



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

RE: Comments on Docket FDA-2015-N-0797-0001: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards

On behalf of the represented members of the National Sustainable Agriculture Coalition (NSAC),¹ I submit the following comments to the docket FDA-2015-N-0797-0001: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards. NSAC is an alliance of grassroots organizations that advocates for federal policies that support small and mid-size family farms, protect natural resources, promote vibrant rural communities, and ensure healthy food access through local and regional food system development. Many of our 110 member organizations work directly with the family farms, sustainable and organic farmers, food hubs, and value-added enterprises that are engaged in direct-to-consumer and intermediated markets and are building local and regional supply chains to improve the health and well-being of American families.

We have been actively engaged in the FSMA process throughout the legislative debates, rulemaking, and now implementation, all with an eye toward ensuring that the Food and Drug Administration (FDA) can meet its public health goals in a way that is scale- and supply-chain appropriate, so the small and mid-sized farms and businesses comprising the Local and Regional Food (LRF) sector can prepare for and adapt to the changing landscape that FSMA brings. These enterprises include diversified, sustainable, organic, and identity-preserved agricultural operations; beginning and socially disadvantaged farmers; value-added farm businesses and small-scale processors; and direct and intermediated supply chain participants. These operations need to be able to meet the new challenges the FSMA brings, while continuing to supply healthy, fresh fruits and vegetables and meet the growing demand for local, organic, identity-preserved, and value-added products.

These comments are informed by our regular food safety committee discussions regarding concerns and ideas for FSMA implementation; participation in the recent FSMA Implementation Public Meeting; review of the Operational Strategy document; and ongoing engagement and conversation with the

¹ Agriculture and Land Based Training Association, Alternative Energy Resources Organization, California Certified Organic Farmers, California FarmLink, C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture), Catholic Rural Life, Center for Rural Affairs, Clagett Farm/Chesapeake Bay Foundation, Community Alliance with Family Farmers, Dakota Rural Action, Delta Land and Community, Ecological Farming Association, Farmer-Veteran Coalition, Flats Mentor Farm, Florida Organic Growers, Grassworks, Hmong National Development, Illinois Stewardship Alliance, Institute for Agriculture and Trade Policy, Interfaith Sustainable Food Collaborative, Iowa Natural Heritage Foundation, Izaak Walton League of America, Kansas Rural Center, Kerr Center for Sustainable Agriculture, Land Stewardship Project, Michael Fields Agricultural Institute, Michigan Integrated Farm and Food Systems, Michigan Organic Food and Farm Alliance, Midwest Organic and Sustainable Education Service, National Center for Appropriate Technology, Nebraska Sustainable Agriculture Society, Northeast Organic Dairy Producers Alliance, Northern Plains Sustainable Agriculture Society, Northwest Center for Alternatives to Pesticides, Ohio Ecological Food and Farm Association, Oregon Tilth, Organic Farming Research Foundation, Rural Advancement Foundation International – USA, Union of Concerned Scientists Food and Environment Program, Virginia Association for Biological Farming, Wild Farm Alliance. The Carolina Farm Stewardship Association, a participating member, also contributed significantly to these comments.

agency. These comments incorporate and build on my remarks from the FSMA Implementation Meeting, and which are included here as an appendix.

Successful FSMA implementation will require continued stakeholder participation and support, and NSAC looks forward to ongoing opportunities to provide feedback and suggestions as the agency crafts a scale- and supply-chain appropriate implementation plan for the new FSMA rules that works for all sectors of the food system. We appreciate your consideration of our views.

Sincerely,

A handwritten signature in cursive script that reads "Sophia Kruszewski".

Sophia Kruszewski
Policy Specialist

I. THE NEED FOR TRANSPARENCY AND FURTHER OPPORTUNITIES FOR STAKEHOLDER INPUT

As with the implementation of food safety practices on farms and in food businesses, FSMA implementation must be an iterative process with an emphasis on continual improvement. The public meeting provided one opportunity for stakeholders to provide feedback on aspects of FDA's implementation plan; it is critical that there be additional opportunities to see how FDA has integrated public input, and provide further feedback into their current thinking. We recognize that this can feel like a lengthy process, but it is incredibly important that stakeholders – particularly the farms and food businesses that comprise the LRF sector – have a sense of ownership over this process. A true culture change will require nothing less.

