



United States Department of Agriculture

Food Safety and Inspection Service

Chain of Custody Resources

November 20, 2013

InFORM 2013 Conference

San Antonio, Texas

Kurt A. Wolter, Investigator

Food Safety and Inspection Service

Office of Investigation, Enforcement and Audit

Compliance and Investigations Division

Houston, Texas

Food Safety and Inspection Service (FSIS)

The Food Safety and Inspection Service is the *public health agency* in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.



Chain of Custody - Definition

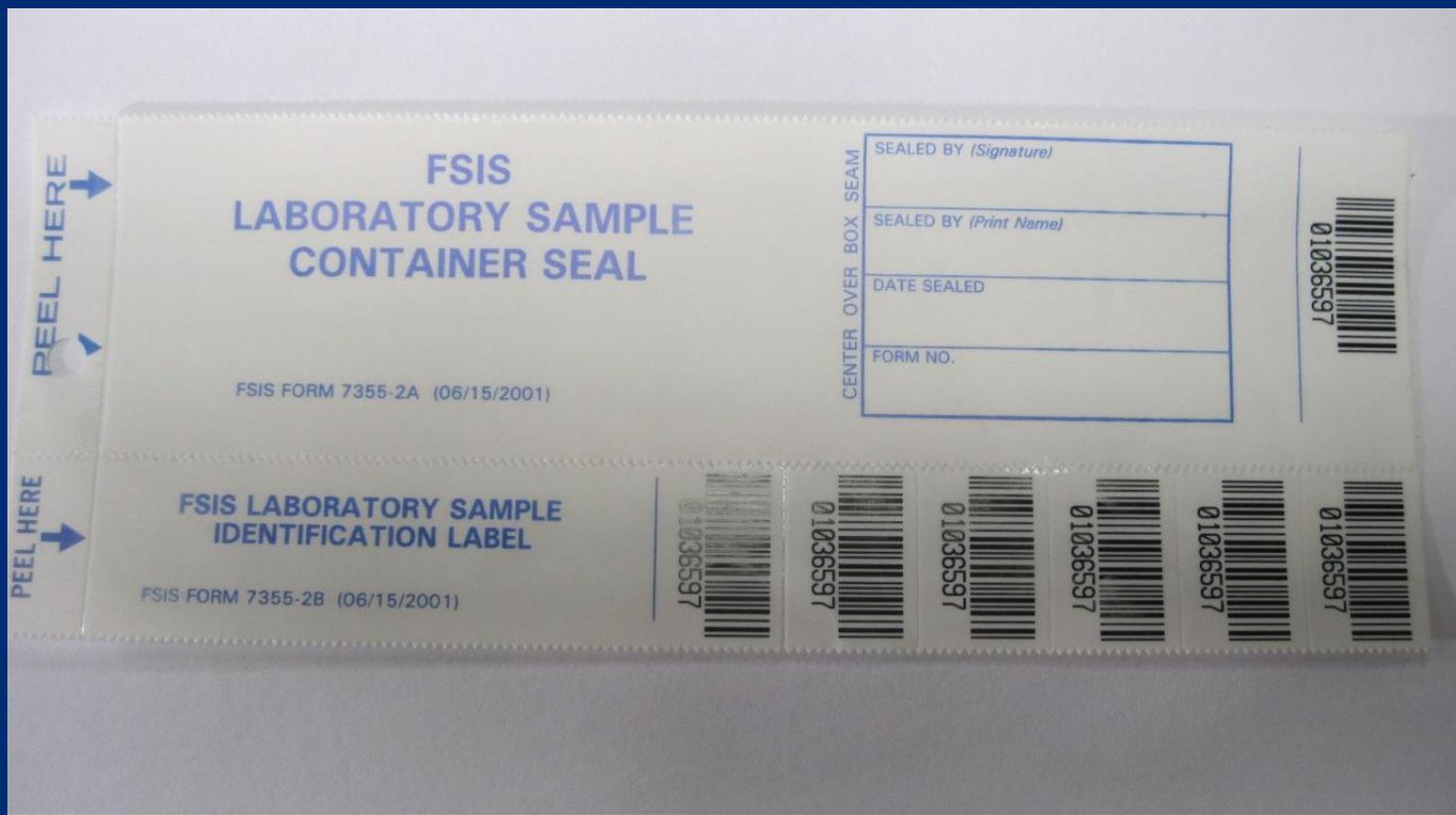
UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC		
FSIS DIRECTIVE	8010.3 Revision 3	10/18/11
PROCEDURES FOR EVIDENCE COLLECTION, SAFEGUARDING AND DISPOSAL		

