

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

November 15, 2013

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

Dear Commissioner Hamburg,

Please accept our gratitude for facilitating meetings in Vermont and New Hampshire on the Food Safety Modernization Act (FSMA) this past September. Those meetings provided an important opportunity for Vermont food producers and processors to learn about and discuss the impact of the proposed FSMA rules on their businesses while also providing an opportunity for Food and Drug Administration (FDA) officials involved with developing FSMA implementation rules to see first-hand the highly diversified and strongly local farm and food production sector that is thriving in New England. We hope that the information gathered during the visits will result in rules that work for this model of food production.

Food safety is our priority and we support the FDA's focus on strong, consistent food safety rules to protect consumers. We understand that food safety is essential to protect the Vermont brand, which is strongly identified with quality. The FSMA can help protect our nation's food supply and inspire confidence among consumers at home and abroad.

It is critical, however, that the FSMA strengthen food systems in all regions of the country. In our state of Vermont, the FSMA must support the dynamic and diverse agricultural enterprises that are strengthening our economy, addressing key public health and environmental issues, and preserving our landscape and our agricultural heritage. A one-size-fits-all outcome tailored for large commodity scale food production, which the current proposal represents, could crush our agricultural economy.

We write to bring your attention to several significant aspects of the proposed Produce and Preventive Control rules that, if implemented as proposed, would not enhance food safety as FDA intends, and would seriously disrupt our Vermont food systems. Please give close attention to the substantive comments submitted by the Vermont Agency of Agriculture, Food and Markets. Below we have highlighted our priority concerns.

**Federal-State Partnership**

The FSMA will be only as effective as its on-the-ground implementation. This requires the FDA to establish clearly-defined relationships with the states as food safety regulators. The state's regulatory authority and relationship with the FDA is not clearly defined. Appropriate and realistic timelines need to be adopted for states to implement the law. At a time when every state

faces tight budget constraints, the states must have access to the funds and technical resources required to fulfill their responsibilities under the FSMA. The new rules will be unworkable and counterproductive unless there is a well-trained work force on the ground working proactively with producers towards the common goal of food safety. We find the draft rules to be critically lacking in these basic requirements. The federal-state relationship must be fully developed before the law can be implemented.

### **Addressing Diverse Business Models in Exemption Thresholds**

The FSMA provides for exemptions or reduced compliance measures for small producers, and we actively sought those accommodations before voting in favor of the legislation. We are concerned that the implementation of these thresholds under the draft rules would cast such a large net as to subvert legislative intent and subject small producers to prohibitive compliance and fee burdens. The thresholds for exemptions must be implemented so that they address a variety of business models and ownership scenarios in order to fulfill our legislative intent. The proposed rules are unclear in their categorization of farms, resulting in many small farms being subject to both rules.

In passing the FSMA Congress included options and flexibility for the FDA to be able to modify requirements to address the diversity of agriculture that we have in New England and across the country. This was done to reduce the regulatory burdens and compliance costs for smaller farms and facilities that participate in our direct-to-consumer supply chains. We are very concerned that by setting the threshold for eligibility based on the calculation of a farm operation's average annual gross sales for 'all food,' rather than just the produce or product regulated will cause many diverse farm operations to absorb significant costs of compliance that were not intended.

This use of 'all food' sales as a calculation will discourage our dairy, livestock, and commodity producers that may be interested in diversifying their operations to meet demand for local produce because they would be forced to come under the full weight of the FSMA regulations and would not be allowed the eligibility levels Congress had intended. The administrative burden and tremendous regulatory costs would discourage farms from diversifying or even setting up a seasonal summer roadside vegetable stand to supplement their income because they would be required to meet the high cost industrial scale regulation even when their produce production is at a very small scale. We encourage you to use the flexibility we gave you in the FSMA to address this eligibility issue so that in the Produce Rule, only covered produce would count towards the threshold for eligibility of modified requirements and in the Preventive Controls Rule, only regulated product would count.

### **Conflicts with National Organic Program**

We are particularly concerned with the many conflicts the FSMA Produce Rule has with the National Organic Program (NOP). Additionally, many Vermont farmers are already compliant with USDA's Good Agricultural Practices (GAP), an effective quality control program. In many cases the proposed rules are at odds with GAP. The USDA and FDA should clearly harmonize their rules and coordinate their interaction with producers. This must be addressed in the proposed rules and not left to chance.

## **Dairy**

We are deeply concerned that the proposed rules pre-empt the successful Pasteurized Milk Ordinance (PMO) and would require significant infrastructure investments by producers for compliance. The PMO has protected consumers and provided successful guidance for the dairy industry for many years. Milk is among the safest food products on the market today and to arbitrarily change an established and highly successful federal food safety program is directly contrary to the goals of FSMA. This change would be inefficient at best and fly in the face of legislative intent.

## **Water and Soil Health**

In these categories, the FSMA proposed rules simply do not reflect scientifically proven best management practices. The nine-month manure application interval is untenable in the Northeast, and Vermont experts find it scientifically suspect and directly contrary to best practices for soil health and water quality. The frequency of required water testing, and thresholds under the proposed rules, also needs further scientific justification to ensure that they produce real food safety outcomes and are not an arbitrary financial burden for farmers.

We have heard from the full range of Vermonters involved in food production, from farmers to distributors to processors, about the impact of this new law on their businesses. They, too, hold food safety as their number one priority; and consumers from local to global rely on these businesses to continue to provide safe, healthy, high quality food products. The FSMA should support and help enhance these efforts.

In conclusion, we support the Food Safety Modernization Act and share the FDA's overarching concern for the safety of the United States food supply. We are very focused on the safety and quality of Vermont's food products because of the considerable value inherent in the "Vermont" brand. But we have grave concerns that the rules, as drafted, are a blunt instrument that will crush Vermont's blossoming diversified, small, local, value added agricultural sector and also harm our dairy industry.

We request, in the strongest terms, that the FDA revise the proposed rule in response to serious concerns from the agricultural sector, and issue a subsequent draft for public review before moving to final rule making. Thank you for your work to date on this very important matter and for your consideration of our concerns.

Sincerely,



PATRICK LEAHY  
United States Senator



BERNARD SANDERS  
United States Senator



PETER WELCH  
United States Representative