Accordingly, FDA should provide clear information to the public that identifies specific processes, mechanisms, and timelines for stakeholder participation in: the development and assessment of compliance and enforcement mechanisms; the structure and implementation of on-farm pre-assessments; the development and execution of outreach and education plans; the development, assessment, and delivery of training curriculum, including a clear process for identifying and validating alternative food safety training programs and adapting/tailoring currently recognized Alliance curriculum; the creation of a curriculum for farm mixed-type facilities; and the implementation plan for farm mixed-type facilities, as entities subject to multiple rules, and, as laid forth in the statutory language, to which the agency has an obligation to assure that burdens are minimized during implementation.

We appreciate the effort FDA put into organizing the FSMA Implementation public meeting. It provided an invaluable opportunity for the public to get a sense of FDA's current thinking on aspects of FSMA implementations plans and for FDA to solicit input. However, there must be additional opportunities for stakeholders to weigh in as the implementation plans are drafted and redrafted. As my remarks that day mentioned: one of the best things FDA did to gain the trust of the regulated industry during the FSMA rulemaking process was demonstrate how much the agency had been listening by revising aspects of the proposed rule, and then providing a second opportunity to weigh in on the revisions. The same transparent, iterative process is equally essential during implementation to ensure appropriately-tailored and well-crafted implementation plans that work for farms and food businesses of all sizes.

II. OUTREACH AND EDUCATION

A robust, well-supported outreach and education plan is critical to a successful compliance strategy for the farms and food businesses that comprise the LRF sector. Developing and supporting effective and diverse means and methods of communication will further serve FDA's goals of fostering industry compliance by building a culture of food safety. This entails structuring outreach and education in a way that guides farmers and food businesses to the training and technical assistance resources appropriate to their operation.

Outreach programs alone will not achieve the cultural changes FDA seeks if there are not thoughtful, well-developed resources to use during and as follow up to those programs. Therefore, FDA must work with the LRF sector to educate farmers and local food entrepreneurs about how FSMA impacts their current operations, and to help those stakeholders understand what impact FSMA will have when they make changes in their businesses. This might be phrased as “food safety risk management decision support.” That is, helping LRF sector businesses decide how to select the most appropriate,

cost-effective FSMA compliance strategy in both the short- and long-term while maximizing the effectiveness of their food safety risk management. Doing so would support FDA's achievement of its 'Strategic Framework' goals by supporting: increased industry understanding; the availability, access, and sharing of technical resources; and improved analysis and risk management.

This outreach and education plan would require agency support for activities at both national and regional/state levels. At the national level, FDA should work with LRF sector partners in the development of guidance documents that include:

- Expectations for exempt and qualified exempt farms and facilities, including documentation requirements and guidelines for facilities working with exempt and qualified exempt suppliers;
- Compliance guides for small and very small facilities, customized to the type of facility (produce distributor, farmstead dairy, maple syrup, animal feed mills, farm mixed-type, etc), including sample HARPC and "HARPC-lite" plans and including plans for low-risk food/activity combinations;
- Scenarios for food safety inspectors that demonstrate the difference between violations that are minor vs. critical using site-specific examples;
- Guidance for LRF sector establishments to understand whether they are subject to the facility registration requirement;
- Implementation of the sanitary transportation rule for LRF sector businesses;
- Determining whether and what portion of the Produce Rule applies to a produce operation;
- How produce farms apply the water standards and select agricultural water sources;
- The crosswalk between FSMA requirements and organic farming system plans;
- The co-management of food safety and conservation practices; and
- How diversified and integrated crop-livestock farms implement Produce Rule requirements.

The development of these materials and resources would form the foundation of an effective outreach and education strategy. Once completed, they would be used in the outreach and education activities of regional and state farmer- and community-based organizations to help farmers and food businesses achieve understanding of the regulatory requirements, and learn where to find the resources available to learn and do more. We urge the agency to partner with LRF sector partners to develop these resources and implement this strategy.

III. INDUSTRY TRAINING

Timing

FDA indicates that in developing and rolling out training activities, it will synchronize to the progression of compliance deadlines for large, small and very small businesses. But this approach would be contrary to FDA's strategic objective in FSMA implementation, and the agency's regulatory impact analyses for the proposed rules documents. According to that analysis, large businesses are very likely to already have the requisite training and knowledge of the practices required by the rules, while FDA expects small and very small businesses to have a much larger learning curve. These assumptions are reflected in FDA's forecast that small and very small businesses will face much higher costs of gaining knowledge about the rules, and in implementing the rules generally, than large businesses.

