CHAPTER 11
JOINT INSPECTIONS & INVESTIGATIONS

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1.0. PURPOSE

Investigations of human and animal food related incidents are often complex and require that multiple agencies conduct activities jointly. This chapter identifies some best practices, basic policies, and important considerations for federal, state,

and local agencies that conduct joint investigations and inspections for human and animal food incidents. This may help groups conducting these activities to develop and improve policy and procedures for this work.

2.0. SCOPE

These best practices apply to situations in which multiple regulatory agencies are on-site at an establishment or when multiple agencies are conducting separate but closely related investigations.

This chapter also establishes basic procedures for the agencies involved in these joint responses and investigations, including that they:

- Meet in advance
- Work through legal authorities and policy documents
- Develop shared plans, training, and exercises.

These procedures also outline that these plans, training courses, exercises, and real-world responses utilize the concepts of the Incident Command System (ICS), particularly focusing on Unified Command scenarios where multiple agencies and jurisdictions work together.

This chapter speaks directly to how state human and animal food regulatory programs can coordinate joint inspections and investigations with the U.S. Food and Drug Administration's (FDA's) inspectorate divisions. However, the principles within this chapter are applicable to other federal, state, and local agencies that have shared regulatory authorities and duties. State, local, and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA Office of Inspections and Investigations (OII)) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement, laboratory) and target response capability levels may differ in how they customize and apply these best practices.

3.0. RESPONSIBILITY

3.1. Agency Leadership (All agencies involved)

Leaders of the involved agencies are responsible for effectively coordinating with each other. Agency administrators are responsible for providing support for joint training, planning, exercises, and responses. This can be accomplished in several ways, ranging from Governors' directives to personal commitments of program leadership to work cooperatively.

3.2. Response/Investigation Team Members

Team members are responsible for ensuring that they are familiar with any agency's joint investigation policies and procedures and can fulfill their assigned roles during joint inspections/investigations.

4.0. DEFINITIONS

See “Glossary of Key Terms” for definitions of terms used in this chapter.

The following terms are used uniquely in this Chapter:

Joint investigation – A multi-agency effort to respond to a disease outbreak, contamination, or other incident within the human and animal food supply.

Joint inspection – A multi-agency effort to collaborate in a regularly scheduled routine review of a facility where each agency has regulatory authority or duties.

5.0. BACKGROUND

Investigations of foodborne illness outbreaks or contamination of livestock feed events are often complex and take several weeks to months to complete. Investigations involve completing epidemiologic studies of ill individuals or animals, tracing products from table-to-farm, seeking contamination sources/modes, testing numerous samples, and writing detailed reports. Public health agencies face significant challenges in determining the exact source(s) and mode of contamination because of the scope and complexity of these investigations and because the contamination events likely happened weeks or months in the past. Additionally, possible duplication of efforts by various involved agencies reduces efficiency and impedes the implementation of targeted preventive measures to prevent recurrence.

In response to the need to improve these kinds of investigations, agencies have developed a variety of approaches. In the late 1990s, the California Department of Public Health and the FDA inspectorate division piloted the California Food Emergency Response Team (CalFERT) to increase efficiency, improve communication and increase the effectiveness of investigations. In 2008, FDA initiated the RRT pilot program with six states to increase collaboration, improve the response to human and animal food emergencies, and reduce inefficiencies as part of the ongoing effort to achieve an integrated national food safety system. In 2009, three additional states were added to the project. This chapter describes the best practices for joint inspections and investigations from the work and experiences of these pilot programs.

6.0. SAFETY

Safety considerations must be addressed jointly before staff respond to an event. Agencies must ensure that staff entering a facility have the equipment and training necessary to safely complete their tasks and that joint teams have comparable (and interchangeable, when possible) equipment.

7.0. EQUIPMENT/MATERIALS

Equipment will vary depending on the inspectional or investigational activity. See attachments for additional details.

