

February 7, 2019

Dear State Agriculture Commissioners, Secretaries, and Directors:

As I have done periodically, I want to provide you, our regulatory partners, with an update on work to implement the Produce Safety Rule mandated by the FDA Food Safety Modernization Act (FSMA).

When I attended the National Association of State Departments of Agriculture (NASDA) conference in 2017, I announced that routine inspections associated with the Produce Safety Rule would begin in spring of 2019 for the largest produce farms (other than sprouts operations, which have requirements specific to them). Routine inspections of small farms (other than sprouts operations), for which the compliance date arrived January 28, 2019, will begin in spring 2020. This timeline was intended to ensure that produce farmers had the tools needed to help them comply with the new rule requirements. Routine Produce Safety Rule inspections will also begin this year for large farms in countries that export produce to the United States, and FDA intends to begin routine inspections of produce importers under FSMA's Foreign Supplier Verification Programs rule in fall 2019.

I am grateful for my dedicated colleagues at FDA who have continued to work to ensure that we are able to maintain our plans to initiate inspections this spring, and I'm grateful to NASDA and individual states for your work to prepare for this critical new phase in our regulation of produce farms.

Below, please find an update on some of the remaining deliverables we have been working on to support a successful initiation of inspections.

IMPLEMENTATION PREPAREDNESS

- **Training**
There has been significant progress in training farmers around the world who must comply with the Produce Safety Rule. Training currently is provided by the Produce Safety Alliance (PSA) domestically and the Produce International Partnership for Education and Outreach (PIP) internationally. PIP is a collaboration between the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and PSA. PIP is charged with implementing the international outreach strategy for the Produce Safety Rule with materials that consider cultural, technological, and language differences and needs.

Through PSA and PIP, 1,359 grower training courses have been conducted domestically and internationally; more than 31,000 farmers have been trained as of mid-December. Seventy-seven domestic and international train-the-trainer courses have been held, with almost 2,500

trainers trained. Internationally, 688 trainers and lead trainers have been trained in 32 countries. In 2018, training was provided to countries in Latin America designated as priorities for produce training. International grower and train-the-trainer courses are being planned for 2019.

For our regulators, we continue to provide training to our staff and our state partners who will be performing farm inspections. We have conducted eight regulator training courses since August 2017, training 177 state personnel on produce inspections since then. Additional courses are planned this year, including one that was held January 29 to February 1 in California.

FDA has worked with NASDA and other stakeholders to enhance the regulator training, and we are updating the course continually in response to participants' comments and to incorporate new materials developed through the FDA/NASDA cooperative agreement. For the regulators who have already attended the course, we are planning a webinar to provide them with the updated materials; this webinar is being planned for February. We have also provided training for the state extension partners so that they have a basic understanding of produce farm inspections.

- On-Farm Readiness Review (OFRR) Visits
FDA has been working closely with NASDA in its development of the OFRR program. Through these efforts, more than 350 farms have already had a voluntary OFRR evaluation. I had the opportunity to visit a farm in Oregon some months ago to get a firsthand understanding of how OFRRs can be a powerful tool in preparing for future inspections. NASDA continues to train our state partners to make more personnel available to do the OFRRs in the future, and we will continue to provide our support to make OFRRs an available tool for farmers even as routine inspections begin for the largest farms (other than sprouts operations).
- Produce Guidance
We published the [Draft Compliance and Implementation Guidance](#)¹ for the Produce Safety Rule in October 2018, along with fact sheets highlighting key information in each chapter. This draft guidance has been a long time in the making, and we appreciate the assistance NASDA has provided during the guidance development. We have conducted four public meetings to discuss the draft guidance with stakeholders.

When finalized, the draft guidance will contain non-binding recommendations that provide a means for us to explain our current thinking on implementation. It provides examples, clarification, and information to help farms develop their own practices because the Produce Safety Rule generally includes enough flexibility for farmers to implement the requirements in a way that best fits their operation. We don't try to describe every possible scenario or solution; there may be several different approaches that all result in compliance.

¹ <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm606284.htm>

Our target audience includes those engaged with implementation on a farm, including the owner, operator agent, and farm management personnel. It also includes organizations that assist farms with implementation, such as extension service, trade associations, and academia. The draft guidance, when finalized, will also be useful to the federal and state inspection staff as they help farmers achieve compliance.

- Creating Specialized Documents

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. As I indicated in my last letter, FDA and NASDA have made major progress on two new documents that will support produce inspections, and these documents are now finalized and publicly available.

