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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 Produce Rules.

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. Any changes or shift in existing rules should not be made without significant and clear scientific evidence which, in the case of some of the conflicting proposed rules like those concerning biological amendments, does not currently exist.

While the proposed rules focus only on microbiological contamination, we ask FDA to please expand its scope to look beyond the acute food safety risks associated with the presence of microorganisms and thoroughly investigate the possible human and clearly evident environmental risk of genetically modified crops and chemical contamination from pesticides and synthetic hormones. There is growing evidence connecting widely used pesticides with a variety of terrible diseases like autism, Parkinson's and cancers. These are uniquely modern food safety problems that an updated Food Safety modernization act must address. For a FSMA to turn a blind eye to GMO and pesticide health effects and to not anticipate the widespread spraying of millions of pounds of 2-4-D as Round Up resistant weeds are now commonplace is not to see the forest from the tree. A clear fact that the average lifespan age of the US population is 74 years and the average farmworker life expectancy age is 49 years should tell FDA that food safety and application and use of toxic and often carcinogenic pesticides should not be separated.

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 regards 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 the FDA in helping to ensure safe food for all Americans however there are parts of the proposed rule that FOG is very concerned about and need further revision. Here are more detailed comments and suggestions for improvement.

Comments on the Overall Regulatory Framework

- FOG strongly urges FDA to keep the proposed "integrated approach" in the final Produce Rule and should not take a commodity-specific approach. Crop diversity is an integral part of sustainable and organic farming and creating a crop by crop set of rules would place undue burden on many growers and would have a potentially devastating economic effect on mixed vegetables operations. A diverse farm is a healthy farm and an integrated approach can insure that food is produced safely without discouraging needed diversity.
- In terms of requiring Farm Food Safety Plans and on farm registration, it is the opinion of FOG that this requirement is inconsistent with FSMA and unreasonable. FSMA does not authorize FDA to require farms to register with the FDA or to perform operational assessments or develop food safety plans. FDA would be guilty of regulatory overreach to require farms to register or perform operational assessments or develop food safety plans in its final Produce Rule.

Comments on General Provisions: Subpart A

- In regards to the \$25,000 gross sales exemption, FOG agrees with the \$25,000 gross sales exemption and believes that it is consistent with Congress' mandate to create risk-based requirements that reflect the diversity of the farming systems. However, FOG asks that the rule be modified to provide exemption based not on gross sales but rather on the value of covered produce. The rule as written would be an incredible disincentive for farms not currently producing covered produce to do so. Take for example a family-run potato farm in Hastings, Florida that grosses \$750,000. This farm may barely break the profit margin for many years, but is interested in diversifying its production in response to market demand. We do not feel that they should immediately have to comply with the full Produce Rule if they grow a very small amount of fresh covered produce for a few years in the attempt to diversify their operation.
- We strongly support FDA's inclusion of qualified exemption and modified requirements for small farms. These exemptions and modified requirements provide much needed relief to small and beginning farmers from while not significantly increasing risk. The small farmer relying on direct customer sales does not pose a food safety risk significant enough to warrant the full requirements of the Produce Rule. FOG appreciates FDA's acknowledgement of this. We are aware that some organizations argue that these exemptions and modified requirements leave out the vast majority of farms, and leave an inequitable burden on a few. While they are correct that the qualified exemption could apply to large percentage of total farms, it would only apply to a small percentage of total produce. According to the USDA's 2010 America's Diverse Family Farms report, the top 12% of farms account for 84% of farm production. Furthermore over 70% of what are defined as farms are either retirement farms, whose operators report they are retired, although they continue to farm on a small scale, or residential/lifestyle farms, small farms whose operators report a major occupation other than farming. It is the large operations

that pose the greatest risk to the largest amount of the public by virtue of the large percentage of produce they produce, and the distribution range that produce covers.

Comments on General Requirements: Subpart B

- The objective is safe food. If a farm operation is able to achieve the same outcome through means that are not provided for in the practice standards, we see no reason why that farm operation should not be granted the opportunity to establish alternative practices provided they have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in the regulation.

