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November 15, 2013

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

Re: Preventive Controls Rule: FDA-2011-N-0920 and RIN 0910-AG36
Produce Standards Rule: FDA-2011-N-0921, and RIN 0910-AG35

To Whom It May Concern:

I am pleased to submit the comments on the proposed rules noted above on behalf of the stakeholders of School Food FOCUS (FOCUS). FOCUS is a national collaborative that leverages the knowledge and procurement power of large school districts to make school meals more healthful, regionally sourced, and sustainably produced. Working with school food service professionals and their district partners in 36 large districts, we develop and share successful models for transforming school meals, backed by respected research and analysis. Most of our stakeholder's comments are specific to how the proposed rules will impact the school food supply chain for regionally and sustainably produced produce for our nation's schools.

General comments
FOCUS stakeholders are pleased to see that the rules include an integrated approach to all produce, rather than a commodity-specific approach. A uniform standard is important to many of the diversified farms we work with, rather than asking them to meet multiple standards for the various produce grown.

However, as noted in Charles Perrow's book, *Normal Accidents: Living with High-Risk Technologies*, (1999, Princeton University Press.) "complex, tightly coupled systems" (such as our industrial food system, which consist almost entirely of large, complex, tightly-coupled farms and especially processing facilities) will inevitably have safety problems, because, as Perrow puts it, "complexity makes failure inevitable." It is why he calls such accidents "normal." The proposed rules will burden ALL players with a control system that is designed to try and prevent these "normal", industrial scale accidents from happening, and in the process burdens small farmer "decoupled" systems with unconscionable and unnecessary financial burdens.

To avoid unintended consequences, the rule must be drafted carefully. As detailed below, the complexity of the rules, as well as their interlocking nature, dictate the need for a more explicit review. FOCUS stakeholders encourage re-opening the rules for public comment after FDA incorporates comments from this period. The current round of comments can be used to shape revisions and to prompt further discussion and exchange of information with state partners and others, altogether allowing for a better final product.

We are also greatly concerned that the proposed rules as written will negatively impact sustainable agriculture and local and regional food systems, as detailed in our comments below.

Need for Training and Technical Assistance
To follow the rules, farmers and packers need to understand what is expected of them. Those enforcing the rules need to know what compliance looks like. A phased approach to education and enforcement—having guidance before the rules are to be implemented—can help remove uncertainty for both producers and regulators.

Further, the provisions of the proposed rules have unequal burdens on different size operations, thus requiring differentiated support for compliance by small and mid-sized farms, facilities and food establishments. FOCUS stakeholders urge the FDA to include a provision and funding for no-cost technical assistance on risk mitigation and compliance as well as additional support to help small and mid-sized operations meet the cost of complying with the proposed rules.

Subpart R of the Produce Safety Rule notes two circumstances when the qualified exemption (for farms selling between $25,000-$500,000) can be withdrawn: 1) in the event of an active investigation of a foodborne illness incident directly linked to that farm, or 2) if the Secretary determines it is necessary to protect public health or prevent or mitigate a foodborne illness outbreak, based on conditions on the farm. The second part leaves the Secretary or designee significant discretion on the issue, as well as a significant lack of clarity regarding ways to regain a revoked exemption. FOCUS stakeholders suggest: 1) FDA clarify the exact circumstances or sets of circumstances that could lead to the determination of the farm losing its exemption; 2)FDA follow a traditional audit process, like those used for compliance with school food regulations. This involves time, technical assistance and support, rather than the punitive approach of immediately revoking an exemption. During this time, FDA could require a suspension in sales until the audit requirements are met, but the exemption should not be removed unless there is a failure to comply after this point.

Impact on Farm to School Programs

As we know, many small and family-sized farms struggle to make a living from farming, and farm to school is an important market for them. The costs of complying with the proposed rules will be significant for farmers of all sizes but most acutely felt by small and mid-size growers. Servicing the farm to school market also presents unique challenges, and a number of provisions of the proposed rules will add to the difficulty, and discourage them from engaging in the farm to school market. Specifically:

- Aggregation: School districts generally need aggregated product from multiple sources to provide enough of a single product for their meals. The proposed rules state that a farmer who aggregates products from other farms also has to register as a facility. Farmers who aggregate would be forced to deal with both produce and preventive control rules. This simple packing process poses minimal safety risk, and could be combined with simple labeling so that items are traceable to the farm of origin, rather than being subject to an additional rule.

