Sections in This Document

1. Purpose

This Field Management Directive (FMD) provides criteria to the Office of Regulatory Affairs (ORA) divisions and laboratories for the release of preliminary and completed laboratory analytical findings for human and animal food product and environmental samples to the responsible party (e.g. the owner, operator, or agent in charge of the establishment from which certain samples are collected.

2. Scope

This FMD provides criteria for the communication of preliminary and completed original analytical findings of human and/or animal food product and environmental samples collected during FDA Office of Human and Animal Food Operations (OHAFO) and Office of Enforcement and Imports Operations (OEIO) Import inspections and analyzed in ORA laboratories. Communications are consistent with the Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for Food and Drug Administration Staff.

This FMD applies to the following types of samples:

A. Finished product samples of human and animal food subject to 21 USC Section 374(d) for 704(d) samples under the Federal Food, Drug and Cosmetic Act (FFDCA).

B. Samples of human and animal food including raw materials, in-process samples, and finished products where the collection establishment or dealer is voluntarily holding product pending receipt of analytical findings (Dealer Voluntary Hold).

C. Environmental samples collected at an establishment where human and/or animal food is manufactured, processed, or packed.

D. For samples when FDA determines the release/non-release of preliminary or final laboratory findings is in the interest of public health as described in the Guidance document, Release of ORA Laboratory Analytical Results to the Responsible Party

This FMD cannot and does not cover all forms of communication that may occur related to any particular assignment, investigation or sample collected. It does not preclude other forms of communications as required by assignment or in cases where there is risk to public health from an adulterated product. For example, there may be internal FDA telephone calls concerning sample results during an outbreak investigation or there may also be telephone calls with firms to alert them to sample results in cases where there is a risk to public health. As such, other internal or external communications are not prohibited by this FMD.

3. Background

FDA provides results from analytical testing of human and animal food and environmental samples without requiring the responsible party to submit a Freedom of Information Act (FOIA) request in following instances:

A. 704(d) Samples

1. 21 USC Section 374(d) “Analysis of samples furnished owner” of the FFDCA requires that, “Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the

results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

2 . "Unfit for food" has been used to describe human and animal foods that have an abnormal odor, abnormal color, are contained in abnormal containers (swollen cans), contaminated with pathogens, contains an undeclared allergen, etc. It has also been used for fish infested with copepods or other parasites. Any human and animal food product that may be rejected by the consumer may also be considered unfit for human and/or animal food.

B. Dealer Voluntary Hold

1. When samples of human and/or animal food (including raw materials, in-process and finished products) are collected during an inspection of a human and/or animal food manufacturer, processor or packer, the FDA investigator determines the manufacturer's intent with respect to holding or distributing products associated with the collected samples while FDA performs analytical testing. FDA desires to promptly provide analytical results to those firms holding products pending FDA results without requiring the firm to submit a FOIA request. Providing analytical results in this manner allows the firm to take appropriate action. The firm is also notified in the event no analysis is to be performed.

C. Environmental Samples

1. When FDA collects environmental samples within a facility where human and/or animal food is manufactured, processed, or packed, the FDA investigator also determines whether the manufacturer intends to hold processed products pending the outcome of the FDA analytical testing. FDA has determined that analytical results of environmental samples collected in human and/or animal food manufacturing establishments for analysis should be promptly conveyed to the firm inspected without requiring the firm to submit a FOIA request. Providing analytical results in this manner allows the firm to take appropriate action.

4. Responsibility

A. ORA Laboratories

1. Receive and analyze the sample.

2. Communicate sample analytical findings, per procedure, to the appropriate compliance units and other FDA Stakeholders identified in the assignment/program.
3. Prepare and send completed original analytical findings to the responsible party named in Collection Remarks on the Report of Sample Analysis form (Form FDA 1551).

B. ORA Compliance Branch (CB) Divisions

1. Orally communicate preliminary laboratory analytical findings to the responsible party such as “Cannot Rule Out (CRO)” results and if a sample is not tested when the dealer is voluntary holding product.