- Chain of custody is the methodology used to maintain, track, and document control of all evidentiary items.
- Chain of custody includes the order of places where, and the persons with whom, evidence collected by program employees was located from the time it was collected to its disposal.
- Failure to safeguard evidence may affect the use of that evidence to support enforcement or legal actions.

Shipping Foodborne Illness Investigation Samples to FSIS Outbreaks Section of the Eastern Laboratory (OSEL)



Seals and Sample ID



Samples





FSIS Form 8000-17 – Evidence Receipt and Chain of Custody

The image shows a blank FSIS Form 8000-17. A red oval highlights Section I, 'EVIDENCE', which includes fields for: 1. FILE NUMBER, 2. LOG NUMBER, 3A. EVIDENCE COLLECTED BY (Signature), 3B. TITLE, 3C. BADGE NO., 4. EVIDENCE COLLECTED FROM (Name, title, address, etc.), 5. LOCATION OF EVIDENCE WHEN COLLECTED, 6. DATE EVIDENCE COLLECTED (mm/dd/yyyy), 7. TIME COLLECTED, and 8. DESCRIPTION OF EVIDENCE (if sample is submitted for lab analysis, include serial number).

The image shows a filled-out FSIS Form 8000-17. A red oval highlights Section II, 'CHAIN OF CUSTODY', which is a table with columns for DATE & TIME, EVIDENCE RELEASED BY (SIGNATURE, NAME, TITLE), EVIDENCE RECEIVED BY (SIGNATURE, NAME, TITLE), and PURPOSE OF CHANGE IN CUSTODY. The table contains one entry with a date of 10/11/2013 and a signature of David A. Miller.

Section I - identifies the evidentiary items collected in an investigation and establishes the chain of custody for that evidence

Section II - tracks the chain of custody to maintain control and accountability for the items