8.0. PROCESS DESCRIPTION

8.1. General

It is important to develop an interagency team with appropriate representation of skills and authorities that can respond to emergencies that arise. The agencies involved may need to pre-establish legal arrangements (e.g., memorandum of understanding) to ensure information sharing is as efficient and effective as possible. These agencies can then coordinate limited resources to efficiently investigate numerous leads; increase sampling collection capacity; increase opportunities to find clues to contamination source(s); reduce redundancy; and improve overall efficiency and effectiveness of investigations, enforcement actions, and public health interventions. This joint approach also provides opportunities for investigators to meet and train together to develop trust, expertise, and shared experiences. This results in a highly specialized and experienced investigation team. Please see Chapter one, “Working with Other Agencies” for background and details on concepts/activities important for joint inspections.

8.2. Joint Management Team

The Joint Management Team is composed of designated individuals or leads from all agencies involved in conducting joint investigations and inspections.

When not engaged in an outbreak or event, these agency designees are responsible for maintaining a properly planned, organized, equipped, trained, and exercised team by:

- Scheduling and facilitating meetings for team members
- Setting thresholds for joint agency response
- Providing updates to the agencies’ senior leadership and other parties
- Coordinating with agencies’ training and exercising officers to develop programs for field team and support team members
- Setting standards for approval of reports and other documentation
- Ensuring that an after action meeting (“Hot Wash”) takes place and that lessons learned are integrated into future operations
- Identifying staff to relieve personnel during extended operations and planning for the transition to normal operations after the incident
- Establishing a process or method for working through disagreements and disputes

During an investigation, these team members may be assigned to a variety of different tasks, including inspections, sampling, records review, laboratory testing, compliance, and enforcement. Team members should receive training in all the assigned tasks and disciplines together including the following: office procedures

and field activities such as sampling techniques at the retailer, distributor, processor, and farm levels.

Teams need to engage in regular exercises using realistic scenarios to continually refine existing procedures and develop new techniques.

8.3. Initial Briefing and Ongoing Information

Each agency will be responsible for preparing and sharing summaries of relevant information (e.g., epidemiological investigations, law enforcement investigations, past regulatory history of the firm) during initial investigation planning sessions. Written summaries are preferable whenever possible. It is important to identify how updates will be provided among involved agencies, particularly if the investigations will take more than one day. Also, agencies must clarify any information sharing constraints (e.g., information that can only be shared with state and local officials holding an FDA commission) ahead of time.

8.4. Documentation

Pre-established procedures should specify whether team members will use a jointly developed form (i.e., common form agreed upon by all agencies) or the forms required within their respective agencies. Designating a lead agency for issuing notices of violations to the firm may ensure that the agency leading follow-up regulatory action has sufficient documentation to support its actions.

Prior to completing inspectional reports, inspectors should strive to coordinate their factual observations with those of other agencies performing joint inspections or investigations. This should be done verbally, on-site at the end of each joint visit, and include additional follow-up communication as necessary. This will help provide establishments with consistent information on violations, recommendations, and corrections.

All involved agencies should have copies of each other's regulatory forms used during the inspection and a set of any records collected during the inspection. To facilitate this sharing of information, agencies may wish to invest in appropriate technologies. For example, a high-speed scanner can be used in conjunction with a laptop to convert all records to electronic form for easy sharing among involved agencies. Team members should also establish a clear, mutual understanding of what, how, and when information will be shared with the firm.

8.5. Seizures, Embargoes, Condemnation, Destruction of Products & Other Regulatory Actions

During joint activities, an agency with the appropriate legal authority may embargo or seize product for suspected adulteration, order condemnation and destruction of products, or take other regulatory actions. Because legal authorities and required levels of evidence to take these actions may differ between agencies participating in the investigation, team members should be aware of both their own authorities and those of cooperating agencies (e.g., the Environmental Protection Agency).

