VABF
Virginia Association for Biological Farming

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

Docket Nos. FDA-2011-N-0921 and FDA-2011-N-0920
RIN 0910-AG35 and RIN 0910-AG36
Submitted electronically via http://www.regulations.gov

Re: Comments on the supplemental proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; and comments on the supplemental proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

To All It May Concern:

The Virginia Association for Biological Farming (VABF) would like to offer the following comments on the Food and Drug Administration's (FDA) supplemental proposed rules on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule) and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule).

On November 11, 2013, VABF submitted extensive comments on the first Proposed Rules for Produce and Preventive Controls. We appreciate FDA's efforts to make the Rules more practical for small and medium scale produce farmers. At the same time, upon review of the supplemental proposed rules, we remain concerned that several provisions in the Re-proposal could impose unwarranted burdens on our farmer members and other family farms across the US, and/or create barriers to the development and expansion of local, sustainable food systems. We address these issues in the following pages.

VABF is a membership-based organization whose mission is to educate about, advocate for, and promote organic and sustainable farming and gardening in Virginia, and to provide practical information and technical support to organic and sustainable farmers in the state. We represent over 260 members, of whom at least 77 are commercial farmers making all or part of their living through production and

sale of produce and other foods. Our member farmers are typically small, partial income operations of less than 15 acres and sell primarily through direct retail markets, such as farmers' markets; our membership also include full time farms of over 1,000 acres. At least 40 of our member producers operate a Community Supported Agriculture (CSA) program.

Most of our member farmers are vegetable producers, many operate integrated crop-livestock farms (such as laying hens and vegetables), and many utilize value-added marketing and on-farm processing of goods (such as jams, jellies, pickles, apple and pumpkin butters, breads, pasta, sauces, etc.) to maximize

returns. Nearly all of our producer members gross less than $500,000 annually and market primarily to "qualified end users" (within state or within a 275 mile radius), and are thus eligible for the modified requirements under the qualified exemption. All of our producer members share a commitment to resource conservation, to ecologically sound and biologically based production systems, and to providing safe, wholesome, high-quality food to their customers. We welcome opportunities to further improve food safety, yet share a deep concern about additional regulation that could add costs that will cause many small farm enterprises to become financially unviable without substantially improving consumer safety. Our mulitple member and supporting organizations and agencies share these concerns.

Among our membership we also count at least four Farmers' Market managers, three who are engaged in processing and/or retail marketing of locally produced food, and a number of people who are interning on working farms, expanding home gardening and homesteading operations with an eye on marketing opportunities, or exploring the farming and local food sector as a profession. We are particularly concerned that additional regulatory hurdles could make it that much harder for new and aspiring farmers to get off to a successful start.

In addition, VABF counts dozens of health- and environmentally-conscious consumers who seek out local sustainably grown foods, and who support VABF principles and programs. Any food safety rules that make it harder for our family farms to enter or stay in the produce or integrated crop-livestock business could restrict their access to the quality fresh local foods they seek.

We appreciate this second opportunity to review and comment on FDA's revised approach to certain issues in the proposed rules. These revisions are a marked improvement over the original proposed rules, but there are still significant changes that need to be made to ensure these rules truly allow and support VABF producer members and other Virginia farmers to continue and expand their provision of fresh, safe, high quality food through the state's growing local food system infrastructure to a consumer public seeking the qualities of locally, sustainably grown.

Thank you for considering our comments.

Sincerely,

Sue Ellen Johnson

Sue Ellen Johnson, Executive Director

Virginia Association for Biological Farming

1. FDA must further modify its definition of "farm" to fully reflect the reality of farming and to allow innovative farmers to continue growing, developing, and serving local and regional food systems.

We appreciate FDA for making significant improvements to the definition of "farm" in the re-proposed rules, especially for allowing the packing and holding of other producers' raw agricultural commodities (RACs) to be considered an activity of a "farm" and not a "food processing facility." This is especially important to many Community Supported Agriculture (CSA) producers, who often include other farmers' RACs in their weekly deliveries to sharers, or participate in multi-farm CSAs, in which several farms cooperatively serve a CSA clientele.

