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Florida Certified Organic Growers & Consumers, Inc (FOG) is a non-profit organization dedicated to educating and furthering the understanding and adoption of organic and sustainable agriculture. We are actively involved in many levels of our food system, from working with home gardeners, commercial farmers, food systems, improvement projects, policy evaluation, advocacy and social justice work. We also operate a certification agency which certifies almost 900 clients in 37 states and 11 countries. The certification program is accredited to perform USDA National Organic Program, GlobalG.A.P., Food Justice and other food safety and ethical certification for qualified operations.

No farmer wants to make someone sick and FOG values and supports the work of FDA and its mission to protect public health by assuring the safety, efficacy and security of our nation's food supply. We appreciate the opportunity to comment on these proposed rules and have several large concerns with the proposed Preventive Control Rule.

First, it is imperative that FDA align all of its proposed and final FSMA rules with the already existing National Organic Program regulations as required by the enabling legislation, and as closely as possible to work with and not conflict with or undermine other existing federal farm programs. It is our belief that the intent of Congress was for FSMA to be applied to large operations that pose the greatest threat of causing a widespread outbreak. It is imperative that FDA write a final ruling that embraces the spirit of the law and allows for an honest and fair exemption or modified requirement to small farms who sell directly to consumers and through short supply chains. We have serious concerns about the lack of clarity in regard to the definition of a farm and to what triggers a farm to be considered a facility. Because of the importance and immensity of these rules, we ask that FDA open up an additional public comment period after the current proposed rules are revised.

FOG is a member of and has been an active and a very involved participant in the development of and drafting comments from several national organizations. We support comments submitted by the National Sustainable Agriculture Coalition (NSAC) and the Organic Trade Association (OTA). FOG was involved with but have some differences with the comments submitted by the Florida Department of Agriculture and Consumer Services (FDACS) whose comments tried to reflect all of Florida's diverse agriculture and thus we feel the need to make clear our perspective.

FOG supports the overall efforts of FDA in helping ensure safe food for all Americans, however FOG finds that the proposed Preventive Controls Rule is incomplete and does not adequately establish a flexible regulatory framework, particularly for value-added businesses and on-farm processors, and could be harmful to organic and sustainable farms without reducing risk. Here are our more detailed comments and suggestions for improvement.

Farms Should Only be Covered by Only One Rule

- FOG is encouraged by statements from FDA that it was not their intent for farms to be covered by both the Cover Produce and Preventive Controls Rules and believes that the that farming activities be required to comply with the proposed Covered Produce rule alone, as it is

sufficiently detailed to address food safety concerns and these. It is the view of FOG that the activities described under harvesting, holding, and packing more appropriately fit under the Produce Safety Rule and not the Preventive Controls Rule, provided RACs are not transformed into a processed product.

- FOG recommends that FDA revise the criteria for applicability of the proposed Produce Rule and proposed Preventive Controls Rule such that, regardless of ownership of the RACs, all activities (including harvesting) would be treated consistently under either the proposed Produce Rule or the proposed Preventive Controls Rule.

FDA Should Adopt a "Very Small Business" Threshold of $1,000,000 in Covered Product

- According to FDA's Preliminary Regulatory Impact Analysis, the highest threshold proposed of $1,000,000 in total annual sales of food would cover only a tiny percentage, less than two percent of the food produced in the U.S. The impact of adopting the highest proposed threshold would be minimal for the vast majority of facilities in the food processing sector but for farms that might fall under the definition of "facility" and are considered "farm mixed-type facilities" under the proposed regulations, the decision will have a very significant impact. The HARPC requirements are designed for industrial food facilities, not for farms, and do not provide sufficient flexibility and are inappropriate for on-farm processors. Adopting at least the $1,000,000 threshold will protect many farms from the inappropriate HARPC requirements without impacting the vast majority of the food processing sector.

Establish an Exemption for Facilities with an Average Annual Monetary Value of Covered Product of $25,000 or Less

- FDA has not built in flexibility for extremely small facilities in the same way it has in the proposed Produce Rule for farms with $25,000 or less in food sales. It is FOG's opinion that the FDA should establish an outright exemption for extremely small facilities to ensure flexibility for the smallest food processing operations. An outright exemption for facilities that have an average annual monetary value of food regulated by the Preventive Controls Rule of $25,000 or less would not significantly add risk to the food supply.

FDA Needs to Expand the List of On-Farm Low-Risk Activities/Food Combinations

- FDA should retain the list of low-risk activities/food and add at least the following low-risk, value-added processing activities in the final rule: Acidifying, pickling, and fermenting low-acid fruits and vegetables made in compliance with existing Good Manufacturing Practices, baking activities involving grain products, roasting grains for animal feed, extracting oils from seeds, extracting virgin olive oil, making molasses from sugarcane and sugar beets, and making syrups from sorghum, rice, and malted barley.

Rule Implementation

- FOG believes that phased approach to education and enforcement, such as having guidance before the rule is to be implemented will do a great service for both producers and regulators. It is not enough to simply develop and distribute guidance materials. Ongoing education, outreach and compliance assistance also will be needed to make the rule effective. Guidance documents should be timely and written in plain language. Multiple formats will be needed for different uses and audiences. Communication may best be accomplished by locally based efforts. This will

require considerable coordination and adequate funding but will be necessary for the rules to have their desired effect without damaging our local food systems.

