



November 22, 2013

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

Federal Docket: FDA-2011-N-0921

The NJ Farm Bureau represents 11,000 members in the state of New Jersey. I would like to thank you for the opportunity to comment on the proposed Produce Safety Rule and the Preventive Controls Rule (Docket Nos. FDA-2011-N-0920 and FDA-2011-N-0921) because this rule has the potential to impact the future viability of our farms. NJ has many medium to small-sized fruit and vegetable farms that market their product retail and wholesale. We wish to bring to FDA's attention some of the impacts that this proposed rule may have on these farms that would be covered by the rule. There is a likelihood that some of these farms could determine the requirements of this rule to be too onerous, and therefore either convert to non-covered crops or cease operations.

Farm Bureau supports the production and sale of safe fruits and vegetables from NJ farms, but is also concerned about the impact these rules may have on farms in New Jersey. NJFB has been proactive in supporting the voluntary USDA third party audit program, which is the most prevalent third party audit utilized by NJ farms. This third party audit system is administered through the New Jersey Department of Agriculture. Our Rutgers Cooperative Extension faculty have also provided training for farms on food safety procedures for all stages of production from growing to storage. Therefore, NJ farmers are not strangers to understanding what is involved in providing food that is safe for consumers. Having said this, many growers may not have the resources or ability to meet all the proposed requirements in the FSMA. The reality that is often overlooked with new rules is the additional expense that farms will have to absorb as a result of the FSMA. Small family farms may already be struggling to be profitable, and this program has the potential to force them out of business. The Produce Safety Alliance has estimated that this rule on average, will annually cost very small farms - \$4,697, small farms- \$12,972, and large farms - \$30,566. NJFB believes these rules should be carefully analyzed and FDA should reconsider the rules for economic impacts may have on farms. We support the NASDA recommendation to republish a second draft of the rules based on some of the major concerns that have been communicated to the FDA. This second draft should precede an interim or final rule publication in the federal register.

The NJFB supports the Tester amendment on small farm exemptions but has concerns that it may be too narrow and may still include some farms that should be exempt. The exemption has an income threshold that Farms with gross food sales between \$25K and \$500K are exempt from most parts of the rule if at least 50% of their sales are to a qualified retailer (consumer,

restaurant, or retailer) and if sales are not more than 275 miles from the farm. Based on our interpretation and the FDA staff responses to our question, the gross sales will include all crops... not just the crops covered under the FSMA. The scenario exists for a NJ farm to have \$500,000 of sales from grain and sell \$10,000 worth of produce, making that farm subject to the rule; whereas, a farm that has \$24,999 in sales of vegetables could be exempt. We believe this threshold should only include produce that is covered under the rule.

One concern NJFB has with the future of the FSMA is how it will be enforced. We think that in each state, the state Departments of Agriculture should have the authority for any enforcement needed. The State Department of Agriculture in NJ is much more familiar with agricultural operations and procedures than are local health departments, especially since the NJ Department of Agriculture has and currently conducts third party audits in our state. The state will also need funding to perform this additional responsibility of enforcing the FSMA. The FDA should also consider streamlining the inspection process for farms already participating in a third party audit program. This qualifier should automatically provide these farms with compliance under the FSMA, therefore not subjecting a farm to multiple inspections or duplicative standards.

Water requirements

The NJFB strongly opposes the frequency of water testing for surface agricultural water. The proposed rule requires weekly testing for produce irrigated with surface water that comes in contact with the produce. This should be based on risk assessment such as previous testing or weather conditions that would cause significant runoff into such water bodies that could impact the ecology. Some surface water bodies may originate as a spring and may not be near any animal agriculture and may not be susceptible to contamination. The use of drip irrigation negates any contact with harvestable produce and the irrigation with drip should provide cause for an exemption from water testing requirements. Rather than relieing on the frequency of water test and making water testing a blanket procedure on one set schedule, science and common sense need to prevail in this case and let test results and physical features of the water body to set the parameters for water testing

Soil amendments

The FSMA rule requires manure to be applied 9 months prior to harvest. This could severely impact organic growers as it is more restrictive than the established organic standards. The application of manure 9 months prior to harvest will have minimal nutrient benefits to the crop, especially since nitrogen that may have benefited the crop will be lost through nitrification and leaching in that timeframe. There are current options based on GAP and the National Organic Standards that work well currently, (e.g. no application within 2 weeks of planting or within 120 days of harvest for covered crops). While not ideal, this is a reasonable compromise between food safety and the benefit of a manure application. Encouraging research to modify application times is helpful, but the starting point should not be a blanket 9 months (270 days).

