than organic for produce farmers is unnecessary and would make organic produce farming nearly impossible.

Finally, the agricultural water standard and testing requirements in the draft Produce Rule must be dropped. As currently drafted, these requirements are unworkable and unaffordable for small farms. Further, there is little evidence of irrigation water causing disease outbreaks or food safety issues, even if farmers could control its incoming quality. FDA should not implement these rules until there is real evidence that they are warranted and enough data exists to determine the best methods for safeguarding produce from and testing irrigation water.

In conclusion, we urge you to rectify the Produce and Preventive Controls Rules such that the final versions ensure that small farms, farmers' markets, and local cooperatives are able to thrive while protecting food safety from the biggest threats. Thank you for your consideration.

Sincerely,

Jon Tester

Kay Hagan