The first document is the form [FDA 4056](#)², “Produce Farm Inspection Observations.” This form represents a new way of providing feedback to farms and documenting observations that is different from FDA’s traditional process of reporting inspection observations made during an inspection, which has traditionally been through the FDA 483 Inspectional Observations Form. The new form (FDA 4056) is designed around the specific provisions in the Produce Safety Rule and was developed to help farmers better understand what is being examined in an inspection. FDA will issue the new 4056 form at the end of every farm inspection, whether or not any non-compliance issues were identified. When observations are noted during an inspection, the format of the FDA 4056 will help farmers understand what is being examined in an inspection and how any observation relates to the regulation. We are working with states to promote consistency across the produce program through use of the new form.

As you know, last summer we also reached agreement on the Dispute Mitigation and Resolution Procedures. While we hope and anticipate that such instances will be rare, we understand the importance of having processes in place to prevent any differences of interpretation and to quickly resolve any disagreements between agencies with produce safety regulatory authority. FDA has now incorporated the finalized Dispute Mitigation and Resolution Procedures into [Field Management Directive 152](#)³, and we are ensuring that our investigators are aware of these new procedures.

FDA will also be rolling out a Regulator Technical Assistance Network (rTAN) to support produce safety inspections. This resource, available to FDA investigators and state inspectors, will be available to provide timely technical assistance from subject matter experts at the Agency before or during inspections. We will be providing more information on this to our state partners in the near future.

- Produce Inspections Web Page

² <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM630765.pdf>

³ <https://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM630608.pdf>

We recognize that keeping track of the many produce-related resources can be a challenge, so we've created a new [Produce Inspections web page](#)⁴ at [fda.gov](#). We hope it will be a useful, central location for our stakeholders and state partners to find resources as they make their final preparations for the start of routine inspections this spring.

RULEMAKING-RELATED UPDATES

- Agricultural Water

We are working to ensure that the standards for agricultural water in the Produce Safety Rule are feasible and effective for all sizes and types of produce farms. We have proposed to extend the compliance dates for these standards (for produce other than sprouts), and we continue to exercise enforcement discretion as we consider how to move forward.

As we work on how best to achieve public health protections related to agricultural water used on covered produce, we are also mindful of recent produce-associated outbreaks. FDA considers that the most likely way romaine lettuce became contaminated with *E. coli* O157:H7 during an outbreak in the spring of 2018 was from the use of water from an irrigation canal. This was the largest multistate outbreak of *E. coli* O157 infections in the United States since 2006, leaving hundreds sick and claiming the lives of five people who consumed contaminated romaine lettuce.

FDA is working with stakeholders, including growers, processors, irrigation districts, and state and local regulatory partners, to better understand potential sources and routes of contamination, and to prevent outbreaks like this one from happening again. For example, the Agency has been collecting romaine lettuce samples at commercial coolers in the Yuma, Arizona, growing region, which service growers in both Arizona and the Imperial Valley in California, and analyzing them for the presence of *Salmonella* and pathogenic *E. coli*. FDA chose to collect samples at leafy greens coolers because we can efficiently collect samples from multiple farms at one location while maintaining the identity of the farm that corresponds to each sample.

The Agency is also working with stakeholders to develop and implement a multi-year study in the Yuma County and Imperial County growing regions to better understand the presence of pathogens, especially *E. coli* O157:H7, in the growing environment.

Knowing where produce was grown and when it was harvested will play an important role in helping retail establishments and consumers avoid contaminated products and facilitating market withdrawals and tracebacks. Thus, we have engaged with the leafy greens industry to implement voluntary labeling to improve FDA's ability to provide, and retail and consumers' ability to use, targeted information about product origin in the event of future outbreaks. And we are strongly encouraging the entire leafy greens supply chain to adopt traceability best practices and state-of-the-art technology to ensure rapid access to key data when leafy greens are involved in a potential recall or outbreak.

⁴ <https://www.fda.gov/ICECI/Inspections/UCM627767.htm>

Outbreaks related to fresh produce reinforce the importance of the work we are doing together to enhance the safety of all fresh fruits and vegetables through science, technology, and the Produce Safety Rule.

NEW LEADERSHIP AT FDA

Dr. Stephen Ostroff, our Deputy Commissioner for Foods and Veterinary Medicine since May 2016, has retired after a distinguished and dedicated career in public service, including more than 5 years of exceptional service at FDA. I am immensely grateful for his dedication to FDA's public health initiatives and our vital consumer mission.

Frank Yiannas, a renowned food safety and supply chain expert, has joined FDA as Deputy Commissioner for Food Policy and Response. Throughout his private sector career, he's been a food safety champion and instrumental in forging public-private collaborations to advance public health. I welcome Frank to our Foods Team, and I know that he will be an invaluable partner in continuing our work with NASDA to ensure the safety of the American food supply.

Sincerely,

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