Laboratory Report Form

GPO U.S. GOVERNMENT PRINTING OFFICE: 2006-328-003

INSTRUCTIONS ON REVERSE OF PART 5 BEFORE COMPLETING Form OMB Approved: 0583-0080

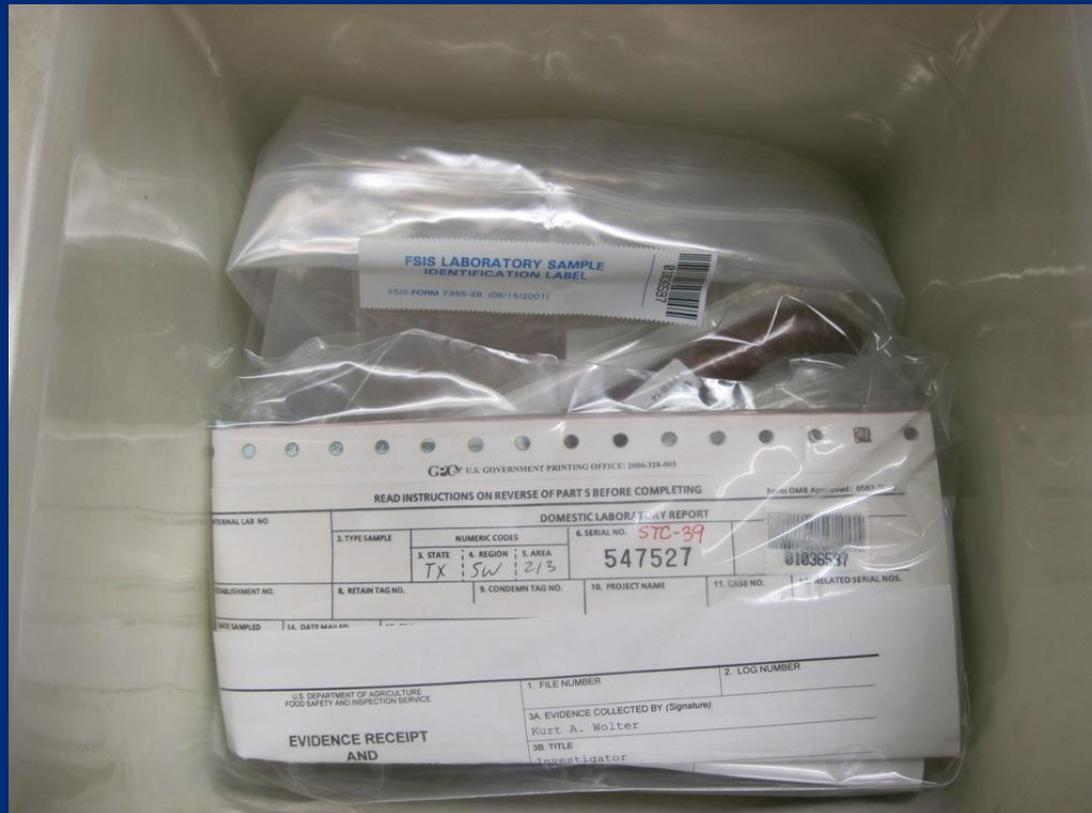
DOMESTIC LABORATORY REPORT

NUMERIC CODES			6. SERIAL NO.		 01036597
3. STATE TX	4. REGION SW	5. AREA 213	547527		
9. CONDEMN TAG NO.		10. PROJECT NAME		11. CASE NO.	12. RELATED SERIAL NOS.

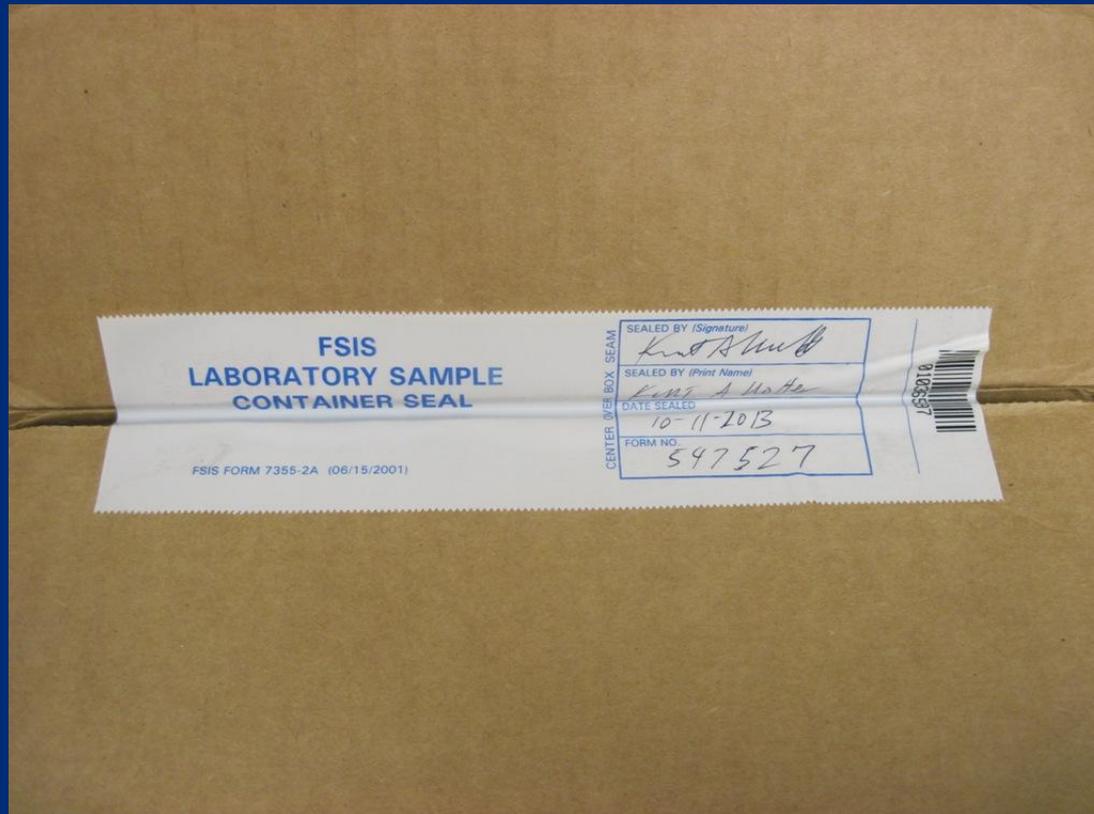
F. To request laboratory analysis of investigative samples, program employees are to:

