



November 30, 2017

Dear State Agriculture Commissioners, Secretaries, and Directors:

We all share the common goal of ensuring the safety and quality of the American food supply. When I spoke this September at your annual meeting of the National Association of State Departments of Agriculture (NASDA) in New Orleans, I emphasized the importance of collaboration between this Agency and the states in continuing our efforts to develop a truly integrated food safety system—specifically, making implementation of the produce safety rule, mandated by the FDA Food Safety Modernization Act (FSMA), a reality. The states and NASDA have been important and trusted partners in the extensive work we have already done.

As we continue to move into the implementation phase, we recognize that there will be challenges ahead; however, maintaining our strong lines of communication will allow us to effectively address important concerns and help ensure our success. I am personally committed to regularly communicating with the commissioners, secretaries, and directors of agriculture in every state about the work we are, and will be, doing together.

In addition, we made some important progress in our work together during a meeting, earlier this month, between members of the NASDA Food Regulation Committee, NASDA staff, and senior FDA leadership. NASDA's representatives included Richard Ball, Commissioner of the New York State Department of Agriculture and Markets; Don Brown, Colorado Commissioner of Agriculture; and Steve Troxler, Commissioner of the North Carolina Department of Agriculture and Consumer Services. I would like to thank all the meeting participants for their contributions. I found it helpful to hear their perspectives on the food safety regulatory issues and challenges that you are facing at the state level.

As a follow-up to our discussion, I would like to provide you with a summary of some of the key topics we discussed and our commitments to next steps. We covered important issues, and I am committed to ensuring that, across FDA, we work with NASDA to address the concerns raised as quickly as possible.

- Packing house/terminal markets

FDA is pursuing a solution to the concerns expressed by NASDA and other stakeholders about whether a packing house or terminal market is required to comply with the preventive controls or produce rules. We agree that there is a need for additional clarification. However, a solution may require rulemaking, an effort that Dr. Stephen Ostroff, FDA's Deputy Commissioner for Foods and Veterinary Medicine, is currently leading. In the meantime, FDA plans to exercise enforcement discretion for certain packing, packaging, and/or holding facilities, and we intend to make our policy public by January 2018.



- Dispute resolution for the produce rule
In light of the concerns expressed about dispute resolution, FDA continues to explore an inspection documentation and review process that is tailored to produce inspections and that enhances fairness and consistency in FDA and state inspections. Melinda Plaisier, FDA's Associate Commissioner for Regulatory Affairs, is leading this work. FDA will be prepared to discuss this in greater detail with NASDA early next year.
- Policy for On-Farm Readiness Review (OFRR) visits
FDA and NASDA have agreed on an approach to this policy, and a revised draft will be discussed with the FDA-NASDA OFRR working group next month. During OFRRs over the next year, if state reviewers—or FDA investigators for those OFRRs in which FDA participates—observe certain serious conditions or practices, but the farm makes immediate corrections to the reviewers' satisfaction and no affected produce has or will enter commerce, then reviewers need not alert FDA (or if FDA is doing the OFRR, need not refer the farm for inspection). However, if such conditions have been observed and produce has already entered commerce, then the observation needs to be documented and/or reported to FDA, as a recall or other action may be triggered. Associate Commissioner Plaisier and Deputy Commissioner Ostroff will ensure that this approach is clearly communicated to all FDA staff involved in OFRR implementation.
- Agricultural water
FDA staff recently spoke with NASDA staff to ensure their active participation in the upcoming summit to discuss agricultural water quality and testing. We are committed to ensuring that NASDA, as well as other key stakeholders, are partners at the table during these discussions. In addition, the produce safety team at FDA's Center for Food Safety and Applied Nutrition will work to develop a more comprehensive plan and timeline for the consideration of agricultural water standards that can be shared with NASDA and other stakeholders.
- Training
FDA is planning to host NASDA for a multi-day workshop on training needs for state regulators and extension staff before the end of the calendar year. The goal of this workshop will be to finalize the number of regulators and extension staff who must be trained, determine the exact training needed, and ensure that adequate training is planned and scheduled. Associate Commissioner Plaisier is leading this effort and will ensure that any remaining resource concerns are addressed by Agency leadership.

Maintaining an open line of communication between FDA and NASDA is vital to our collective success in achieving our shared public health mission and food safety goals. FDA has long valued our partnerships with the states, and I want to further strengthen our relationship moving forward. We look forward to continuing to work together on these and other topics.



We are working with NASDA leadership to set up future meetings of this group to further our commitment to ensuring the safety of our food supply. I will also continue to share updates like these on a regular basis.

Sincerely,

Scott Gottlieb, M.D.

Commissioner of Food and Drugs