For example, the regulatory impact analysis suggests that very small facilities will incur 73 percent of the aggregate cost of compliance with the Preventive Controls Rule. If FDA is correct that small and very small businesses are so behind in terms of meeting FSMA's standards, then the agency should not delay

in rolling out education and training programs to meet the needs of these establishments, especially given the huge proportion of affected businesses that these businesses represent. If large operations are, as FDA suggests, already substantially in compliance with the rules, then the burden of compliance education should not be significant for these entities. It is critical that FSMA implementation lead with robust outreach, education, and training resources for small and very small farms and food businesses. Putting those resources in place first – that allow for farms and small food businesses to adopt new or modify existing practices, and learn to demonstrate a culture of food safety – will only reduce the need for enforcement activities later.

Curriculum

We were pleased to hear FDA adopt the “one size cannot fit all” mantra as the FSMA rulemaking progressed. However, this fundamental principle must extend beyond the rules themselves. We have consistently stated at public meetings, briefings, stakeholder events, and meetings with the agency that FSMA implementation – including education, outreach, training, and technical assistance – must be developed and delivered in a way that is scale- and supply-chain appropriate; that accounts for local and regional variations; and that is tailored to a diversity of farming operations, food businesses, and markets. Failure to recognize and support alternative and tailored training programs results in a one-size-fits-all approach to food safety training and education, which will alienate many farmers and small food businesses from the compliance process.

The Food Safety Preventive Controls Alliance (FSPCA) curriculum was developed with no input from the LRF sector, or small and very small businesses generally, and so the curriculum will not represent or address the diverse needs of the thousands of small and very small businesses affected by the Preventive Controls Rule. This is particularly true for the farms considered “farm mixed-type facilities” and subject to multiple rules.

Large-scale food facilities are complex and capital-intensive enterprises, and the hazard analysis and the scope of preventive controls for such businesses is dramatically different from local and regional produce distributors, farmstead cheese makers, and other small entrepreneurial businesses. FDA’s FSMA implementation plan must support the development of a preventive controls curriculum better-tailored to the needs of small businesses and LRF sector producers, including farms subject to the Preventive Controls as farm mixed-type facilities, which the FSPCA curriculum fails to account for.

We also find the Produce Safety Alliance (PSA) curriculum and approach concerning. Although the PSA has been welcoming of our sector’s perspective and feedback on the curriculum, we do not share the FDA or PSA’s confidence that their curriculum and approach is the best option for all small and mid-sized farming operations, particularly operations with diversified operations and markets, integrated crop-livestock systems, or farms doing value-added processing that might count as farm mixed-type facilities. And it certainly cannot be the only option. Again, one size *cannot and does not* fit all. The PSA curriculum may work very well for some producers. But there must be support for alternative approaches and a process in place to validate them in order to reach more farms and food businesses and explain what FSMA requires in a clear and appropriately-tailored manner.

We do not believe that the PSA curriculum should be finalized before the rules are finalized. The current message from PSA is that their curriculum will go live in June. We believe this is in error, as it will create more confusion among farmers, not less, and create pressure for farmers to take the PSA training even if it is not the best option for their operation. As discussed above, we first need robust outreach and education, so that farmers can be directed to the training and technical assistance

resources best suited to their operations. Therefore, we strongly urge FDA to work with USDA and PSA to delay finalizing the PSA curriculum until the rules are finalized, and outreach and education can get underway. PSA could certainly continue piloting the trainings – we believe this is a wise way to field test the curriculum. However, we recommend that FDA, USDA, and PSA make it clear that farmers have options, and that PSA is only one way to satisfy the FSMA training requirement. Concurrently, FDA should create a process by which non-Alliance training programs can be validated. We discuss the need for alternative training programs in more detail below.

Alternatives

As discussed in our comments during the stakeholder panel, we acknowledge and appreciate that FDA is making significant internal changes to take a systems-approach to food safety oversight, which demonstrates a willingness to think creatively about their role. We urge the agency to allow for the LRF sector to similarly pursue creative approaches to compliance, which will allow small farms and food businesses to manage food safety risks while sustaining the impacts FSMA may bring. FDA’s preliminary regulatory impact analysis unambiguously acknowledges that small and very small businesses will be disproportionately impacted by these rules, and that some may find that the costs of compliance exceed their profits. FDA – in partnership with USDA, state partners, and local and regional farmer- and community-based organizations – must ensure that these most vulnerable entities are able to receive the training and technical assistance they need to comply with FSMA and stay in business.

