

ORA-WIDE PROCEDURE Food and Drug Administration Office of Regulatory Affairs	Document #: FMD-152 (DIR-000044)	Page 1 of 7
Title: FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures	Revision 00	Effective Date 01/31/2019

Sections in This Document

1. Purpose	1
2. Scope	2
3. Background.....	2
4. References	2
5. Procedures/Responsibilities	2
5.1. Pre-Dispute Procedures and Protocol.....	2
5.1.1. Resources and Other Dispute Resolution Processes Already Available During and Post- Inspection	4
5.2. Informal Dispute Resolution Process	5
5.3. Formal Dispute Resolution Process and Panel.....	5
6. Glossary/Definitions.....	6
7. Records	7
8. Supporting Documents	7
9. Document History	7
10. Change History	7
11. Attachments.....	7

1. Purpose

The purpose of this Field Management Directive (FMD) is to define a dispute resolution process for produce safety that:

1. Reflects the partnership approach to produce safety inspections and facilitates strengthened relationships leading to proactive engagement and improved communication among all regulatory parties;
2. Can be used to resolve disputes between agencies with produce safety regulatory authority (whether implementing the federal Produce Safety Rule or comparable state regulations), but is not intended to resolve disputes between a regulator and industry; and
3. Helps ensure that regulatory partners issue consistent inspection findings across all inspections, keeping in mind:
 - a. Food and Drug Administration (FDA) can revise its own inspectional observation documents where appropriate and issue an amended document;

ORA-WIDE PROCEDURE Food and Drug Administration Office of Regulatory Affairs	Document #: FMD-152 (DIR-000044)	Page 2 of 7
Title: FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures	Revision 00	Effective Date 01/31/2019

- b. States have their own process for how to revise their respective observational documents;
- c. This informal mechanism could be used before or after the issuance of inspectional observation documents; and
- d. Should be used sparingly, and only when there are significant and time-sensitive disputes about the suitability of including certain items on an inspectional observation document.

2. Scope

This document applies only to the Office of Human and Animal Food Operations (OHAFO) divisions in Office of Regulatory Affairs (ORA).

3. Background

FDA and states agree that disputes should be resolved at the lowest level possible within their respective organizations, and all parties are committed to the goal of minimizing disputes through training, education, and clear, distinct, and up-to-date policies and procedural documents. When disputes do occur, this dispute resolution process, collaboratively developed by FDA and states, should be used whenever possible. Because this dispute mitigation and resolution process contains new operations and is focused towards a new type of inspection, these procedures will be piloted and refined as needed.

4. References

- A. None
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5. Procedures/Responsibilities

5.1. Pre-Dispute Procedures and Protocol

- A. FDA and states will jointly develop inspectional procedures to promote uniformity and consistency of produce safety inspectional processes.
- B. Procedures specific to produce safety inspections should be designed in accordance with FDA and state regulatory authorities' mission to protect the public health while remaining focused both on the

ORA-WIDE PROCEDURE Food and Drug Administration Office of Regulatory Affairs	Document #: FMD-152 (DIR-000044)	Page 3 of 7
Title: FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures	Revision 00	Effective Date 01/31/2019

educational needs of farmers under a new regulatory scheme and prevention of contamination.

- C. It is critical that FDA and states set up procedures for documenting produce safety inspectional observations, focusing on assuring that conditions with significant public health impacts are recorded (for FDA, in accordance with 21 USC 704(b)). Verbal discussion and all other communication mechanisms available to the investigator/inspector will also be used to communicate recommended and/or required improvements with farmers.
- D. Inspections conducted by FDA will be led by a dedicated cadre with training specific to produce safety. Training of investigators/inspectors will emphasize that there should be a discussion with management as any observations are identified, or on a daily basis, to clearly identify any potential observations the investigator/inspector has identified (for FDA, per existing procedures), and to serve as an opportunity to clarify any unresolved issues and avoid surprises during the closeout of an inspection. These practices should be explained to industry to ensure understanding and expectations. It is expected that states will use the Produce Farm Inspection Observations form in conducting state inspections.
- E. FDA and states will train investigators/inspectors to recognize significant deviations that should be listed on an inspectional observation document versus issues where investigators/inspectors should have a discussion with a farmer, contact the Regulator Technical Assistance Network (“TAN”) or supervisors, or utilize other communication mechanisms available before finalizing the document. Training will emphasize the types of observations that should be listed on the inspectional observation document. FDA and states agree to communicate with firms, farms, and other non-regulatory parties within the produce supply chain the purpose of the inspectional documents that are provided during an inspection.
- F. Prior to the closeout of any inspection where FDA is considering issuing an inspectional observation document with reportable observations, an FDA produce safety compliance staff and/or supervisors will review the document. As part of this process, the FDA investigator will discuss within FDA to ensure that the observations are documented consistent with current agency policy. FDA will strive to have this review occur within one business day. FDA will discuss with states before changing this approach. This will not apply to state-issued inspectional observation documents. States may have their own process in place.