However, in order to ensure that certain farms are not subject to regulation as "food facilities", we urge the FDA to make the following additional changes:

- Drop the provision that limits a farm to "one general physical location." Many farms consist of two or more non-contiguous tracts of land, and/or operate a packing and holding shed separate from the main production area. Since the harvesting, packing, and holding activities conducted by these operations are not inherently any more risky than those of single-location farms, these operations should be recognized and regulated as farms and not subject to the Preventive Controls rule for facilities.
- Drop the provision that a farm must be "under one ownership." This definition would exclude cooperatively or joint-owned farming operations, and could subject cooperative packing and holding of RACs at an off-farm location to regulation as a "facility," even though the packing and holding activities in such a location entails no greater risk than on a farm under single ownership. More and more producers and producer groups are utilizing such cooperative arrangements to aggregate RACs in order to market them and to meet local demand more effectively. By removing the phrase "under one ownership" from the definition of "farm", the FDA can guarantee that the ongoing development of such innovative arrangements (that increase availability of fresh local produce and thus improve public health) is not thwarted by inappropriate regulation as a "facility."
- Add packaging and labeling to the list of low-risk activities that does not change an operation's status from "farm" to "facility."
- Clarify that "harvesting" activities can also include the following activities: removing foliage, removing roots, bunching, and braiding; and that "holding" activities include the blending or mixing of different intact RACs (for example, making salad mix from lettuce, spinach, and arugula).

Our overall concern and objective here is to ensure that farmers who enter into innovative cooperative agreements, or conduct routine activities associated with harvesting and holding produce, do not find

themselves faced with over-burdensome regulation under two Rules – a situation that could put many of these local food system leaders out of business.

2. FDA must specifically clarify that CSAs, including multi-farm CSAs, as well as farmers markets and all other direct marketing venues, are retail food establishments, not facilities subject to the Preventive Controls Rule.

In the FSMA legislation, Congress mandated FDA to clarify that CSAs, farmers' markets, and other direct marketing venues are not "food facilities" subject to the Preventive Controls Rule. Neither the original proposed rules nor the Re-proposed ruled do so. It is vital to the economic sustainability of direct-marketing farms that FDA correct this omission. Specifically, we urge FDA to:

- Include in the Final Rule clear language stating that Community Supported Agriculture farms (CSAs), farmers markets, farm stores, direct internet sales, tailgate markets, pick-your-own operations, and other direct-to-consumer venues are "retail food establishments," and not "facilities," and are thus not subject to regulation as facilities.
- Issue a separate rulemaking and public comment period for this additional language, to ensure it fully addresses this issue.

3. Annual sales thresholds for the full exemption and the modified requirements ("qualified exemption") must be based on sales of those food items covered by the Rule in question.

In the re-proposal, the $25,000 threshold for full exemption and the $500,000 threshold for qualified exemption (simpler compliance requirements) for farms regulated by the Produce Rule, is based on "all produce." While this is an improvement over the original proposed rule, which based the thresholds on all food sold, it can still create a barrier to farm diversification. For example, a farmer who grows potatoes, winter squash, and other non-covered produce might want to diversify into salad greens or tomatoes, beginning on a small scale (say, $10-20,000 annually). As the Produce Rule is currently proposed, that farmer would be subject to regulation under the Produce Rule, and would face the full regulation if annual proceeds from non-covered produce exceeds $500,000. This would make diversification too costly for most such producers to consider.

Similarly, as the re-proposed Preventive Controls Rule is currently written, small food processing enterprises whose annual sales of "human food" exceed the $1 million threshold for "small business" would be subject to the full regulation, even if sales of products covered by the Preventive Controls Rule are well below this figure.