The most effective means for increasing small farms’ and facilities’ capacities for risk assessment and management, and so for reducing the foodborne illness risks they present, is grassroots outreach and technical assistance, tailored to the scale and markets those businesses serve. Cookie-cutter training programs may nominally allow producers to meet FSMA training requirements, but they will not be truly useful in helping firms achieve better food safety risk management. FDA must recognize in particular the diverse nature of farms in the LRF sector—commodity-specific guidance will not be sufficiently useful for these farms that rely on diverse crop mixes for financial risk management. We cannot allow these small farms and food businesses to go out of business simply because food safety resources and technical assistance do not meet their needs.

We recommend FDA embrace and foster innovative and decentralized approaches to compliance by recognizing and supporting alternative training programs, community- and farmer-led outreach and education, group- or hub-based compliance strategies, and farm and facility accountability systems for LRF sector businesses, such as Group GAP.

We are well aware that, in the proposed Produce Rule, the preamble noted that FDA had, at that time, “no plans to publish a list of ‘approved’ courses other than the Alliance course materials.”² However, in subsequent conversations, FDA has stated to us that the PSA program is not the only option, and that farmers are not required to take the PSA training course (though some training is required), and that they will make this clear to farmers. This clarification has not been made publicly, however.

Meanwhile, the PSA curriculum is expected to go live in June. It is critical that FDA demonstrate the same understanding of the unique needs and attributes of the LRF sector that the agency developed during the past two and a half years since the proposed rule was first published, and apply that understanding to this issue of training. The training requirements and programs developed to satisfy

² 78 Fed. Reg. at 3556

them must have the same flexibility built in to accommodate sustainable food and farm systems as other aspects of the FSMA rules. Failure to do so does an incredible disservice to the trust that has been built between FDA and the sustainable agriculture and LRF sector over the past few years. To avoid a one-size-fits-all approach to FSMA implementation, there must be a mechanism by which FDA will validate alternative (i.e. non-Alliance) approaches to training, and support for the development and delivery of those alternatives.

It was our view that the National Coordination Center could serve that validation function, and that the regional centers would administer grants to support the delivery of training programs by farmer- and community-based organizations at the state and local level. However, the process by which FDA and USDA have rolled out the food safety training program has left us doubtful that the national and regional food safety training centers are being set up in a way to serve either of us those crucial functions. We do not believe that this uniform, singular, top-down approach can be justified as appropriate to meet the diverse needs of the smallest and most vulnerable farms and food businesses.

Regulator Training

FDA indicates that regulator training efforts have been underway since January 2015, yet we are not aware of any involvement of the LRF sector in those efforts. While the agency claims to identify partnership with industry associations as a key training, outreach and implementation strategy, there has been little meaningful engagement of LRF sector producers so far in the extensive implementation planning FDA has done so far. The only partners the agency has identified so far for providing technical assistance on compliance and scientific support to industry and regulators are government and academic institutions, such as the PSA and PCA, NASDA, and NIFA. We encourage the agency to look beyond its traditional partners; LRF supply chain participants want to be partners in reducing the risk of foodborne illness, and help provide information and build understanding between regulators and farms and small food businesses, but limited time and resources may prevent them from being regular participants in stakeholder forums, public dialogues, and the like. These are organizations and businesses with extensive connections and relationships throughout the LRF sector, and they should be more intentionally and regularly consulted throughout this process.

IV. PRE ASSESSMENTS

We have been quite surprised by how quickly pre-assessments for produce farms have become part of FDA's implementation plans. They were brought up publicly for the first time that we are aware of at the FSMA Implementation Meeting in April, but the press following that event gives the impression that pre-assessments are a done deal.

We do not think that pre-assessments are a bad idea, but we do believe that they still require significantly more clarification, public testing, and industry input before they considered a given component of FDA's compliance strategy.

The effectiveness of pre-assessments as a piece of the compliance strategy will rely on cooperation from the farming community, so there must be more opportunities for the farming community to weigh in on the process, its structure, and its goals. We therefore encourage FDA and state regulatory partners to consider the following and integrate these considerations into a draft proposal for pre-assessment program for further public input. These considerations are non-exhaustive, but include:

- Pre-assessments must be carried out in a clear, non-regulatory manner, whether they are done by federal or state agencies;
- Consider first conducting pre-assessments off-farm, with a discussion of records and other indicia of a culture of food safety, before coming on the farm;
- No records should be created during the visit, except for the notes that the farmer takes for their own reference;
- Work with local farmer-based and grassroots organizations to ensure that farms of all types and sizes are aware of the pre-assessment opportunity. Local organizations (e.g. farm associations that the farmer belongs to) should be welcome and invited to attend the assessment at the farmer's discretion;
- Work with partners in the farming community to create and distribute in advance documents containing helpful questions to remember to ask (e.g. some sort of worksheet to help the farmer keep track of all bases); and
- Ensure that whoever comes on the farm to conduct the pre-assessment is well-trained, makes it clear that this is non-investigative and wholly voluntary, and comes prepared to direct the farmer to the resources available to answer their follow up questions and provide technical assistance.

