

July 31, 2018

Dear State Agriculture Commissioners, Secretaries, and Directors:

Last year I committed to communicating with you about the work we are doing to implement the Produce Safety Rule mandated by the FDA Food Safety Modernization Act (FSMA). As I stressed at both the National Association of State Departments of Agriculture (NASDA) annual meeting and the winter policy conference, I value the partnership the Food and Drug Administration (FDA) has with NASDA. I receive regular updates on the work that is taking place between FDA staff and the states to successfully implement the FSMA Produce Safety Rule. The work that NASDA and the states are undertaking is critical to success, which is why I feel it is important to continue our dialogue and for FDA to continue updating you on the progress we have made on issues of joint interest.

RULEMAKING-RELATED UPDATES

- The Definition of “Farm”

We are reconsidering the definition of a “farm” as used in the FSMA regulations. NASDA and other stakeholders, including the farming community, have expressed concerns about whether and when packing houses, terminal markets, and other entities conducting farm-related activities are required to comply with the preventive controls or produce rules. We agree that there is a need for additional clarification, and are actively working on proposing a draft rule, expected in the next year, that would make changes to general provisions related to the registration of food facilities rule—including edits to the farm definition. In the meantime, we announced in January of this year that we intend to exercise enforcement discretion for certain facilities, such as some that pack and hold raw produce, that are subject to preventive controls provisions because they are not considered farms. We intend to exercise enforcement discretion until we have completed our rulemaking to address this issue.

- Agricultural Water

In February, we joined a very successful summit, hosted by the Produce Safety Alliance, on the agricultural water standards. There were hundreds of participants at the summit in Covington, Kentucky, and 28 satellite locations across the country. Discussion focused on how agricultural water is an important and challenging area that should be addressed by Produce Safety Rule requirements. There were frank conversations about the challenges presented by the current requirements in the Produce Safety Rule, and alternate water testing and management strategies were discussed. Feedback from these discussions will help inform further dialogue with stakeholders and other next steps on these important issues. We are currently collecting information about on-farm conditions and water systems. During this

process, we are engaging with stakeholders through on-farm visits and other meetings to learn more about the diverse ways water is used and to ensure that the standards will be as practical and effective as possible for all farming operations. We aim to be as transparent as possible moving forward, and we remain committed to protecting public health while implementing rules that are workable across the diversity of the food industry.

- Biological Soil Amendments of Animal Origin (BSAAOs)

Work continues towards creating a framework for evaluating the safe use of untreated BSAAOs, such as raw manure, on farms. We have concluded a major research initiative involving the United States Department of Agriculture's (USDA) Agricultural Research Service and several state universities to develop a multi-year, seasonal and regional dataset involving the persistence of pathogenic *E. coli* and *Salmonella* in the growing environment. This dataset will be instrumental in the development of a survival model as a major component of our risk assessment to inform future policy decisions on this issue. We are currently engaged in three more research projects to inform other aspects of the risk assessment activities.

- Produce Guidance

We continue to develop the draft guidance for the Produce Safety Rule and anticipate that it will be released for public comment in the near future. I know this guidance is long awaited, especially with inspections around this rule scheduled to begin in 2019. To accommodate growing practices that vary by region and commodity, a great deal of flexibility was built into the rule, and there are different approaches that farms can take to meet the requirements. In this draft guidance, FDA will explore some of these approaches by discussing and demonstrating how they might be implemented. FDA has also committed to holding four public meetings around the country, where stakeholders will have the opportunity to publicly discuss the document. We intend to announce those dates soon via a notice in the *Federal Register*.

- Domestic-Foreign Parity

We are working hard on multiple fronts, including by implementing FSMA's Foreign Supplier Verification Programs (FSVP), to ensure that food imported from abroad is as safe as that produced domestically. In addition to FDA inspections of foreign facilities, we have conducted hundreds of inspections under the FSVP final rule since the first compliance date arrived in May 2017. As more FSVP compliance dates roll out, we are continuing to build our FSVP importer inventory.

Following the recognition of the first three accreditation bodies under FDA's Accredited Third-Party Certification Program earlier this year, we are reviewing additional applications and looking forward to the accreditation of third-party auditors (also known as certification bodies). Audits and certifications of foreign facilities under the Third-Party Certification Program are another way in which FSMA strengthens FDA's oversight of imported foods.

The new tools provided under FSMA, together with foreign inspections and screening, examination, and sampling at the port of entry, help FDA ensure parity in our oversight of foreign and domestically produced food. This means that we are holding all food producers

to the same standards, no matter where in the world they are located. Additionally, FDA's ability to allocate resources efficiently is enhanced by cooperation with international regulatory counterparts through comparability assessments (i.e., Systems Recognition), equivalence determinations, and food safety partnerships.

IMPLEMENTATION PREPAREDNESS

- Training

There has been progress on Produce Safety Rule training for 2018. Through the Produce Safety Alliance training, almost 600 grower training courses have been conducted domestically and internationally. Through these programs more than 14,000 farmers have been trained. Domestically, 49 train-the-trainer courses have been held in 30 states, with more than 1,500 trainers trained. Internationally, 246 international grower trainings have been held in 14 different countries that trained 5,988 farmers.

