Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Preventive Controls Rule: FDA-2011-N-0920 and RIN 0910-AG36

Dear FDA:

The undersigned organizations represent farmers, food businesses, and consumers across the United States. We jointly submit these comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (hereinafter, proposed rule for Preventive Controls).

I. Definition of "very small businesses"

In the proposed regulation, the FDA has already used the Small Business Administration's definition of "small business." The FDA's proposed definition of 500 employees reflects the SBA's classification of food manufacturing businesses as "small business" if they have fewer than 500- 1,000 employees, depending on the precise type of food manufacturing. *See* http://www.sba.gov/content/small-business-size-standards, Subsector 311.

To be consistent, we encourage the FDA to look to SBA's classification for "very small businesses" as well. While SBA does not have a definition for "very small businesses" specifically in the food sector, the agency has referred to businesses in general that have fewer than 20 employees as "very small." *See, e.g.* *http://www.sba.gov/advocacy/809/480821*, New Report Offers State-by-State Analysis of America's Small Businesses (Feb. 14, 2013). Considering the many other costs faced by food businesses – both the raw food and the buildings, equipment, and other hard costs – a food business with 20 employees is likely to have gross sales of well over $1 million.

Although the multiplier is different for each business, the average revenue per employee in 2012-2013 was over $500,000 in the food processing industry. *See* http://csimarket.com/Industry/industry_Efficiency.php?ind=505 According to a CNN Money report, the "food consumer products industry has an average revenue per employee of $400,000. http://money.cnn.com/magazines/fortune/fortune500/2007/performers/industries/revenues_per_employee/ (2006 numbers). The "food production" industry, ranked much lower, still has an average revenue per employee of $200,000. Even McDonalds, with one of the lowest revenue per employee ratios of all businesses, had a revenue of $65,000 per employee in 2011. http://www.foxbusiness.com/economy/2012/09/28/companies-with-least-valuable-employees/ Using **any** of these multipliers supports the contention that a business with 20 employees (SBA's

common definition for “very small business”) would have significantly over $1 million in gross sales.

Therefore, of the options that FDA is considering for “very small business,” ($250,000, $500,000, or $1 million in gross sales), the most appropriate definition is $1 million.

As the agency has noted, businesses with less than $1 million in total annual sales of foods produce less than 2% of all food produced in the United States when measured by dollar value. *See* Regulatory Impact Analysis at p.4. Exempting these businesses from the new Hazard Analysis and Risk-Based Preventive Controls (HARPC) requirements will not affect the vast majority of food sold in this country.

At the same time, such an exemption is important to protect the viability of these very small businesses. The FDA has significantly underestimated the cost of formulating, updating and verifying a HARPC plan. Small facilities do not have the staff capacity or the funds to incur the respective proposed costs of compliance, which will be prohibitive. Businesses will be forced to downsize and to break successful relationships with wholesale buyers in order to qualify for the Tester-Hagan qualified exemption, or face business failure.

A recent study from Michigan State University found:

> The range of food hubs’ total gross sales for 2012 varied widely, with $324,500 the median amount. The average sales amount for all food hubs was $3,747,044, and the range was $3,206 to $75 million. Most food hubs were on the small side of the sales spectrum, with more than half of food hubs moving $500,000 or less in 2012.” (Fischer, M., Hamm, M., Pirog, R., Fisk, J., Farbman, J., & Kiraly, S. (September 2013). Findings of the 2013 National Food Hub Survey. Michigan State University Center, p.22).

This suggests that many of the food hubs will either have to stunt their growth to maintain exempt status or downsize if they are grossing just over $500,000 (the limit for the Tester-Hagan exemption). Food hubs provide a needed avenue to reach and build the capacity of small and midsize farms, encourage plant diversity and sustainable growing practices, and provide healthy food to low income communities. Many of these facilities are within their first 5 years of development and have limited capital and revenue to initially develop an HARPC plan for every seasonal food item, hire a certified inspector, and compensate the necessary support staff to measure and record the required data.

The FDA proposes no technical assistance to very small business facilities in order to understand or finance new compliance regulations. Businesses will incur both the direct cost of educational programs and the indirect costs of paying employees to work while receiving training. The FDA estimates that solely the cost of paying employees for time spent training will cost a business anywhere from $560-$28,000 per facility (depending on the number of workers). This issue applies directly to the definition of a “very small business” in that this requirement will cause financial distress for many facilities grossing as much as $1 million.