V. STRATEGIC FRAMEWORK CROSS-CUTTING RESULTS – METRICS

At its public implementation meeting, FDA presented a draft of its ‘Current Thinking’ on the outcomes it could measure to demonstrate the impact of FSMA implementation, including an overall ‘Strategic Objective’ of ‘Reduced Illness or Injury.’ Under that strategic objective, FDA described metrics related to reduced risk of illness from foods and produce governed under the FSMA rules. Unfortunately, risk reduction in the food supply is a difficult quality to measure, and one upon which there is little agreement as to direct metrics. Indeed, arguably from a public health perspective, the US food supply already faces a very low level of risk from significant foodborne illness outbreaks, especially in comparison to other public health crises related to food consumption such as obesity and chronic diet-related disease. Certainly the causative links between any particular preventive controls mandated by FSMA and foodborne illness are in most cases speculative at best. That lack of causation is evidenced by the fact that the vast majority of outbreaks in FDA-regulated foods that do occur are associated with large food facilities (500 or more employees) that according to FDA are already substantially in compliance with the preventive controls rule.

In the context of goals for a FSMA implementation plan and FDA’s inherently limited resources relative to the scale of the food and agriculture sector, reduction in risk would be best measured by the improved ability of regulated entities to assess and manage food safety risks in their operations. Operators of farms and food businesses are already under market pressure to improve their risk assessment and management capacity, and FDA can best leverage this market demand for prevention to achieve the agency’s risk reduction objective by enhancing the ability of producers to understand their operations’ risk profiles and address their highest priority concerns.

Because it would take advantage of producers’ inherent necessity to meet market demands and not injure the health of the ultimate consumers of their products, FDA action to improve risk analysis and management will be the most cost-effective means of reducing foodborne illness risk.

We recommend that programs that build risk identification and reduction capacity among farms and food facilities be the primary activities that FDA undertakes in implementing FSMA, and

improvement in producers' capacities should be the metric against which FSMA implementation is evaluated. Related useful results metrics would be in the areas of increased availability and distribution of training and technical resources and increased industry understanding of the rules.

As FDA looks to develop specific metrics within the areas of training programs and increased understanding, we strongly encourage that FDA recognize a wide variety of training programs to ensure that operations of all scales and markets, and in particular LRF sector producers, can choose options best suited to their operations. Limiting this measurement to participation in Produce Safety Alliance or Preventive Controls Alliance programming would not be a good metric because those programs are poorly designed for the LRF sector.

Metrics around increased regulator understanding would potentially be useful in demonstrating progress toward FDA's overall strategic objective, but only to the extent that regulator understanding and knowledge of the regulated community, and not merely the rules themselves, are at the heart of regulator education efforts.

Obviously FDA and state regulatory agencies face a huge challenge in developing the cadre of inspection staff sufficient to carry out the functions mandated by FSMA. Failure to effectively educate these staff about the economic and market realities farms and food producers face, especially the highly diverse array of small- and mid-sized operations that dominate the market for local and regional food, will be counter-productive to FDA's food safety goals because it will drive those businesses underground or out of business altogether.

Measuring FSMA implementation results in terms of reduced contamination, actual reduction in illnesses, or increases in 'compliance' will not only be counterproductive, but unrealistic and erroneous. Here it is useful to refer to comments submitted by NSAC on the original regulatory impact analysis for the Preventive Controls rule, wherein we anticipated the possible evaluation of FSMA's effectiveness in terms of reduced foodborne illness, and demonstrated the fallibility of such a measurement approach:

FDA acknowledges that the Preventive Controls Rule will not eliminate foodborne illness, but fails to acknowledge that there is no realistic benchmark for evaluating if it will even significantly reduce foodborne illness outbreaks. Given that more than 90 percent of foodborne illness purportedly goes unreported, it will be difficult to evaluate whether these provisions were ultimately effective. ... FDA states in the Preventive Controls Rule EIA: "We lack sufficient information to fully estimate the proposed Rule's likely benefits. Instead we attempt to estimate the total economic burden of the illnesses that could potentially be prevented by this Rule. We do not expect that all of these illnesses will be prevented; rather, we expect that the Rule would prevent some portion of them from occurring. We estimate that there are close to 1,000,000 illnesses each year that are attributable to FDA-Regulated food products that would fall under the scope of this propose Rule. The monetized cost of these illnesses is estimated to be nearly \$2 billion."³