1. Complete FSIS Form 10,000-2, Domestic Laboratory Report, or Form 10,600-1, Domestic Chemical Lab Analysis;

Sample and Forms in Shipping Container



Container Seal



Shipping Container with Seal



Sample Collection and Custody

When an investigative sample needs to be obtained for a foodborne illness investigation, the Investigator:

1. Notifies the laboratory and determines how the sample is to be collected, prepared, and shipped
2. Completes FSIS Form 10,000-2, Domestic Laboratory Report,
3. Identifies the investigative sample in red text as STC-39 on the form, and
4. Places sample associated bar-coded pressure sensitive sticker from FSIS Form 7355-2B, Sample Seal, on the form.

To identify the investigative sample, the Investigator:

1. Photographs the product before and after sample collection,
2. Obtains identifying information (invoices, labels, product identification, etc.),
3. Obtains signed statement or memorandum of interview from witness,
4. Completes the appropriate data fields in Section I of an FSIS Form 8000-17, Evidence Receipt and Chain of Custody form then places sample associated bar-coded pressure sensitive sticker from FSIS Form 7355-2B, Sample Seal, in the appropriate block on the form, and
5. Maintains all other identifying information (invoice, etc) under separate Evidence Receipt and Chain of Custody form.

Prior to transferring investigative sample to the FSIS Laboratory, the Investigator:

1. Completes the first entry in Section II of an FSIS Form 8000-17, Evidence Receipt and Chain of Custody form to initiate the chain of custody,
2. Maintains a copy of the signed form,
3. Places the original signed form in the shipping package with the investigative sample,
4. Seals the sample in accordance with FSIS Directive 7355.1, and
5. Transfers the sample to the laboratory via overnight courier.

FSIS Directive 10,000.1 - Policy on Use of Results from non-FSIS Laboratories

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC		
<h2>FSIS DIRECTIVE</h2>	10,000.1	5/11/07
POLICY ON USE OF RESULTS FROM NON-FSIS LABORATORIES		
I. PURPOSE		
<p>Periodically, results from non-FSIS laboratories are presented to FSIS, such as from outbreak or illness investigations. If FSIS decides to accept the results from the non-FSIS laboratory, it may take action (e.g., request a recall or detain product) based on those results. If FSIS decides not to accept the results, it still may collect a sample of the product in question for testing in an FSIS laboratory. This notice describes the decision-making process FSIS uses when determining whether it is appropriate to accept the testing results. It covers results from State and local government laboratories, academic laboratories, and private sector laboratories.</p>		

http://www.fsis.usda.gov/wps/wcm/connect/41bd6d4b-7251-4cdf-bdee-11edbf9f10c5/10000_156.pdf?MOD=AJPERES

FSIS, Office of Public Health Science, Science Staff microbiologists are guided by FSIS Directive 10,000.1 when contacting State agency or other laboratories that are testing FSIS-regulated foods.