- Minimal processing: Because many schools have very limited kitchen equipment and staff, they require minimal processing of many types of produce (e.g. cutting apples, shredding lettuce, chopping carrots) to be able to efficiently use produce. Under the proposed rule, farmers that can supply these services will have to register as a facility. FOCUS stakeholders recommend that these types of activities be monitored under existing programs, such as GAP/GHP or HACCP, rather than the complex proposed rules.

  In addition, low-risk activities, when conducted off-farm or by multiple farms working together, should not be subject to the same requirements as high-risk processing activities. The rules fail to protect a host of low-risk processing activities (e.g. making pickles and salsa) that are already considered low-risk by many states. FDA needs to develop an evidence-based approach to defining activities as low or high risk.

- Food Hubs: School districts often rely on food hubs to meet the challenges of aggregation and distribution. Many of these critical facilities are now being developed across the country. The added burden and expense of the proposed facilities rule could prevent newly formed food hubs from becoming financially viable or discourage entrepreneurs from developing additional facilities. This would seriously hamper this burgeoning procurement pathway of local food for schools and other institutions. FOCUS stakeholders recommend that FDA adopt at least the $1,000,000 threshold for a very small business and base it on the value of 'regulated product,' not 'all food,' to ensure smaller farms and businesses (like food hubs) fall under the scale-appropriate requirements and are not subject to high cost, industrial-scale regulation.

Impact on Sustainable Agriculture

FOCUS stakeholders are greatly concerned that the FDA's "one size fits all" approach expresses a lack of understanding of the unique character of sustainable farming. The proposed rules take a "guilty until proven innocent" approach to many traditional farming practices, forcing farmers to present scientific evidence in order to continue using farming methods that have been used for decades or even centuries. The final rules should allow farmers to use sustainable farming practices, *including those already allowed and encouraged by existing federal organic standards and conservation programs*. The rules also must ensure that diversified and innovative farms, particularly those pioneering models for increased access to healthy, local foods, continue to grow and thrive without being stifled. Specifically:

- Evidence-based Standards: The agency should not restrict sustainable methods of farming without data showing an actual, verified increased rate of foodborne illness.

- Retail Food Establishments: FDA must affirm that school cafeterias, farmers markets, CSAs, roadside stands, and other direct-to-consumer vendors fall under the definition of a "retail food establishment" and are therefore not facilities subject to additional regulation.

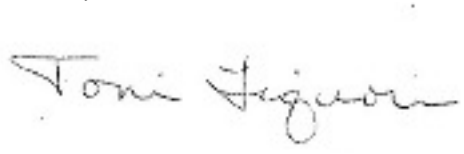
- Manure and Compost: FDA must not exceed the already strict standards for the use of manure and compost used in certified organic production and regulated by the National Organic Program.

- Water Requirements: FDA's proposed rule would require farmers to test their irrigation water weekly if they use a surface water source, such as a river or stock pond. FOCUS stakeholders believe that testing requirements should reflect the level of risk. Farms and water sources with an established good history and food safety plan that addresses water quality should need testing less frequently than those identified at higher risk. Testing untreated surface water every seven days will likely capture the impacts of "events", as intended, but a requirement to test after specified events or at times when contamination is most likely would also be effective. Identifying such events and times of highest risk, regardless of the water source, should be part of the food safety plan for the farm, and could be part of voluntary compliance. Time-consuming, unnecessary and costly water measures, which are contrary to farmer and consumer preference, could lead farmers managing small and mid-sized operations to exit the field altogether.

- Domestic Livestock and Wildlife: FDA's proposed regulations also require farmers to take steps to prevent contamination by domestic livestock or wildlife, but they leave the specifics of what is required to the discretion of the field inspectors. Diversified farms are efficient, both biologically and economically, yet they would be hard-pressed to comply with the proposed rules. At the least, it would be very expensive; in many cases, the farmers simply could not comply without changing their entire approach to farming. Field inspectors must be educated and provided with a set of evidence-based guidelines to judge if there will be a negative impact on produce grown by exposure to domestic livestock or wildlife.

We appreciate this opportunity to provide comments, and look forward to working with you to improve the proposed rules.

Sincerely,



Executive Director
School Food FOCUS