However, FDA arrives at this estimate of illnesses from a very limited set of data covering foodborne illness. During the years 2003-2008, 16 outbreaks of foodborne illness (resulting in 1,655 illnesses) associated with foods that would be governed by the Preventive Controls Rule were documented over a six-year period.⁴ While the importance of these illness incidents is not

³ Preventive Controls EIA, p. 6

⁴ Ibid., p. 14

to be minimized, it is a long extrapolation indeed to move from this figure to one million illnesses *per year*.⁵

If, six years into the new Rule, FDA could document 32 outbreaks of foodborne illness over that six-year period, would it consider this a success by simply estimating that overall illnesses had declined, say to an estimated 750,000? Or would it cite such data as an indication that our ability to document cases of foodborne illness had improved due to a Rule that created new paths for tracing the source of future foodborne illness outbreaks? Or would the agency say that even more restrictive measures were required, since documented outbreaks had doubled? Unfortunately, any of these conclusions would be possible, based on such a small sample of foodborne illness outbreaks, and such large extrapolations to the presumed incidents of foodborne illness.

Conversely, if in a hypothetical six-year period after adoption of a final rule, only eight outbreaks of foodborne illness were documented for FDA-regulated foods, would FDA claim it had succeeded in reducing outbreaks by half, even though it would be impossible to document any reduction in the projection of one million annual illnesses occurring currently? Since FDA cannot now confirm that foodborne illness outbreaks are more likely to occur in unregulated industries than in regulated ones, how could anyone document whether this shift had occurred because of the new Rule?

We also pointed out that:

FDA recognizes there is uncertainty in its ability to track foodborne illness (FDA 2013c, p. 3512). Studying an outbreak of hepatitis A associated with green onions, investigated by a team of USDA scholars, Calvin (2004b, p. 2) concludes that “Even growers with the best food safety practices may still have contaminated product—all sources of risk cannot be controlled.”

FDA makes the assumption that a percentage reduction in pathogen levels will be associated with an identical reduction in illness. Yet this is only an assumption, as Crutchfield (1999, p. 58) points out: “The relationship between human exposure to microbial pathogens and any resultant illness is very complex. A number of factors influence whether a person, once exposed, becomes ill, the severity of the illness. Factors include the level of pathogens in the food, the way the consumer handles the product before cooking, the final cooking temperature, and the susceptibility of the individual to infection. In addition, the relationship between pathogen levels and disease varies across pathogens.” ...

As Calvin (2007, p. 25) concludes, “Because most fresh produce is grown in a natural environment, it is vulnerable to microbial contamination. No set of practices would eliminate all risk.”

In the absence of clear evidence of contamination, and the inherent difficulties of tracking the source of contamination, or proving a connection between contamination and illness, the science of foodborne illness necessarily relies upon considerable estimation. This uncertainty in tracking foodborne illness, when combined with the uncertainty of FDA’s calculations of proposed economic benefits attributable to the Produce Rule, starkly illustrates the inherent uncertainty in this realm of regulation.

⁵ Ibid., pp. 15-16

In all likelihood, the enhancement of surveillance tools, and better integration of foodborne illness response programs under FSMA, will result in better identification and attribution of illness. Surely FDA doesn't want to put itself in a position where the application of better surveillance and coordination results in measurements that suggest FSMA is ineffective.

We also strongly discourage benchmarking FSMA implementation results in terms of 'increased compliance', 'expanded use of incentives,' or 'more efficient enforcement,' as all of these metrics would tend to encourage regulation at the expense of education.

These criteria would also create a bias toward larger farms and facilities that can undergo the costs of third-party inspections. FDA has already indicated in the FSMA supplemental rules that it will rely on third-party inspections, and the Produce Rule implementation strategy development proposal from the National Association of State Departments of Agriculture (NASDA) specifically suggests rewarding farms that undergo third party certification with a reduced chance of regulatory inspection. We oppose these strategies.

