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

December 15, 2014

Re: Preventive Controls Rule: FDA-2011-N-0920

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 HARPC Rule).

I. Very Small Business

We strongly support the definition of "very small business" in the proposed HARPC Rule as a business that grosses $1 million or less in sales of human food annually.

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. Exempting these businesses from the new HARPC requirements will not affect the vast majority of food sold in this country.

This 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 costs of compliance, which will be prohibitive. Without the exemption for very small businesses, 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.

By defining "very small business" as those with sales less than $1 million, the FDA has simplified the application of the qualified exemption in the HARPC Rule without sacrificing food safety. We support this definition, and encourage the agency to further refine the definition to base the threshold on "covered human food," as discussed next.

II. How to calculate sales for determining the size of the farm or business

When Congress passed FSMA, it did not give FDA authority over all types of food. In addition, FDA has already recognized that even some of the food types within its jurisdiction should not be covered by the new rules.

These limitations on the scope of the FSMA rules should be reflected in the calculations of sales in determining whether and to what extent a farm or food business is covered under the rules. We support the proposed change to base the definition of small and very small businesses on sales of "human food" as opposed to all "food." We urge the agency to go further, however, and base the definitions for all size-based determinations on "covered human food."

III. Definition of a "farm"

FDA should not classify "farms" as "facilities," and thus impose additional regulations on them, unless there is a specific risk-based reason to do so. A farmer-operated business that engages in farming activities (growing, harvesting, packing, and/or holding raw agricultural commodities) should be consistently classified as a farm, not a facility.

We recommend the following changes in the proposed rule:

- FDA should remove the phrase "in one general physical location" from the farm definition, to reflect the fact that farms are not always contiguous and that farms may include structures in different locations or on different parcels of land; these aspects do not increase the risk of foodborne illness.
- FDA should remove the phrase "under one ownership" to reflect the fact that farmers may join together in food hubs and cooperatives to market their products without increasing the risk of foodborne illness. For purposes of the definition of a farm, a multi-ownership operation should be included so long as all of the partial owners are themselves farmers.
- Farmer should be defined as a person who actively participates in the management or daily operations of a farm.

IV. Qualified Exemptions under the Tester-Hagan amendment

FDA should implement the Tester-Hagan provisions in a manner that respects normal principles of due process and that doesn't risk pushing a small-scale producer out of business with a too-hasty or erroneous decision to revoke their exemption and too-short deadlines for compliance.

As the agency has acknowledged, it has other mechanisms to address urgent problems, such as mandatory recall or administrative detention. Not only should those other mechanisms be considered, **but their existence means that revocation of the exemption is not an urgent affair that must be rushed through.**

The top three changes required to ensure that the Tester-Hagan amendment is fairly implemented are:

- Require that FDA include a specific statement of the reasons in the notice of revocation, so that the producer can respond to the specific issues of concern.
- Provide appropriate time (at least 90 days) for producers to submit the facts and documentation showing that their exemption should not be withdrawn.
- Provide at least one year for a previously exempt farmer or producer to come into compliance with the FSMA regulations after revocation. Large facilities are given one year to come into compliance – requiring these small and micro-businesses to comply in just four months is not reasonable.

We also urge the agency to make the following additional changes:

- Require FDA to have probable cause before initiating an investigation of an exempt farmer or food facility, and to present clear and convincing evidence for revoking the exemption.
- Guarantee a hearing so that producers can present their case in person before having their exemption revoked.
- Provide the standard post-decision procedural protections, such as motion for reconsideration and a motion for stay.
- Specify that the reinstatement would occur within a reasonable period of time.

We support the agency's proposal to calculate the date of compliance from the date of the receipt of the order, rather than the issuance of the order. We also support the proposal to extend the time for compliance to 120 days rather than the original60 days, although we continue to urge a longer time for compliance, as stated above.

V. Supplier Verification Program

The supplier verification requirements in proposed §117.136 should not be adopted in the final rule because of its excessive costs in relation to likely benefits. Moreover, when applied to facilities that are receiving raw produce, the supplier verification program effectively imposes an entire second layer of regulation on produce farms, an unnecessary burden that is not authorized by FSMA.

At a minimum, if FDA does include requirements for supplier verification in the final rule, FDA should remove the onsite audit requirement from the supplier verification program. In many cases, onsite audits would require both expertise that the facility owner does not have and extensive travel, imposing huge burdens in both time and out-of-pocket expenses. In practical terms, this turns into a requirement to hire third-party auditors, which is not authorized by FSMA.