5. Procedure-Communications to Responsible Party

A. Laboratory Communication of Preliminary Results:

1. In certain instances, the Office or Regulatory Science (ORS) internally communicates preliminary analytical findings.
2. ORS communicates the preliminary interim /CRO information of the sample to the applicable Agency compliance unit and assignment/program designees.
    a. CRO results; when ongoing laboratory analysis is being conducted but such results may present a public health hazard and prompt notification is necessary.
    b. The lab communicates to ORA’s Division’s CB and investigation branch (IB) when it is determined not to analyze the sample.

B. Laboratory Communication of Final Sample Analytical Findings:

1. Upon completion of analysis, the laboratory documents and communicates final analytical findings to the applicable Agency compliance unit and assignment/program in accordance with the ORA Laboratory Manual.
2. Issue original lab final results to the firm by completing Form FDA 1551 in accordance with the ORA Laboratory Manual.

C. ORA Division Compliance Branch Communication of Preliminary Results:

1. When preliminary findings/CRO results are received, the Division CB:
    a. Shares findings with the responsible party when dealers are voluntarily holding product.
    b. When necessary for public health protection, shares CRO preliminary laboratory analytical findings with the responsible party before the completed original analytical findings are confirmed based on the specific case.
    c. Center Offices of Compliance are consulted/included as appropriate.
2. When adverse findings sample results are provided by the analyzing laboratory the Division CB contacts the responsible person at the firm for the product and informs them of the results.
    a. Center Offices of Compliance are consulted/included as appropriate.
    b. State partners, Federal partners, and any other stakeholders receive a summary of what was communicated by the compliance unit to the responsible party after this action takes place as appropriate.

D. Laboratory communicates instances when analysis cannot be completed:
1. During the course of the inspection the Consumer Safety Officer (CSO) requests the responsible party who, if voluntarily holding product, to notify the appropriate FDA Division of any subsequent change in the decisions to hold or distribute the product in question.
2. For these rare situations when the CSO learns that a sample will not be analyzed by the ORA lab, the CSO notifies the responsible individual at the firm.
3. For other “no test” situations, the laboratory notifies the ORA Division’s CB and IB to determine the course of action moving forward.

6. References

A. Compliance Program Guidance Manual (CPGM) 7303.836, Chapter 03 – Foodborne Biological Hazards

B. FD&C Act 21 USC Section 374(d) for 704 (d) samples

C. Outbreak Investigations

D. Investigations Operations Manual (IOM): Chapter 4 – Sampling

1. 4.1.1.4 – Report of Analysis
2. 4.1.6 – Investigational Samples
3. 4.3.7.7– Environmental Samples
4. 4.4.10.1.3. – Dealer Voluntarily Holding
5. 4.4.10.1.5 – Factory Food Sample
6. 4.4.10.3.9 – Collection Remarks
7. 4.4.10.3.64 – 704(d) Samples

E. ORA Laboratory Procedure, ORA–LAB.5.10, Reporting Laboratory Data

F. Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for Food and Drug Administration

7. Glossary/Definitions

A. Acronyms

1. CB: Compliance Branch
2. CRO: Cannot Rule Out
3. FDA: Food and Drug Administration
4. FFDCA: Federal Food, Drug and Cosmetic Act
5. FMD: Field Management Directive
6. FOIA: Freedom of Information Act
7. IB: Investigations Branch
8. OEIO: Office of Enforcement and Imports Operations
9. OHAFO: Office of Human and Animal Food Operations
10. ORA: Office of Regulatory Affairs