When taking these actions, it is important to:

- Identify or immediately request adequate supporting documentation so the agency taking the regulatory action possesses the information necessary to support the action. These documents should be obtained in advance of taking regulatory action (e.g., embargo or seizure) if the delay is unlikely to create a public health hazard.
- Develop a plan identifying follow up actions to be taken (e.g., inspections, sampling, obtaining process authority input, destruction) and assign team members for completion of those tasks. The plan should consider and identify expected actions for release of embargoed or seized products, product reconditioning, and product disposal or destruction.

8.6. Recalls

Some of the involved agencies may have a responsibility to work with manufacturers and/or distributors to initiate a recall to protect the public health from products that present a risk of injury or gross deception or are otherwise defective. The legal authority to initiate or require a recall varies. In the joint planning process, the involved agencies need to predetermine their policies, procedures, and thresholds for recalls. Cooperating agencies should be familiar with each other's standard operating procedures or with a jointly developed or shared procedure.

8.7. Environmental Sampling

Environmental sampling activities require multiple person teams with specialized training or experience. Staff may be asked to serve on sampling teams with staff from more than one regulatory agency. Leadership from all involved agencies should consider the size and complexity of each sampling assignment when forming sampling teams. The role of each team member should be clearly defined before sampling teams arrive at the food establishment. This includes chain of custody protocols, labeling, documentation, and related procedures. To be most effective, these multi-agency teams should train and exercise together. Teams should also consult laboratories to ensure appropriate use of sampling protocols and sample shipment methodologies.

8.8. Environmental Assessments[1]

Multiple agencies (e.g., FDA, state) may also be involved in conducting joint environmental assessments to determine the root causes of contamination as part of a long-term response effort. The same principles of joint planning and communication covered elsewhere in this chapter apply.

8.9. Public Information

During a joint investigation, the cooperating agencies need to:

[1]Also termed "Environmental Health Assessments"

- Know their procedures and rules/constraints for release of public information and integrate this into their joint planning efforts.
- Utilize the ICS concepts of a Joint Information Center (e.g., designated interface with media, coordinated communication) to ensure accurate and reliable information is disseminated and to ensure that all agencies have input into any public communication.

ICS functions and roles such as public information officer and liaison can assist with coordination to address and overcome these communication issues.

9.0. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

The levels described below assume that agencies with higher level capacities meet all the elements for lower level capacities.

Level	Description
1	Joint inspections not conducted with other agencies.
2	Joint inspections are conducted, but there is no formal written procedure for conducting joint inspections and investigations with other agencies.
3	Formal written procedures for conducting joint inspections and investigations with other agencies is in place.
4	Formal written procedure is in place and a joint inspection, investigation, or exercise has been conducted within the last 12 months.
5	Formal written procedure is in place, a joint inspection or investigation or exercise has been conducted within the last 12 months, and a formal review process with implementation of lessons learned is in place.

10.0. RELATED DOCUMENTS

Other RRT Manual Chapters: Incident Command System, Working with Other Agencies, Communication SOPs, and Training.

11.0. REFERENCES AND OTHER RESOURCES

(Full citations are in the References Section, "List of Reference Documents," listed by author.)

- State-specific manuals (to request, email odp.feedback@fda.hhs.gov)
  - CalFERT Manual
  - Michigan Department of Agriculture's Food & Dairy Division Manual
  - Minnesota Department of Agriculture's RRT Investigations SOP
- FDA Investigations Operations Manual (IOM), 2023 (http://www.fda.gov/ICECI/Inspections/IOM/default.htm)

- Food and Agriculture Sector Specific Plan: An Annex to the National Infrastructure Protection Plan, 2015 (https://www.dhs.gov/publication/nipp-ssp-food-ag-2015).