The FDA should create a "safe harbor" provision that provides that the supplier verification requirement is met by having the supplier provide a copy of any permits they hold from, or the most recent inspection done by, federal, **state, or local health** authorities. The FDA has already

proposed that an inspection by FDA or an equivalent foreign authority may substitute for an on-site audit, and it should extend the same recognition to state and local health authorities.

If the supplier does not have such permits (such as in the case of a produce farm, which is not required to be permitted), then the supplier verification program should able to be met by a review of the relevant records and/or sampling of the raw material **based on the scale of production.** Scale-based requirements, such as testing one sample for every 1,000 lbs of produce, ensures that smaller producers do not have disproportionate testing requirements imposed.

The FDA should also remove the provision that qualified farms or facilities provide written assurances that they meet federal requirements. This provision threatens to indirectly impose requirements on exempt producers and create barriers to marketing through its sheer ambiguity. Exempt farmers and facilities, by definition, are small-scale producers who are subject primarily to state and local laws. Asking them to provide written assurances that they are complying with unspecified federal regulations is both ambiguous and deeply troubling.

In practice, without seeking legal counsel, many exempt farmers would be unable to provide such written assurances, creating a significant barrier to marketing their products to non-exempt facilities. Since non-exempt facilities comprise the overwhelming majority of the food market, according to the FDA's own estimates, this severely limits the ability of these exempt farmers and facilities to market their products. The ambiguity around actual requirements converts a seemingly minor requirement (providing written assurances) into a very significant barrier.

We urge the agency to amend the proposed provision for a supplier program to provide that, if the supplier is a farm or facility that is subject to an exemption or qualified exemption, then (a) the receiving facility does not need to conduct any supplier verification activities on the items from the exempt farm, so long as it (b) obtains written assurance that the farm supplying the ingredient or item is exempt (either entirely or under a qualified exemption) from the on-farm produce safety standards and HARPC rule.

VI. Environmental and Product Testing

The addition of product and environmental testing in proposed §117.165 vastly increase the cost of the proposed rule and will drive many businesses out of business without necessarily improving food safety. Not only is such testing costly under the best of circumstances, but many facilities do not have ready access to qualified laboratories. FDA should drop these provisions entirely.

At a minimum, the agency should adopt the following changes to reduce unnecessary expense:

1) Clarify that the environmental testing should be conducted only for surfaces that come into contact with the food under the normal operations of the facility, rather than encompassing every potential location within the facility. If a surface does not come into contact with the food, then the risk of contamination is very low and cannot justify the cost of the tests.

2) Have scale-based requirements, i.e. base the frequency of testing on the volume of food produced. For example, a test should be conducted for every X pounds or gallons of product. Any other approach will impose disproportionate costs on small and mid-size facilities.
3) Provide federally funded technical assistance for facilities to develop the environmental and product testing protocols.

VII. Re-urge previous comments

We re-urge the comments submitted by our organizations on November 22, 2014. In particular, we urge the agency to consider the comments about:

- Including additional activities in the list of on-farm, low-risk activities;
- Providing that facilities that are exempt from the HARPC requirements are also exempt from the good manufacturing practice requirements;
- Exempting low-risk activities conducted off-farm, or allowing for a simplified HARPC plan for such activities;
- Revising the definition of "retail food establishment" as directed in FSMA and extending or re-opening the comment period on the proposed HARPC Rule to allow individuals to comment on the HARPC Rule once FDA has clarified who is, and who is not, subject to the rule.

We also re-urge our comments on the issue of the cost-benefit analysis. These are copied below:

> 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)
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> 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.
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> 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.

Conclusion

We urge the agency to make the changes discussed above, as well as the additional changes urged in our earlier comments submitted on November 22, 2013.

Submitted:

Farm and Ranch Freedom Alliance
By: Judith McGeary, Executive Director

Weston A. Price Foundation
By: Sally Fallon Morell, President

Local Food Association
By: John-Mark Hack, Executive Director

National Family Farm Coalition
By: Kathy Ozer, Executive Director

Massachusetts Farm Bureau Federation
By: A. Richard Bonanno, PhD, President

Powder River Basin Resource Council
By: Bill Bensel, Lead Ag Staff