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MEMORANDUM

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Re: Produce Safety Rule Inspections Will Begin Soon

U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb recently issued a statement affirming that Produce Safety Rule inspections will begin this spring. ^{1/} Last year FDA chose to delay routine inspections to allow more time for farmers and state regulators to receive training on the rule. Routine inspections for large farms (i.e., farms with more than an average \$500,000 in produce sales during the previous 3-year period) were delayed until spring 2019, and routine inspections for small farms, other than sprouts operations, were delayed until spring 2020. In his statement, Commissioner Gottlieb confirmed that routine inspections for large domestic and foreign farms will commence this spring, as planned.

FDA also has established a Produce Inspections webpage to serve as a central location for farms and state partners to find resources related to inspections. ^{2/} The webpage includes a new Fact Sheet with information on what farms should expect of their first inspection. It also includes new documents to be used during Produce Safety inspections, including the recently developed inspectional observation form and a procedure for dispute mitigation and resolution. This memorandum briefly summarizes the fact sheet and new inspection documents.

Fact Sheet – What to Expect of a Regulatory Inspection

FDA's newly issued documents include a Fact Sheet detailing what farms should expect during Produce Safety Rule inspections. ^{3/} The first step is a pre-inspection call, during which a state inspector or FDA investigator will ask questions to make a preliminary determination as to whether the Produce Safety Rule applies to the particular farm. If the farm is determined to be eligible for a qualified exemption or produce is eligible for the commercial processing exemption, the inspector or investigator will review records that support this status. If the farm is covered by the rule, the inspector or investigator will schedule an inspection date, typically within five days. The Fact Sheet

^{1/} Paving the Road to Produce Safety Rule Inspections (Feb. 7, 2019), available at <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm630790.htm>.

^{2/} Produce Safety Inspections, available at <https://www.fda.gov/ICECI/Inspections/ucm627767.htm>.

^{3/} "What to Expect of a Regulatory Inspection," Informational Handout for Farmers, available at <https://www.fda.gov/downloads/ICECI/Inspections/UCM630682.pdf>.

also outlines the circumstances under which an unannounced inspection may occur (e.g., in response to a foodborne illness outbreak investigation).

Additionally, the Fact Sheet includes recommendations on the farm personnel who should be present the day of the inspection and provides an overview of the initial inspection interview, the walk-through of the farm, and the exit interview.

FDA Form 4056 – Produce Farm Inspection Observations

FDA also released Form FDA 4056, “Produce Farm Inspection Observations,” which will be used to provide feedback to farms and document observations. ^{4/} This document will be used in the same way as the Form FDA 483 Inspectional Observations document is used for facility inspections, but there are significant differences in the two forms. Form FDA 4056 was designed around the specific requirements of the Produce Safety Rule and is intended to help farmers better understand what is being examined during an inspection. The Produce-Safety-Rule-specific form is a checklist that itemizes each of the requirements under the rule, so it is more similar to the type of inspectional documents that are typically used on the state and local level. Unlike 483s, a Form FDA 4056 will be issued at the end of every farm inspection, regardless of whether any non-compliance issues are identified.

Produce Safety Dispute Mitigation and Resolution Procedures

FDA has issued Field Management Directive (FMD) 152, *Produce Safety Dispute Mitigation and Resolution Procedures*, which outlines a process that can be used to resolve disputes between agencies with Produce Safety regulatory authority. ^{5/} The document does not address disputes between a regulator and industry. One of the goals of the procedure is to ensure consistent inspection findings across state and federal inspections. Also included in the document are pre-dispute procedures and protocol, which include FDA and states collaborating to develop inspectional procedures to promote uniformity and consistency of inspections. While the document is directed to FDA inspectional staff, farms should review the document, as it provides additional insight into what farms may expect during a Produce Safety inspection.

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We will continue to monitor developments concerning the Produce Safety Rule and FDA’s FSMA implementation. Please contact us if you would like further information on this issue.

^{4/} Form 4056 (Produce Farm Inspection Observations), available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM630765.pdf>.

^{5/} FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures (Effective Jan. 31, 2019), available at <https://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM630608.pdf>.