Comments on Agricultural Water: Subpart E

- Our concerns with the proposed agriculture water rules are that they place too much of a burden on the farmer without demonstration of a science and risk-based evidence for the rules. FDA should conduct additional and sufficient research to develop an appropriate, science-based numerical standard, which might vary according to the region for pathogens or pathogen indicators before establishing thresholds. The water situation in Florida is unique and we have doubts that the metrics for safety in Florida would be the same as for Montana.
- Once sufficient research has been completed to inform the development of an appropriate, vigorous science-based numerical standard, the numerical standard should be included in guidance, not in the regulation itself to allow for the standard to be updated if, and when new research becomes available. FDA references for water quality are not actually irrigation water quality standards, thus it seems unreasonable.
- It is also critical that FDA should not increase pollution and decrease the safety of the food supply by encouraging treatment of irrigation water with chemicals.

Comments on Biological Soil Amendments: Subpart F

- The proposed Subpart F, Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste conflicts the Organic Food Production Act of 1990. It also fails to provide to sufficient flexibility, and does not take into consideration, nor is it consistent with existing environmental practice standards established by federal natural resource conservation, wildlife conservation and environment agencies. Thus, it fails to meet the requirements of FSMA.
- Congress made it very clear in FSMA that nothing in the Produce Rule should conflict with or duplicate the requirements of the National Organic Program. There has been very little research conducted on many of the topics related to the application waiting periods for raw manure and compost and there is not sufficient scientific evidence to support many of the proposed produce standards. Even the scientific literature cited in the proposed rule does not support the nine month interval between the application of manure and harvest. We understand FDA's desire to set metrics but there needs be further research before any metrics not aligned with current federal policy are set. This will eliminate regulatory conflict without a reduction in food safety. Organic operators must maintain or improve natural resources (defined as soil, water, wetlands, woodlands and wildlife). Additionally, many farmers participate in voluntary federal conservation programs such as the Conservation Stewardship Program and the Environmental Quality Incentives Program. In FDA's preamble to FSMA, FDA includes important text relating to conservation such as "the application of practices that can enhance food safety, including

sustainable conservation practices”; and “proposed rule would not require the destruction of habitat or the clearing of farm borders.” FDA should more strongly support conservation in the final Produce Rule by incorporating statements and concepts like these from the preamble into the regulatory text.

- We strongly encourage FDA to revise the proposed Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste to align with the existing standards set by the Organic Food Production Act, Conservation Stewardship Program and the Environmental Quality Incentives Program which have proven records of governing safe food production.

Comments on Domesticated and Wild Animals: Subpart I

- We are also concerned with the proposed rules effect on diversified crop-livestock farming systems. We support that FDA states that the “proposed rule would not prohibit the use of on-farm domesticated working animals.” However, in addition to the significant issues with the nine month waiting period between the application of raw manure and harvest, FDA should not imply that an “adequate” waiting period between grazing and harvesting is nine months because there is no scientific basis for that assumption.

Comments on Withdrawal of Qualified Exemption: Subpart R

- In FSMA, it states that a qualified exemption could be withdrawn “[i]n the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm subject to an exemption under this subsection, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or harvested at such farm.” This creates two standards with high thresholds that FDA must meet before contemplating the withdrawal of a farm’s qualified exempt status: direct linkage and necessity.
- These high thresholds should act as a limit to FDA’s authority to act broadly in the use of the power to withdraw a farm’s qualified exemption. Qualified exemptions will be crucial to the viability of small and very small farms and to insure these high thresholds are met. FOG asks FDA to establish an evidentiary standard for withdrawing a qualified exemption, including evidence that shows direct linkage to a problem on a specific farm, and should require the FDA officer recommending the withdrawal order to show credible and substantial evidence that merits an order to withdraw. FOG also supports the inclusion of definitions of key terms, such as directly linked, necessary, and materiality.
- FOG would like to see a more fair and clear process for withdrawing and reinstating a farm’s qualified exempt status and believe FDA should substantially revise Subpart R.

A Second Proposed Rule Should be Released Before a Final 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.