11. ORS: Office of Regulatory Science

B. Definitions

1. 704(d) Sample: A 704(d) sample is a commonly used term that references 21 USC Section 374(d) "Analysis of samples furnished owner" of the FFDCA requires that, "Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."
2. Cannot Rule Out (CRO): A preliminary indication that the sample may yield a final result that could present a public health hazard or threat. A CRO finding indicates that the laboratory analytical testing is ongoing, and final results have not yet been determined. A CRO indication may ultimately be determined to be negative or positive in its final result.
3. Completion of Sample Analysis: The date of the laboratory management's completion of the FACTS Sample Summary.
4. Dealer Voluntary Hold: The responsible party is refraining from or restricting product distribution when samples of human and/or animal food (including raw materials, in-process and finished products) are collected during an inspection of a manufacturer, processor or packer pending analytical results. See IOM 4.4.10.1.3.
5. Environmental Sample: A sample consisting of various items including, but not limited to: swabs, process or agricultural water, animal scat, soil, and/or other items found in and/or around a farm, food processor, packing house, vehicle, conveyance or other location where food is exposed to environmental or processing conditions that could result in adulteration with microbiological or other contamination.
6. Food Sample: A sample consisting of raw materials, in-process and/or finished products that an FDA investigator collects during an inspection or investigation at a human and/or animal food grower,

processor, or manufacturer. This includes medicated and non-medicated feeds.

7. Home Division: The division is the programmatic organizational unit most likely to pursue action if required as identified on the CR as "Original CR & Records To" and in which the firm or individual responsible is physically located.
8. Home District: The home district is the district in whose territory the sample was collected, or in whose territory the firm or individual responsible is physically located.
9. Laboratory Finding: Consists of Cannot Rule Out (CRO) and original laboratory findings and does not include additional analysis nor further speciation of pathogens.

8. Records

A. Report of Sample Analysis (Form FDA 1551)

9. Supporting Documents

None

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	3/1/2011		Operations Management
2.0	D	8/22/2014	Donald A. Bennett Quality System Manager	Ellen Morrison
2.0	R	5/20/2015	Donald A. Bennett Quality System Manager	Ellen Morrison
03	R	See Date in Header	Bruce Ross Senior Advisor, OHAFO	Michael Rogers, Assistant Commissioner for Human and Animal Food Operations Paul Norris, Director of Office of Regulatory Sciences

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

11. Change History

Revision #	Change
03	• Broadened applicability to cover official and environmental samples collected by ORA investigators as part of inspections under section 704(d) of the FFDCA that are either analyzed by an ORA laboratory or a center laboratory. • Added Cannot Rule Out (CRO) notifications into communication process. • Clarified ORA/Division Compliance Branch will be responsible for orally communicating both potentially violative (Lab Class 3) and/or CRO sample findings to the responsible party in real time, in consultation with the center, and other stakeholders (i.e. CORE, CDC) as appropriate. • Specified and clarified roles/responsibilities for the actions needed Developed a process map of the “lifecycle of a collected sample” and include “predictable time frame targets” for pathogen analysis. • More clearly identified what parts of the Agency need to be informed about analytical findings (especially when they are positive). • Renumbered as a directive in QMiS and released in the PCC Vault

2.0	• Title changed from "704(d) Letters" to reflect communication of analytical findings for a variety of sample types.
	• Standardized Lab use of Form FDA 1551 for communication of results.
	• Standardized Lab as transmitter of Form FDA 1551 to Firm/Dealer in all cases.
	• Standardized information Lab is to include in notification emails to districts (sample number, product and classification).
	• Clarified when results will be communicated to districts via established email process:
	  ○ 704(d) Samples when Class 3 or Class 5.
	  ○ Dealer Voluntary Hold in all cases.
	  ○ Environmental Samples in all cases.
	• Clarified that when called for (as above), the results will be transmitted to the division BEFORE the Form FDA 1551 is sent to the Firm/Dealer.
	• Specified results to be sent to the responsible person in charge of the firm in all cases. This is an effort to standardize routing of communications and facilitate automation for future communications.
	• Specified collection of email addresses on the Collection Report for use in transmitting analytical results from the lab to the firm.
	• Added timeframe for notification of results to districts under special conditions (3., A., 2.) "When required per the procedures identified below, communicate sample results to collecting districts within 24 hours of completing sample analysis and in advance of sending the FDA Form 1551, Report of Sample Analysis, to the collection or dealer firms."
	• Document Number: FMD.147
	• Title: Communication of Sample Analysis Results for Food Products and Environmental Samples (FMD-147)

1.0	• New

12. Attachments

None