ORA-WIDE PROCEDURE Food and Drug Administration Office of Regulatory Affairs	Document #: FMD-152 (DIR-000044)	Page 4 of 7
Title: FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures	Revision 00	Effective Date 01/31/2019

- G. States with Produce Safety Cooperative Agreements that include Competition B/inspection program development funding (under PAR-16-137) will have primary responsibility for routine on-farm inspections within their states (except on federally recognized tribal lands).
- H. If FDA plans to go on a farm for produce safety purposes, including for surveillance assignments or outbreak investigations, FDA will invite the state to conduct a joint FDA-state inspection or investigation, with the option for both parties to fully participate in all aspects of the inspection or investigation.
 - 1. For states not participating in Competition A and/or B, National Association of State Departments of Agriculture (NASDA) will identify a list of State offices to be contacted and it will update the list as necessary.
 - 2. For investigations, FDA and states will engage the other as early as is practical, with both parties acknowledging that time sensitivity may be heightened, and protection of public health must remain the primary concern.
 - 3. FDA commits to proactively engage states with Competition B funding before issuing an inspectional observation document, except when this could jeopardize public health.
 - 4. Efforts will be made to resolve potential disputes before an inspectional observation document is issued, but this is not intended to encourage minor wording debates on individual items.
- I. Where possible, in the interest of timely resolution, a dispute may be bifurcated (for example, the scientific matter can be sent to the appropriate channel, and the time- sensitive inspection observation document issue can enter the informal process).
- J. Analysis of trends identified through the dispute resolution process (e.g., common issues of dispute) or other matters that emerge will be discussed in regular meetings with FDA and NASDA.

5.1.1. Resources and Other Dispute Resolution Processes Already Available During and Post- Inspection

- A. FDA has an existing process under 21 CFR 10.75 that is available to request internal agency review of the decision of an FDA employee.
- B. Within Center for Food Safety and Applied Nutrition (CFSAN), there is an additional, internal FDA process for scientific disputes, with some formal procedures.

ORA-WIDE PROCEDURE Food and Drug Administration Office of Regulatory Affairs	Document #: FMD-152 (DIR-000044)	Page 5 of 7
Title: FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures	Revision 00	Effective Date 01/31/2019

C. The FDA Regulator TAN can also be used when there are questions during the inspectional process to get clarity on issues that are unclear.

5.2. Informal Dispute Resolution Process

Note: It is expected that this process will be used during an open inspection or within 30 days after the close-out of an inspection.

- A. Identify the dispute and attempt to resolve through discussion at the lowest level possible, which may be discussion between State Supervisors or a State Supervisor and an ORA Produce Safety Network Branch Chief.
- B. FDA may issue an amended inspectional observations document if FDA determines that there were errors or that an observation should not have been listed based on agency policy. (The correction can happen in a matter of days for FDA; states may have their own processes in place).
- C. Unresolved disputes will be escalated to supervisors on both sides.
- D. State Director or Program Manager and/or FDA will decide whether to escalate disputes to the next level.
- E. Unresolved disputes may utilize the **Formal Dispute Resolution Panel**.

5.3. Formal Dispute Resolution Process and Panel

- A. Unresolved disputes can be escalated to an ORA OHAFO Program Director who will convene a panel facilitated by the ORA Ombudsman's Office (in most cases by telephone or other electronic means). A state may trigger this formal process after discussions with a farm, if the state believes the issue needs to be further disputed.
- B. Panel members should not be directly involved in the dispute and must be FDA employees, or state officials commissioned by FDA. Parties can submit documentation from any relevant source.
 1. The panel, assembled by the ORA Ombudsman's Office in consultation with NASDA, may consist of:
 - a. An appointee from the FDA Food Safety Modernization Act (FSMA) team;
 - b. One or more appointees from the FDA Produce Safety Network;
 - c. Two or more State appointees from a list of approximately 20 candidates; and
 - d. Additional Subject Matter Experts, Technical Experts, or Policy Experts, identified by either side, to meet specific needs.

ORA-WIDE PROCEDURE Food and Drug Administration Office of Regulatory Affairs	Document #: FMD-152 (DIR-000044)	Page 6 of 7
Title: FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures	Revision 00	Effective Date 01/31/2019

2. All parties (FDA and the impacted state[s]) have a chance to present their positions to the panel.
 3. The members of the panel will each individually provide his or her recommendations, which could involve actions not proposed by either party, to the ORA OHAFO Program Director who decides.
- C. If any party determines that the issue needs to be further escalated, the issue may be raised to ORA's Assistant Commissioner for Human and Animal Foods Operations for a decision.
- D. If any party determines that the issue needs to be further escalated, the issue may be raised to the Associate Commissioner for Regulatory Affairs for a decision.
- E. Further FDA review is discretionary.
- F. The process under 21 CFR 10.75 is available.
- G. If the Program Director or Assistant Commissioner determines that an observation on an inspectional observation document was erroneous or should not have been listed based on agency policy, the Agency will:
1. Issue an amended document to the firm along with a cover letter describing the changes made
 - a. The amended inspectional observation document will be issued as a clean version, unless the inspected entity specifically requests a redline version with the changes.
 - b. The original document will remain, subject to federal records retention and disclosure requirements of the Agency. If the original document is released, the amended document will be included.

6. Glossary/Definitions

- A. CFSAN: Center for Food Safety and Applied Nutrition
- B. FDA: Food and Drug Administration
- C. FMD: Field Management Directive
- D. FSMA: Food Safety Modernization Act
- E. NASDA: National Association of State Departments of Agriculture
- F. OHAFO: Office of Human and Animal Food Operations

ORA-WIDE PROCEDURE Food and Drug Administration Office of Regulatory Affairs	Document #: FMD-152 (DIR-000044)	Page 7 of 7
Title: FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures	Revision 00	Effective Date 01/31/2019

G. ORA: Office of Regulatory Affairs

H. TAN: Technical Assistance Network

7. Records

None

8. Supporting Documents

None

9. Document History

Revision	Status* (D, I, R, C)	Date	Author Name and Title	Approving Official Name and Title
00	I	01/31/2019	Michael Rogers, Assistant Commissioner for Human and Animal Foods Operations	Michael Rogers, Assistant Commissioner for Human and Animal Foods Operations

* - D: Draft, I: Initial, R: Revision, C: Cancel

10. Change History

Revision	Change
00	Initial Release

11. Attachments

None