Sample Handling/Storage Prior to Collection

1. Was the sample handled and stored properly prior to collection?
 - *FSIS will request information regarding how the sample was handled and stored (e.g., in a case-patient's home or a retail establishment) before collection to ensure that it was not inadvertently cross-contaminated or subject to temperature abuse.*
 - FSIS may ask about storage and handling conditions prior to sample collection for analysis for pictures/information about the condition of the product as it was collected (i.e. frozen, refrigerated, open packaging, sealed packaging, repackaged, etc).

Sample Collection/Integrity and Chain of Custody

2. Did the party responsible for the sample collection maintain the sample's identity and integrity properly (e.g., through handling and storage) before submitting for testing? Did the party responsible for the sample properly ship it to the laboratory?
 - *FSIS will determine whether and how those responsible for maintaining the identity and integrity of the sample did so (e.g., there was an appropriate chain of custody, the sample was not subject to temperature abuse).*
- FSIS will ask for chain of custody documentation, as well as conditions of the sample (i.e. sealed/labeled) and type of transportation to the laboratory.

Method of Analysis

3. Did the non-FSIS laboratory use a methodology appropriate for the analysis in question?
 - *FSIS will review the methodology used by the non-FSIS laboratory on a case-by-case basis to determine whether it is similar in sensitivity or specificity to that used by FSIS, if applicable.*
 - FSIS typically evaluates the appropriateness of the method for testing by determining if the method has been validated (internally or externally) for detection of the pathogen in a similar matrix
 - FSIS follows methods outlined in the Microbiology Laboratory Guidebook (MLG)

Laboratory Quality Assurance / Quality Control Procedures

4. Did the non-FSIS laboratory ensure that the results of its analysis are reliable and accurate?
 - *FSIS will assess the available information about the laboratory (e.g., participation in quality assurance programs, whether it uses appropriate controls) to determine whether the Agency can confidently rely on the non-FSIS laboratory's results.*

FSIS Directive 10000.1: Use of Reviewed Results

- If the Agency finds that the answers to the four questions listed above are "yes" or "**acceptable**," FSIS will likely consider that there is an appropriate basis to rely on the results of the analysis by the non-FSIS laboratory. If so, FSIS would be prepared to take action on the basis of that analysis (e.g., request a recall or initiate a regulatory action)
- If the Agency finds that the answer to any of the questions is "no" or "**inconclusive**," then it will likely then not be able to use the sample result

Decision Criteria for Relying on non-FSIS Laboratory Test Result (per FSIS Directive 10000.1)

- Sample handling/storage prior to collection
- Sample collection/integrity & Chain of custody
- Method of Analysis
- Laboratory Quality Assurance/Quality Control procedures

References

- FSIS Directive 8010.3, Revision 3 “Procedures for Evidence Collection, Safeguarding and Disposal”
 - http://www.fsis.usda.gov/wps/wcm/connect/776dbd09-1e66-488c-b95c-75d15d399f89/8010_58.pdf?MOD=AJPERES
- FSIS Directive 10000.1 “Policy on Use of Results from Non-FSIS Laboratories”
 - <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10000.1.pdf>
- FSIS Directive 8080.3 “Foodborne Illness Investigations”
 - <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.3.pdf>
- FSIS Microbiology Laboratory Guidebook (MLG)
 - <http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook>



Thank you!

Acknowledgements

FSIS Office of Public Health Science

- Stephanie Defibaugh-Chávez
- Kristin Holt
- Bonnie Kissler