Local food sellers currently control less than 1% of the market and the HARPC requirements would likely decrease that amount significantly. Defining a "very small business" as one that grosses $1 million annually will allow many food hubs and CSA programs to continue their work directly with wholesale markets in their region, providing small farmers with a reliable market and greater community access to local food.

We urge the FDA to define "very small businesses" as those businesses with $1,000,000 (one million dollars) or less in sales of foods annually.

II. Exemptions for on-farm, low-risk activities

Under proposed section 117.5(g), the agency proposes to exempt "on-farm packing or holding of food by a small or very small business if the only packing and holding activities" the farm conducts involve hard candy, cocoa beans, cocoa products, grains and grain products, honey, intact fruits and vegetables, jams, jellies and preserves; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugars.

Under (h)(2), the agency also proposes to exempt a specific list of manufacturing/processing activities conducted by a small or very small business located on a farm on raw agricultural commodities (RACs) from other farms, including such things as artificial ripening of intact produce, coating of intact produce, dehydrating intact produce, extracting oils from grains, making candy, making jams and jellies, and making honey. The same activities are exempted when done on a farm's own raw agricultural products, either by listing in (h)(1) or because they aren't classified as manufacturing/processing when done on a farm's own RACs.

FDA's recognition in the proposed regulation that these food/activity combinations are low risk is correct. These activities do not present significant threats to public health and should not subject a farm to the requirements under the proposed Preventive Controls rules.

We urge the FDA to maintain the exemptions currently listed in section 117.5(g) and (h).

We further urge the FDA to add the following low risk activity/food combinations, which pose equally low risks, whether conducted on the farm's own RACs or the RACs of another farm:

1. Making syrups from sorghum, rice, malted barley, etc. Sorghum is commonly grown in the Southeast and Midwest for the production of sorghum syrup. The manufacturing process is substantially the same as sugar from sugarcane.
2. Making molasses from sugarcane and sugar beets.
3. Making vinegar, including infused and flavored vinegars.
4. Extracting virgin olive oil.
5. Extracting oil from seeds.
6. Drying/dehydrating herbs and mixing dried herbs for mixes.
7. Baked goods that do not require time or temperature controls for safety to limit pathogen growth or toxin production. Many foods that are baked do, in fact, encompass "inherent controls for food-borne pathogens" in the process of arriving at the final product.

III. Exemption for low-risk activities conducted off-farm and larger farm mixed-type facilities

Section 117.5(g) and (h) only provide an exemption when the low-risk activity/food combination occurs on a small or very small farm mixed-type facility. But the designation of these combinations is based on an assessment of the risk of pathogen contamination and activity, which does not depend on the location at which the food is produced or the business structure governing its production. Therefore, limiting these exclusions based on location is not based on science or a risk-analysis.

We urge the FDA to exercise its discretion under the FFDCA to extend its low-risk activity/food combination exclusions to very small or small businesses that are not co-located on farms, as well as to mid-sized and large farm mixed-type facilities.

At a minimum, if FDA does not extend the exemption to cover these activities to mid-sized and large farm mixed-type facilities, we urge the agency to implement one of these options:

1) Exempting those activities that do not involve commingling of products, namely where the mixed-type facility maintains the original identity of each item;
2) Allowing for a simplified HARPC plan for the low-risk activities

IV. Application of Subpart B, Good Manufacturing Practices

The proposed exemptions for "qualified facilities" under the Tester-Hagan amendment, low-risk on-farm activities, and very small businesses is only from Subpart C, the HARPC requirement. FDA has proposed that these small, low-risk and direct-marketing facilities should still be subject to Subpart B, Current Good Manufacturing Practices (proposed sections 117.10 – 117.110), however.

The CGMPs cover everything from personnel cleanliness, education and training, the grounds and area around the facility, plant construction and design, operational aspects, sanitary facilities and controls (including toilets), equipment and utensils, processes and controls, raw materials and ingredients, and warehousing and distribution. These types of process-based regulations typically favor large operations and are not often feasible or cost-effective for small-scale operations.