Under these scenarios, limited resource operations that can't afford participation in third-party inspection schemes that FDA might recognize as equivalent, and participants in emerging self-certification regimes, would be disproportionately subject to inspection and enforcement. To incentivize enforcement and inspection by making such actions the measurement of FSMA implementation success would ensure that those types of operations would bear the brunt of enforcement efforts, regardless of the risk they present. Moreover, benchmarking FSMA in terms of compliance and enforcement efforts fails to recognize the inherently limited resources that FDA and state agencies will have available to enforce FSMA relative to the size of the food industry. In this context, it is impossible to see how enforcement and compliance benchmarks will actually contribute to FDA's strategic objective.

VI. ADDITIONAL GENERAL COMMENTS

HAACP

FDA cites the implementation of juice and seafood HACCP as a successful model for FSMA implementation. However, the agency should examine the impact of the implementation of the juice and seafood HACCP on small firm participation in those markets, and evaluate whether and to what extent those implementation plans disproportionately negatively affected small firms.

Enforcement Actions as a Continuum

We support FDA's expressed intention in FSMA enforcement to recognize that there is a sliding scale between mere rules violations and actual public health risk, and to have a continuum of enforcement actions appropriate to the scale of the actual risk that a violation presents. Minor infractions should not trigger increased inspection frequency or any other enforcement action disproportionate to the actual risk such infractions create. Success in attaining this intention for proportionality will completely depend on the effectiveness of regulator and inspector training, and in particular on that staff's familiarity with and awareness of the diversity of farms and food facilities, especially small-scale enterprises.

Establishment of enforcement priorities for the Preventive Controls Rule must take into account FDA's own determination of the low-risk nature of a long list of food/activity combinations, as

documented in the agency's Draft Qualitative Risk Assessment of the Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm. Low-risk food/activity combinations should be treated as low-risk for purposes of determining inspection frequency and enforcement actions, regardless of whether they occur on a farm-based facility or a non-farm-based facility.

Produce Rule On-Farm Inspection Program

Farms should not be subject to regulatory inspections under the Produce Rule unless there is an actual indication of a potential risk to public health from the activities on a particular farm. FDA regulatory efforts for the Produce Rule should focus on farms' self-assessment of risk and development of management strategies to address high-priority risks. There are many ways to address this, for example through tailored training and education; through the submission or off-farm review of records; or through non-regulatory and voluntary assessments done by FDA, state, or local partners, in cooperation with farmer-based organizations.

Farm Mixed-Type Facility Study

Despite the statutory obligation to prepare a detailed study of farm mixed-type facilities prior to rulemaking, FDA has yet to conduct this study. When the proposed rules were issued, FDA claimed there was insufficient time to do so, and therefore needed to wait until the implementation phase. Plans for undertaking and completing a full-scale study to quantify and analyze this sector must now be part of the implementation phase, but to our knowledge this critical component has not yet been addressed by FDA as part of its current thinking on implementation.

In conclusion, any options that FDA is considering regarding Produce Rule and Preventive Controls Rule compliance must be presented for more industry input and dialogue prior to finalization. The initial FSMA implementation public meeting and Operational Strategy document have provided stakeholders with only the bare skeleton of FDA's implementation plans. The details that will need to be fleshed out in coming months will require significantly more extensive, detailed, and transparent discussions to ensure widespread industry support, particularly for small very small businesses, and producers that have not been exposed to market-driven food safety requirements.

APPENDIX

Remarks by Sophia Kruszewski at the FSMA Implementation Meeting Washington, DC April 27, 2015

Thank you for the opportunity to speak today. Before I begin, I'd like to tell you a little about our coalition, to give you context for my remarks today.

The National Sustainable Agriculture Coalition is an alliance of grassroots organizations that advocates for federal policies that support small and mid-size family farms, protect natural resources, promote vibrant rural communities, and ensure healthy food access through LRF system development. We are comprised of 110 member organizations, many of whom represent and work directly with sustainable and organic farmers, food hubs, and value-added enterprises that are engaged in direct-to-consumer and intermediated markets and are building our local and regional supply chains.

We have been actively engaged in the FSMA process through the legislative debates, rulemaking, and now are looking to implementation, all with an eye toward ensuring that FDA can meet its public health goals in a way that is scale- and supply-chain appropriate, so our sector can prepare for and adapt to the direct and indirect impacts of FSMA, while continuing to supply healthy, fresh fruits and vegetables and meet the growing demand for local, organic, identity-preserved, and value-added products.

The previous panelists and many commenters during yesterday's sessions, have raised a number of important issues for FDA and other stakeholders to consider as we look at FSMA implementation and issues of compliance, but I'm going to focus on a few key themes.