FDA's regulator training has also been a key focus. We have conducted six of seven produce regulator training sessions planned for 2018, and we remain on-target for reaching the NASDA-informed number of state regulators that need training to be ready for initiation of inspections in 2019. FDA continues to work with NASDA on enhancements to the regulator training, which will be evaluated and updated as the inspection, compliance, and enforcement documents are reviewed within the Agency.

We are also offering two virtual training programs this fiscal year. One, entitled "[Produce Inspections for Regulators Virtual Produce Tour](#)," was posted on YouTube in June. The video is intended for produce inspectors, regulators, growers, extension agents, and others interested in produce inspections conducted in accordance with the Produce Safety Rule. A second webinar will be available by September 30 entitled "An Overview of the Produce Inspections Training Curriculum for Extension Service Agents."

- On-Farm Readiness Review (OFRR) Visits

NASDA, in collaboration with FDA, has invested significant resources into developing and implementing OFRR visits to help farmers assess how prepared they are to comply with the Produce Safety Rule. These voluntary On-Farm Readiness Reviews are beginning this summer. There are 14 OFRR training sessions being completed, and states are working to set up mechanisms for farms to request OFRRs. I applaud NASDA's education efforts and encourage states to continue working with NASDA staff on these activities.

- Inspectional Documentation and Dispute Mitigation and Resolution Procedures

Recently, FDA and NASDA have worked to explore new ways of ensuring objectivity and consistency for produce inspections as well as ways to handle disagreements between regulatory agencies conducting produce inspections. After exploring options extensively, we have made progress on both initiatives.

For produce inspections, FDA and NASDA have been working on alternatives to the traditional 483 inspectional observation form. The idea is to pilot a produce-specific

inspectional form that recognizes the unique issues associated with produce farm inspections. It holds promise as a tool for both helping farmers understand what is being examined in an inspection and promoting consistency among inspections by providing a structured format that closely tracks the Produce Safety Rule provisions. FDA is working with NASDA to finalize this alternative form in the near future.

While it is our hope that a produce-specific inspectional form may reduce the likelihood that incorrect or extraneous information is recorded—and our training efforts have aimed at reducing the chance that will happen—we also want to be prepared for the rare possibility that this does occur. In particular, we want mechanisms to quickly resolve any disagreements between agencies with produce safety regulatory authority. That is why FDA and NASDA have held extensive discussions on Dispute Mitigation and Resolution Procedures. In our most recent conversations, we have been able to reach agreement on a path forward for avoiding the use of strikethroughs when correcting documents. We recently received a final round of feedback from NASDA on our draft procedures, and expect to finalize these shortly.

FDA's expectation is that dispute resolution between FDA and state regulatory bodies will be rarely needed because the vast majority of produce inspections will be conducted by states and because of the mitigation steps we have committed to for the small number of inspections we will perform. Nevertheless, we feel we are now taking an important step to finalize the Dispute Mitigation and Resolution Procedures in a way that addresses NASDA concerns.

BUILDING ON PARTNERSHIPS

- Partnership with States
Most states are well on the way to implementing produce safety programs, including outreach, education, identifying inventories of covered farms, and preparing for the initial inspections of large farms in 2019. In recent years, FDA has provided technical support and funding to help states build the infrastructure for these new programs, and earlier this month, we announced new cooperative agreements with three additional states as well as renewed agreements with states already taking part in cooperative agreements. [This brings us to a total of 46 states and one territory participating.](#) We welcome remaining states that have not applied for cooperative agreements (or those that would like to expand their cooperative agreements to Competition B funding) to contact our Office of Regulatory Affairs' Office of Partnerships for assistance with the application process.
- FDA/USDA Formal Agreement
On June 5th, [we formally recognized the USDA's Harmonized Good Agricultural Practices \(H-GAPs\) Program as aligned with the FDA Produce Safety Rule.](#) Produce growers have repeatedly expressed concerns about facing multiple market access audits from produce buyers and now additional inspections for compliance with the Produce Safety Rule. While this recognition does not exempt farms covered by the Produce Safety Rule from state or federal inspections, it is intended to help farmers meet the requirements as efficiently as possible.

FDA takes our responsibility for assuring the safety of the food supply seriously, and food safety is one of my highest priorities as Commissioner. While the United States has one of the safest food supplies in the world, recent outbreaks continue to highlight the all-too-real consequences of foodborne illness, and the need to ensure that the goals of FSMA are fully achieved. Our goal, through better communication, smart regulation, and enhanced use of technology, is to shift our food system from one that reacts to problems to one that prevents them from happening in the first place. Food safety needs to be priority number one from the farm to table. I know you all share this goal and that together we are leading the implementation of this critical food safety program.

We look forward to continuing our interactions with NASDA leadership to discuss these and other issues. I will be back in touch as our work evolves.

Sincerely,

Scott Gottlieb, M.D.
Commissioner of Food and Drugs