Every state already regulates food handlers, processors, and manufacturers to comply with a variety of food safety regulations and licensing requirements that address many of the same issues as the CGMPs. Many local governments have additional regulations.

In fact, according to FDA, all of these state codes are based on FDA's own Food Code. [1] According to the Harvard Law School Food Law and Policy Clinic:

> While necessary to protect the public from foodborne illness and food contamination, these regulations often have the unfortunate side effect of making it difficult for small-scale producers and retailers to compete or even survive in the local food industry…
>
> While the FDA Food Code and related laws were meant to safeguard public health and uphold sanitation standards, certain provisions may interfere with small-scale, local processing operations that might otherwise provide nutritious foods to residents of food deserts and other high-need regions.[2]

The Clinic goes on to recommend the review of state rules "to eliminate, where possible without risking food safety, provisions that are barriers for small-scale food producers."[3]

Indeed, many states have carefully crafted such exemptions, including cottage food laws that allow home processing of low-risk foods.[4]

As with the HARPC requirement, we believe that this state and local regulation is sufficient for small-scale, direct-marketing operations.

We therefore urge FDA to exempt qualified facilities and mixed-use farm facilities that are conducting only low-risk activities from Subchapter B as well as Subchapter C.

V. Retail food establishment definition.

In the FSMA, Congress directed FDA to clarify the definition of "retail food establishments," which are exempt from the registration requirements of the 2002 Bioterorrism Act and the new FSMA requirements. Under the agency' regulations implementing the 2002 Biotoerrorism Act, it was unclear whether farms that sold their products off-site through farmers' markets, CSAs, farm stands, or similar venues would be considered "retail food establishments" for both locations.

FSMA states:

> (c) CLARIFICATION OF INTENT.—

[1] http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FederalStateCooperativePrograms/UCM230336.pdf

[2] "Good Laws, Good Food: Putting State Food Policy To Work For Our Communities", Harvard Law School Food Law and Policy Clinic, November 2012, p. #. Available online at http://www.markwinne.com/wp-content/uploads/2012/09/food-toolkit-2012.pdf

[3] Id, p. ___

[4] "Legislative and Regulatory Recommendations to Allow Home-Processing of Low-Risk Foods in Mississippi", Health Law and Policy Clinic of Harvard Law School and Harvard Law School Mississippi Delta Project, December 2010, http://blogs.law.harvard.edu/foodpolicyinitiative/files/2011/09/In-Home-Food-Safety-FORMATTED.pdf

> (1) RETAIL FOOD ESTABLISHMENT.—The Secretary shall amend the definition of the term ‘‘retail food establishment’’ in section 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include—
> (A) the sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;
> (B) the sale and distribution of such food through a community supported agriculture program; and
> (C) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.

See Food Safety Modernization Act §6102(c). The agency needs to incorporate the legislative changes into the regulatory definition.

VI. Qualified Exemption

The FDA is proposing that small, direct-marketing facilities be required to resubmit their information every two years to continue to qualify for the "qualified exemption." *See* proposed section 117.201(c). The agency has not provided specific reasons as to why such a requirement is appropriate.

To qualify for the Tester-Hagan exemption, a facility need only gross under $500,000 in food sales annually and sell more than half of that directly to individual consumers or to restaurants and retailers within the same state or within 275 miles. There is no reason to expect that these conditions will change on a frequent basis for the vast majority of small, direct-marketing facilities.

Imposing a 2-year renewal requirement simply increases the costs in time and labor on these very small businesses. The renewal requirement also imposes a cost on the taxpayers.

We urge the FDA to require facilities that qualify for the Tester-Hagan exemption to re-register only every five years or whenever there is a material change to the information.

VII. Supplier approval and verification

Any requirements for supplier approval and verification should **not** prevent regulated facilities from purchasing ingredients and products from exempted facilities. (Appendix, Section II, pages

660-665.) Producers and facilities that are exempted from portions of these rules because they are already appropriately regulated by state and local requirements should be treated the same as those facilities that are regulated by FDA's rules.

Farmers markets, joint CSA programs and local food hubs have all created sustainable infrastructure that has allowed small farmers to tap into larger wholesale markets. Wholesale relationships provide a reliable market for small farms and greater access to and knowledge of healthy local food generally.