12.0. ATTACHMENTS

- Attachment A – Draft Field Joint Investigation Checklist
- Attachment B – Inspection Equipment Example

13.0. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT Joint Investigations/Inspections WG (MI**, WA, CA, MN)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/2013	ORA/OP
1.3	R	5/26/2017	ORA/OP
2.0	R	6/1/2023	ORA/OP-AFDO Compiled Revisions
3.0	R	12/1/2024	ODP-AFDO Compiled Revisions

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History
1.1 – Editorial revisions made by ORA for document clearance.
1.2 – Revisions to achievement levels (Section 3) based on recommendations from the RRT 2012 Face to Face Meeting (November 2012).
1.3 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.
2.0 – AFDO compilation for 2023 Edition of RRT Manual
3.0 – AFDO compilation for 2025 Edition of RRT manual. Updated FDA program names resulting from the 10/2024 FDA reorganization

Attachment A – Draft Field Joint Investigation Checklist

Investigation Field-Team Procedures (SAMPLE)
Planning
☐ Meet with supervisors or Unified Command to develop a plan to clearly identify investigation activities.
☐ Identify team leaders and members and define roles or responsibilities for each.
☐ Obtain contact information for all those involved.
☐ Ensure that there will be enough team members to complete the objectives by the deadline.
☐ Determine need for specialized equipment and ensure that it is made available for the team (i.e., sampling supplies, pH meter, protective equipment).
☐ Plan to meet before the investigation at an offsite location to review/confirm pertinent information, create a strategy, and coordinate arrival at the firm.
☐ Review facility history, layout, and sample collection objectives.
☐ Review epidemiological information and identify potential products of interest.
☐ Review laws, guidance documents, policies and protocol.
☐ Inform facility management of the purpose and timeframe for investigation.
☐ If collecting samples, notify laboratory of the estimated time of arrival for samples. Determine sample sizes, amounts, and special techniques required. Arrange to drop off or send samples to lab.
☐ Use principles of ICS and Unified Command.
Objectives
☐ Identify objectives and tactics (e.g., complete an assessment, collect 100 environmental samples, conduct traceback investigation).
☐ Document objectives, tactics, and timeframes for the investigation
Onsite
☐ Complete investigation as agreed upon during the planning meeting (e.g., split assessment and traceback assignments)
☐ Designate a single point of contact for communications with the firm (if possible)
☐ Coordinate any multi-agency requests for information from the firm (e.g., invoices, production logs).
☐ Document investigational findings on appropriate Inspectional, Special, Sample, or Seizure reports to provide to the firm.
☐ Team leaders provide updates as necessary to Supervisor or Unified Command.
☐ Team leaders ensure assignments will be completed in accordance with policies and protocols.
☐ Request information and assistance as necessary.
☐ Compare investigational findings with other agencies involved to ensure consistent findings, recommendations, and actions are documented.
☐ Mutually agree upon information sharing details (e.g., what will be shared, with whom, how often, what format, and when), including coordination with supervisors.
Post Investigation Activities
☐ Finalize and submit all reports to Supervisor or Unified Command for review.
☐ Document specialized details of the joint investigation on an internal memo.
☐ Provide information with other agencies (per agreement with supervisor approval).
☐ Retain records in accordance with agency policy.
☐ Participate in after action reporting or other authorized information sharing of lessons learned during the investigation.

Attachment B – Inspection Equipment Example

Inspection Equipment Example	Agency A	Agency B	Needed
Computer and printer			
Camera			
Digital camera			
Credentials			
Important phone numbers (supervisor and servicing laboratory)			
Laws, Regulations, and policies			
Paper, pen, masking tape, and permanent marker			
Clipboard			
Required forms			
Alcohol swabs and wipes			
Flashlight and holder			
Blacklight			
Light meter			
Thermometer			
Infrared thermometer			
Exacto knife and scissors			
Putty knife and scraper			
Sampling devices (sieves, triers, probes, and swabs)			
Sampling equipment (sterile containers and scoops)			
Coolant (ice and freezer packs)			
Shipping containers			
Appropriate sanitizer test strips			
Official seals			
Protective clothing (lab coat, gloves, and boots)			
Eye protection			
Hair restraint			
Hearing protection			
Hard hat			
Safety shoes			
Respirator			
Other recommended equipment:			
Portable high speed scanner			
Cell phone			