First -- Deputy Commissioner Taylor kicked off this event mentioning that FSMA implementation will require a "coalition approach." I work for a coalition, and we know that one of the most important components to a successful coalition is having the buy-in of coalition partners. One of the most important ways to obtain buy-in is through transparency. Transparency of ideas, of plans, and of processes. Fostering a collaborative spirit between stakeholders and regulators at the state and federal level will require the identification of clear mechanisms that explain how and when implementation plans will be re-evaluated; impacts – particularly on the smallest and most vulnerable entities – will be assessed; and policies and actions will be adjusted to integrate new information and understanding. And most importantly, how stakeholders will be continuously consulted and engaged in this process.

During the rulemaking process, after the initial proposed rule comment period closed and FDA said "we hear you, and we're going to try again" and reissued supplemental proposals and gave stakeholders another opportunity to weigh in – that was such an important moment in building trust between FDA and the farming community. And so this is one of what I hope will be many opportunities during FSMA implementation for FDA to say "here's what we're thinking, what do you think?" and then repeat as many times as necessary.

To that -- one area in particular that I don't think was discussed nearly enough during this event was the implementations plans as they relate to farm mixed-type facilities subject to multiple rules. This is one of the most confusing aspects of the rule for farmers, and there is still a lack of clarity regarding FDA's plans for these types of operations. Where is data to determine impacts on operations of this type? Where is their training curriculum? How will the separate arms of FDA work together to

increase clarity and avoid the burden on those farms? Clearly, more needs to be done to engage this sector to develop an appropriate implementation framework – and we would welcome the opportunity to work with the agency in the development of those plans.

Second – we’ve heard a lot about the outreach, training, and education needs for FSMA implementation. It has been our position from the beginning that any food safety oversight system must lead with robust and well-funded outreach, education, and training programs that support locally-led efforts to help bring previously unregulated farms and food businesses into compliance. Diverse, smaller-scale farms and food enterprises are making decisions now about their businesses based on the very real concern that FSMA will not be flexible enough to be workable for operations of their size and complexity. The need for outreach and education on the rules – whether they apply to your farm, to what extent, what to expect, and how to prepare – cannot be put off until closer to the compliance timelines for small and very small businesses.

We heard often during the rulemaking (and said frequently ourselves) that the rules can’t be one-size-fits-all, and the same is just as true for the implementation of those rules – and this includes the outreach, training, and technical assistance necessary to achieve compliance. But if training is required to comply with FSMA, and there is only one FDA-recognized training curriculum, how can we say this isn’t a one-size-fits-all approach to compliance? FSMA requires a flexible, scale and supply chain appropriate regulatory framework; and this applies equally to the way these regulations are implemented through appropriately tailored outreach, training, and education.

Through strategy documents and public statements, we see that FDA is making significant internal changes to take a systems-approach to food safety oversight, which demonstrates a willingness to think creatively about their role. Similarly, we urge the agency to embrace and foster innovative and decentralized approaches to compliance by recognizing and supporting alternative training programs, community- and farmer-led outreach and education, group- or hub-based compliance strategies, and the like. Training and technical assistance on food safety practices will be essential, as will be trainings for inspectors on the diversity of farming systems, and -- crucially -- training for farmers on what compliance really looks like, and what to expect in the event of an inspection. These trainings are absolutely critical, and will require significant public investment and commitment from FDA and partners.

Finally, I emphasize the outreach, education, and training needs first, because building the capacity of farmers and food businesses to prepare for and adapt to FSMA should be the first step in a compliance strategy. Yet, we are concerned that outsized reliance on third party audits will overshadow the important role of training and education as a way for farmers to demonstrate a culture of food safety and move toward FSMA compliance. Third party audits can serve a valuable function, but they are only one tool.

We continue to be very concerned that overemphasis on the role that third party audits play in the FSMA framework could result in a de facto regulatory requirement for audits, despite clear congressional intent to the contrary: namely, that the rules cannot require that a farm or food business hire a third party to verify compliance with the rules. FDA must recognize this, and be transparent in their intentions regarding the role and relative importance of third party audits. Again – one size cannot fit all. For farms that are new to the process, FSMA and market requirements are coming at them almost simultaneously; there need to be alternative compliance indicators and processes for these entities rather than simply defaulting to third party audits out of convenience.

With that, I'll just reiterate that I heard a lot of great conversation and comments over the last few days, and appreciate the opportunity to present our views here to all of you. We look forward to ongoing opportunities to work together to revise and craft a FSMA implementation strategy that works for all sectors of our food supply. Thank you.