If regulated facilities are required or encouraged not to purchase products from exempted facilities, small farm sales opportunities become drastically limited and require extensive marketing skills most farmers do not have time to develop or commit their resources to. Buying locally from small-scale farmers should be an incentive for wholesale buyers who will maintain individual procurement and storage standards for the safety of their produce.

We urge the agency to explicitly clarify that regulated facilities can source ingredients and products from exempted farms and facilities without penalty.

VIII. FDA has overestimated the benefits and underestimated the costs of the proposed rule

As with the analysis of the proposed rule for Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, the FDA has overestimated the benefits of the proposed rules by inappropriately using the multiplier from Scallan et al.'s study to unknown pathogens. (see comments submitted by the undersigned on FDA-2011-N-0921)

The proposed rule suggests that inspectors will be required to have specific training designed and approved by the FDA. With the quick turn-around time for small food businesses, the limited number of projected inspectors suggests that the cost of hiring such personnel will be significant. An inspector pay rate must be established and respective results considered in the process of defining a "very small business". The current proposal suggests unknown costs to the facility and vague projections on the number of certified inspectors.

The proposal does not consider the potential costs to consumers as a result of increased compliance costs for businesses. Research is needed on the market effects of increasing the cost of food production and processing. Small farmers already struggle with economies of scale and increased cost of food safety measures could impact pricing and respective consumer sales.

Millions of urban and rural residents in very low- to upper-income brackets rely on local farmers at farmers markets, CSAs, schools and grocers, for healthy, fresh produce, grains and value-added products. John Ikerd, University of MO-Columbia Professor Emeritus, spoke at the 2005 Eat Local Challenge kickoff in Banks, Alabama. His address is linked at http://www.nalusda.gov/afsic/pubs/csa/csa.shmtl:

> Over the past five years, I have had the privilege of speaking at 35 to 40 different venues a year, and most of those were conferences associated in one way or another with sustainable food and farming systems. These conferences range in size from a few dozen people to a few thousand. At least six conferences in North America now average over 1500 attendees a year, several others draw 500-700 people, and so many have 100-250 attending they would be difficult to count. Increasingly, these conferences are planned by farmers in collaboration with consumer groups or by consumer groups collaborating with farmers. Clearly, sustainable agriculture is moving into the food system, and equally important, the emphasis of sustainable agriculture is shifting toward eating local.

We urge the agency to re-evaluate both the costs and the benefits of the proposed rule.

IX. Request for extension to comment period

The Regulations.gov website was not functioning for multiple periods of time between Monday, November 4, and Tuesday, November 12. For much, if not all, of the last weekend of the comment period, individuals were unable to submit comments online. It is unknown how many people were unable to submit comments as a result. We urge FDA to extend the comment period for at least a week to compensate for this problem.

X. Conclusion

Consumer demand for local food is growing rapidly. Farmers and producers are seeking to meet this demand, but the Preventive Controls rule is likely to limit their ability to do so. The consequences will be not only the loss of healthy food availability for consumers, but the loss of many of the other benefits provided by small and very small food businesses. For example, local food hubs and CSA's have greatly impacted many communities, providing new jobs, ensuring local farmers a fair wage and providing consumers with a direct access link to their food source. Putting unfeasible limitations on these businesses will harmfully impact their goals and mission of providing healthy and safe food at a fair price.

Submitted:

Submitted:

Judith McGeary
Executive Director
Farm and Ranch Freedom Alliance

John-Mark Hack
Executive Director
Local Foods Association

A. Richard Bonnanno, Ph.D
President
Massachusetts Farm Bureau Federation, Inc.

Kathy Ozer
Executive Director
National Family Farm Coalition

Sally Fallon
President
Weston A. Price Foundation

Mabel Dobbs
Chair of Ag and Food Campaign Team
Western Organization of Resource Councils

and

Dakota Resource Council (ND)

Dakota Rural Action (SD)

Idaho Organization of Resource Councils

Northern Plains Resource Council (MT)

Oregon Rural Action

Powder River Basin Resource Council (WY)

Western Colorado Congress

North Carolina Association of Black Lawyers Land Loss Prevention Project

Community Farm Alliance (KY)

Ashtabula, Geauga, Lake Counties Farmers Union (OH)