We recommend:

- For the Produce Rule, that FDA base annual sales thresholds for full exemption and qualified exemption on sales of covered produce.
- For the Preventive Controls Rule, that FDA base annual sales thresholds for modified requirements on sales of those foods covered by the Preventive Controls Rule.

4. Consider the costs to small, local food businesses of the new environmental monitoring and product testing provisions, and make these guidance for public comment, not regulation.

The Re-proposed Preventive Controls Rule includes new provisions for environmental monitoring and product testing, which would require businesses to regularly take samples of work surfaces and products being processed and test them for pathogens. These new proposed regulations would impose substantial additional costs on small and very small businesses. In the FDA's own estimation, costs to a small salad processing facility (<20 employees) would come to $2,891 annually for environmental monitoring, and another $12,000 for product testing. In the event that a facility must hold product pending test results, the latter figure could soar to $28,000, and product freshness could also suffer.

Furthermore, FDA anticipates that, as a result of the proposed food safety regulations, some farmers and facilities will go out of business, fewer people will start to farm, and more farmers will have to seek off-farm jobs to keep farming. Surely, this will make fresh produce – so vital to human health – scarcer and more expensive, rather than safer and more widely available. We urge FDA to go beyond merely acknowledging the adverse financial impacts of the proposed rules on producers, and modify them so that they do not create unwarranted barriers to farm prosperity and local food system development. Specifically:

- Make the environmental monitoring and product testing newly added in the Re-proposal *guidance* available for public comment, not part of the enforceable regulation.
- Conduct additional research into the costs and benefits of proposed environmental and product testing protocols, and develop a science-based and balanced approach.

Develop guidelines based on levels of risk associated with locally distributed products.

5. Remove the supplier verification provision from the final regulation.

In the FSMA legislation, Congress excluded the use of third party audits of suppliers (i.e., farmers) as a means of product verification. This was done to protect producers from having to undergo on site audits *in addition to* complying with the Produce Rule and any voluntary Good Agricultural Practices (GAPs) measures agreed between producer and buyer.

As currently written, the Re-Proposed Rule includes a supplier verification program that requires manufacturing facilities to seek on-site audits for their suppliers who provide ingredients that could

cause "significant adverse health consequences or death." This added expense would land squarely on the farmer, would be over and above the costs of farmer compliance with the Produce Rule, and would conflict with the FSMA regulation. Therefore,

- We strongly urge FDA to remove the supplier verification provision from the final rule.

6. Develop and implement a risk-based and science-based approach to agricultural water and food safety.

We appreciate that, in the Re-proposal, FDA modified proposed agricultural water quality requirements by developing a more flexible formula for assessing water quality, by reducing the required frequency of water testing, and by allowing for pathogen 'die off' between time of irrigation water application and harvest. However we remain concerned that the proposed water testing protocol and standards impose unwarranted burdens that are not science based. Proposed testing protocols and schedules still entail a substantial labor and financial cost, and the criterion used to evaluate the safety of a water supply – *generic E. coli* – shows poor correlation with the presence or absence of foodborne pathogens. Therefore, we recommend that FDA:

- Reduce the required number of water tests to three per year per water source (the current USDA GAPs guideline) for both surface and ground water.
- Allow a running average of the four most recent tests to establish the baseline, rather than requiring a new baseline to be established every 10 years.
- Allow multiple farms that share a single irrigation water source to share the costs of a single set of three water tests annually, rather than requiring each farmer to conduct tests.
- Undertake a thorough research program, similar to that proposed by FDA for manure and other biological soil amendments of animal origin, to determine a more science-based and risk-based approach to monitoring water quality.

Many of VABF's member producers, and other farmers within the state of Virginia, use surface waters to irrigate their crops during dry spells, and would be significantly impacted by the proposed testing requirements. Although our average annual rainfall is sufficient for crop production, droughts do occur, and can have disastrous impacts on vegetable production and producers in particular if the producer is unable to irrigate the crops as needed. Thus, this is a critical issue for our member farmers and other producers as well as our consumers.