Wildlife

The proposed rule requires the grower to assess the presence of wildlife in the field and determine whether the produce has been adulterated by the presence of wildlife. This is a

subjective assessment and it will be difficult for growers to determine the sections of a field that should be harvested and what parts should not. The slim chance that wildlife fencing would help limit wildlife presence in fields is not a cost effective method for most farms and also does not address avian species. It is also not feasible to fence in every field to prevent animal entry based on many economic, ecological and social reasons in our state and elsewhere. The presence of wildlife manure should be the determining factors for crop exclusion rather than just the presence of animals.

Record keeping

There needs to be additional clarification on the record keeping that is required under the FSMA. The documentation of daily activities will be burdensome for small farms that are covered and do not have the resources or manpower to document every activity conducted during the day. A checklist of what is recommended should suffice, so that the grower knows what he or she should be doing but not have to be burdened with compulsory paperwork and record keeping.

Mixed-type Facility

According to the proposed rule, a “farm mixed-type facility” is an “establishment that grows or harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered as a food facility.” (78 Fed. Reg. 3541). The proposal’s produce safety regulations only apply to the “farm” activities, and the onerous regulations proposed in *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (“preventive control rules”) apply to the “non-farm” activities. (78 Fed. Reg. 3646, Jan. 16, 2013). This regulation raises questions about whether a farm could be subject to the preventive control rules for packing a neighboring farm’s product. As technology increases for packing equipment thus increasing the expense of such equipment, it is common for farms to pool resources for packing equipment and storage facilities. This creates the scenario where farm A would be subject to the preventive controls rule because the farm would be considered a mixed use facility because the farm is packing farm B’s product just as it does for its own product. The classification may be justifiable if the farm was altering the produce by slicing or processing. This mixed-use facility definition would also impact the NJ bee industry because of the large number of small beekeepers in the state that supplement their honey production by buying neighboring beekeepers excess supply to help create their products. The FDA should not consider any farm a mixed –type facility unless the product is altered from its natural form. These type farms should only be subject to the produce safety rules since they are not performing any additional activities outside of harvesting, packing and storing the product.

Conclusion

The FDA will need to better account for small farms as it reviews the comments to adopt the final rule. The final rules need to acknowledge small farms and adjust rules so that the FSMA provides for preventive measures that will not incur significant expense and that will limit excessive recordkeeping. For farms that currently conduct third party audits, the FDA needs to create a uniform audit process to eliminate multiple food safety audits with varied requirements. Additionally, the FDA should consider that not all crops have the same risk level and that some crops may be more susceptible to possible contamination. Therefore, the rule should not be a “one size fits all” program. A cost/benefit analysis of the rule should be developed based on the

history of a specific crops being identified as a potential cause, or not, for food contamination outbreaks.

Looking at the larger issue, we all need to realize that the well- being of our country is dependent on maintaining and increasing domestic food production without incidentally reducing the amount of farmers in the United States. We all must do everything in our power to ensure Americans do not become dependent on foreign food in the future. Domestic food production is still the safest and most reliable source of human energy in our country. Creating programs that may place unnecessary burdens on farmers is unacceptable.

Thank you for considering these views,

Sincerely,

A handwritten signature in black ink, appearing to read "Ryck A. Sudam". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ryck Sudam, President
New Jersey Farm Bureau
168 W. State St.
Trenton, NJ 08608

Cc: Douglas Fisher, Secretary, New Jersey Department of Agriculture