

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,000.1
Revision 1

8/4/20

POLICY ON USE OF RESULTS FROM NON-FSIS LABORATORIES

I. PURPOSE

Under certain circumstances, such as during outbreaks or illness investigations, results from non-FSIS laboratories are shared with FSIS. If FSIS decides the results are acceptable, the Agency may take an action (e.g. recommend a recall or detain product). This directive describes the decision-making process FSIS follows to determine appropriate use of the non-FSIS test results. FSIS is reissuing this directive in its entirety to clarify the documentation and information needed by FSIS to complete the review of results provided to FSIS by non-FSIS laboratories.

II. CANCELLATION

FSIS Directive 10,000.1, *Policy on Use of Results from Non-FSIS Laboratories*, 5/11/2007

III. BACKGROUND

A. As a public health regulatory agency, FSIS investigates reports of foodborne illness, contamination, and adulteration potentially associated with FSIS-regulated products. Leading up to or during these investigations, non-FSIS laboratories may test FSIS regulated product and share the results with FSIS. FSIS Office of Public Health Science (OPHS) will review the results and associated documentation shared by the non-FSIS laboratory to determine whether FSIS will accept the results.

B. This directive supplements, but does not conflict with or supersede, instructions as specified in [FSIS Directive 8080.3](#), *Foodborne Illness Investigations*.

IV. PROCEDURES

A. OPHS assigns a lead investigator to review the results shared by non-FSIS laboratories and consult with other Agency subject matter experts where appropriate.

B. The lead investigator is to obtain the external party contact information for the non-FSIS laboratory from the appropriate FSIS personnel.

C. The lead investigator is to contact the non-FSIS laboratory to begin the review process. During the initial contact with the non-FSIS laboratory, the lead investigator is to:

1. Provide a copy of and review the contents of this directive;
2. Determine what information FSIS needs to complete the review; and
3. Set a mutually agreeable timeframe for receiving information.

D. The lead investigator is to perform the review and coordinate all follow-up meetings with the non-FSIS laboratory, if clarification or more information is needed.

E. To complete the review, the lead investigator is to follow and document responses to the criteria in Section V in this directive.

F. The lead investigator is to draft a summary determination of acceptability and provide that draft with supporting information for OPHS approval.

G. When approved, the lead investigator is to finalize the summary determination of acceptability and provide it to the appropriate FSIS officials.

H. The lead investigator is to ensure the information and documentation related to review is appropriately labeled, maintained, and accessible.

V. CRITERIA USED TO REVIEW ACCREDITED NON-FSIS LABORATORY RESULTS

A. The lead investigator is to verify that the accredited non-FSIS laboratory can provide at least one of the following:

1. Documentation of accreditation to the ISO 17025 standard through a third-party accreditation body, covering the testing methods performed;
2. Clinical Laboratory Improvement Amendments (CLIA) certificate covering the testing methods performed; or
3. The most recent FSIS audit documentation for state laboratories that participate in the Meat Poultry Inspection (MPI) program covering the testing methods performed.

B. If the accredited non-FSIS laboratory meets at least one of the criteria in A of this section, the lead investigator is to verify that the laboratory has the following documentation:

1. A completed form similar to the FSIS Form 8000-17, *Evidence Receipt and Chain of Custody* (The use of form 8000-17 is not required; it is cited to provide an example of the information needed for documentation);
2. Laboratory Report, such as:
 - a. Laboratory report with sample identification, final results, and authorization by the responsible official for affirming results; and
 - b. National Center for Biotechnology Information (NCBI) number (if applicable); or
3. Point of contact information such as e-mail address and phone number.

C. The lead investigator is to inquire how the laboratory stored the samples, whether sample reserves exist, and whether FSIS can obtain any of the reserves.

VI. CRITERIA USED TO REVIEW NON-ACCREDITED NON-FSIS LABORATORY RESULTS

A. The lead investigator is to verify that a non-accredited non-FSIS laboratory can provide, in addition to information in Section VB, the following:

1. Laboratory Methods:

- a. Copy of the screening, isolation, extraction, clean up, digestion, confirmation, and characterization (e.g., molecular serotyping, whole genome sequencing, etc.) methods used, as applicable;
- b. Method validation/verification documentation showing that the laboratory method was appropriate for the analyte and matrix;
- c. Test kits documentation and test kit validation information by independent organizations (e.g., AOAC International, Association Française de Normalisation (AFNOR));
- d. Copy of laboratory procedures and work instructions related to the applicable methods; and

2. Quality Assurance Records, such as:

- a. Records for lot acceptance to include materials, test kits, buffer, media, mobile phase, columns;
- b. Calibration records for equipment and instrumentation, that correlate with analysis dates;
- c. Sample data and result worksheets/reports documenting the data recorded during the sample analysis; and
- d. Training records for all personnel involved in testing procedures, and the last set of laboratory proficiency results.

VII. POSSIBLE OUTCOMES AFTER REVIEW

A. If OPHS determines the non-FSIS laboratory result is acceptable, FSIS may use the result to inform Agency action (e.g., recommend a recall or detain product).

B. If OPHS determines the non-FSIS laboratory result is not acceptable:

1. FSIS may request that remaining sample be submitted to an FSIS laboratory for testing as outlined in [FSIS Directive 8080.3](#), or
2. FSIS personnel may collect a verification sample if the appropriate product is available, following procedures outlined in [FSIS Directive 8010.3](#), *Procedures for Evidence Collection, Safeguarding and Disposal*.

C. FSIS will base the collection of reserve or verification samples on the epidemiological link between clinical cases and the product to be tested. FSIS will attempt to collect verification samples of the same product and lot code from the same location from which the non-FSIS laboratory collected the previously tested sample.

D. The lead investigator issues an internal report that describes the outcome of the review and assist FSIS program area representatives to ensure factual, technical, and scientific accuracy of the non-FSIS laboratory results is maintained during public communications.

VIII. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through [askFSIS](#), or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **FSIS Directive 10,000.1**.
Question Field: Enter question with as much detail as possible.
Product Field: Enter **General Inspection** from the drop-down menu.
Category Field: Enter **Sampling** from the drop-down menu. Select
Policy Area: **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press Continue and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development