7. Remove unwarranted barriers to the use of compost, manure, and other biological soil amendments of animal origin; and complete research into science- and risk-based guidelines in a timely manner.

Nearly all VABF farmer members, and many other farmers across the state of Virginia, depend to a significant degree on compost, manure, and other biological soil amendments to provide crop nutrients and maintain soil organic matter, soil life, and soil quality. Some producers compost manure and other materials of animal origin to FDA and National Organic Program (NOP) standards (>131 degrees F for 15 days in a turned windrow system), but others do not have the means to do so, and generally use the NOP guideline for uncomposted manure (120 day interval from application to harvest). Food safety regulations that would impose longer intervals, or that would require any waiting interval for finished compost (heated to NOP / FDA criteria) would make it more difficult for producers to utilize these soil-building sources of crop nutrients.

Therefore, we want to thank FDA for removing the impractical 9 month application-to-harvest interval for manure in the Re-proposal, for dropping the 45-day interval for finished compost, and for committing to conducting in-depth research in conjunction with USDA and farmers into the question of manure- and compost-related food safety risks and their mitigation. We also agree with FDA that, pending completion of the needed research, the NOP requirements regarding manure and compost offer an appropriate interim guideline for safe handling and use of these materials.

In order to arrive at the best possible outcome for sustainable agriculture and food safety with regard to compost, manure, and other biological soil amendments, we recommend the following:

- Be sure to include representatives of the sustainable and organic farming communities in advisory board(s) overseeing the process of conducting research and developing science- and risk-based criteria for safe use of soil amendments of animal origin.
- Clarify in the final rule that, in addition to applied manure, livestock grazing in production fields is also not subject to the unrealistic 9 month interval. Remove reference to such an interval for grazing from the Preamble of the final rule.
- In the final rule, explicitly affirm the NOP criteria for manure (120 day interval if produce has potential contact with soil particles, 90 days for produce that has no such contact) and compost (no time interval required if composted to >131 degrees F for 15 days with five turns) as sound interim guidelines with a good track record for protecting food safety.
- Clarify that insulation of composting windrows is *not* required. The NOP criteria for finished compost include no such requirement, and insulation is impractical in windrow systems, as it would interfere with proper composting every time the windrow is turned, thereby incorporating the insulating layer into the composting mass.

8. Include in the Final Rule language that explicitly supports farmers to implement good ecologically sound resource conservation systems, and encourage "co-management" practices that simultaneously promote conservation and help protect production fields from foodborne pathogens.

We thank FDA for improving language related to conservation practices in the Re-Proposed Produce Rule, so that farmers are less likely to be deterred from installing conservation buffer plantings or impelled to destroy wildlife habitat. However, we urge the FDA to go further, and to specifically recognize the benefits that conservation and habitat plantings such as field borders, buffer strips, windbreaks, hedgerows, and riparian buffers can intercept foodborne pathogens in overland water flow (runoff) and in windblown particulates (dust). Research has shown substantial pathogen attenuation in runoff by a 30 ft vegetated buffer between a produce field and a potential source of contamination, such as a livestock pasture. Similarly, a tall windbreak, hedgerow, or forest buffer can effectively intercept pathogen-containing dust from nearby animal production areas.

Specific recommendations include:

- Include in the Rule a definition of "co-management" as follows: *farm system management approaches that respond to site-specific conditions by integrating cultural, biological and mechanical practices that promote both ecological balance and public health by conserving and improving biodiversity, soil, water, air, energy, and other natural resources, while also reducing pathogen hazards associated with food production.*
- Add language in the Preamble to the Produce Rule that directly encourages producers to implement conservation / food safety co-management practices such as buffers that help protect produce fields from exposure to pathogens in runoff and airborne particulates, and other practices that are known to confer food safety as well as conservation benefits.
- Mandate training of FDA personnel in the value of conservation measures for protecting food safety.