Foreign and Domestic Suppliers Must Have Same Requirements

- It is essential that as the rules come into enforcement that that there are adequate resources to provide oversight and compliance of these food safety requirements for both domestic and foreign supplies. If the requirements and regulations created by the law are enforced on domestic supplies, but not on foreign imports, the nation's food supply will be no safer than before and it will create an uneven playing field for our nation's farmers as foreign imports will not incur the costs of compliance. Adequate oversight and certification of third-party inspection firms is vital, and variances for imports must be as strictly controlled as those for states.

Comments on the Definition of "Retail Food Establishment" for Direct Marketing

- FOG asks FDA to amend the definition of "retail food establishment" to clarify that the sale of food directly to consumers includes the sale of food through community supported agriculture programs, roadside stands, farmers' markets, , farm stores, direct internet sales, tailgate markets, and pick-your-own operations and other direct-to-consumer venues. Without this required clarification, the direct-to-consumer venues could be regulated like food facilities that must register with FDA and are subject to the Preventive Controls Rule. This would be inappropriate and inconsistent with the statute and with the clear Congressional intent that these entities are not required to register and are not subject to the Preventive Controls Rule.

Comments on the definition of "Harvest"

- FOG asks FDA to redefine "harvest" for the fundamental need to capture farming practices as they exist. The "same ownership" provisions and the complexity of today's food and farming operations lead to many farms being required to register with FDA.

- FOG is in agreement with the definition of "harvesting" except for the condition that the RACs be grown on the farm or another farm under the same ownership. While this requirement makes sense at first glance, advanced farming practices, unique crop harvesting methods, and the incredible expenses of such systems make the sole ownership of some harvest equipment not possible in all situations. As a result, it is common to perform job sharing and equipment sharing for harvesting functions. FOG requests that FDA consider removing the sentence "[h]arvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown, raised, or another farm under the same ownership" from the definition of harvest. Removing this limitation will allow "harvesting" activities to remain part of "farm" activities.

Ownership Should Not be a Safety Measurement

- It's not uncommon for several smaller farms to send their produce to a larger farm with on-site packing sheds where the produce is packed for distribution. These kinds of situations offer a combination of production, aggregation, distribution, and marketing services, and make it possible for producers to gain entry into new and additional markets that would be difficult or impossible to access on their own. FOG does not agree that a farm or farm mixed-type facility that places others' Raw Agricultural Commodities into consumer containers should be classified as packaging (manufacturing/process), and therefore subject to the Preventive Controls Rule. It is the view of FOG that the activities described under harvesting, holding, and packing more

appropriately fit under the Produce Safety Rule and not the Preventive Controls Rule, provided RACs are not transformed into a processed product. The proposed Produce Safety Rule includes standards directed to harvesting, packing, and holding activities that will adequately ensure safe food regardless of the ownership of the farm the produce was grown on.

- Rather than focusing on the ownership of the product, FOG suggests FDA focus on "risk" and supplier verification. Farms should be required to assess their suppliers and accept produce from farms under different ownership provided they are receiving produce that was grown and harvested in a safe manner. Food borne pathogens do not care about the ownership of a farm. It's the farm activities that matter. A farm operating in compliance with the Produce Safety Rule will be able to ensure the safe harvesting and packing of raw fruits and vegetables regardless of the ownership of the farm the produce was grown on.

Building on Existing Standards

- Currently, many handlers/processors use and understand voluntary auditing programs such as Hazard Analysis and Critical Control Points (HACCP) and the Global Food Safety Initiative (GFSI). Customers demand these audits and because of market demand handlers will likely not stop requesting them. The differences between the proposed preventive rule and HACCP are insignificant. HACCP programs clearly focus on identifying preventive measures for hazards of concerns, and satisfy the proposed requirements for a food safety plan and the specific components therein. Also, the meat, juice and seafood industries currently work under federal HACCP guidelines identifying risks and applying appropriate control & mitigation strategies, which are well accepted in those industries. FOG urges FDA to recognize operations that have an established HACCP Program implemented by a qualified individual (including the PMO voluntary HACCP program) as meeting the requirements to the Preventive Control Rule. Recognizing HACCP and HACCP-based programs in general as equivalent would allow FDA to maintain consistent regulation of the industry through codifying a well-established program with proven efficacy. This, in turn, would reduce the regulatory burden on industry.

A Second Proposed Rule Should be Released Before a Final Rule

- As written, the rule will have significant impact on establishments throughout the country. Considering the number of questions asked in the preamble of the proposed rule and the number of tentative conclusions, the quality and legitimacy of a final rule would be improved if FDA were to consider and respond to the extensive comments received, and then issue a second proposed rule.

- FOG thanks FDA for its open approach and for its request for comments and for now considering the extensive comments submitted by thousands of stakeholders across the country. It is FOG's opinion that the numerous questions and comments like those listed here demonstrate the need for more time to continue this rule making process. An additional comment opportunity after the rules have been revised will prompt further discussion and exchange of information, and ultimately result in a better final rule.