

**“At Least Equal To” Compliance Guideline for State Meat and Poultry Inspection (MPI)
Programs for Laboratory Methods**

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I. Purpose

This Compliance Guideline supplements the “At Least Equal To” Compliance Guidelines for State Meat and Poultry Inspection (MPI) programs. It specifically supplements the guidance material in Component 3 - Product Sampling, of the guideline in that it provides additional instruction and recommendations on product sampling, laboratory methods and quality assurance.

II. Background

FSIS has entered into cooperative agreements with various states that administer their own MPI programs in a manner that is “at least equal to” the Federal inspection program. To be “at least equal to” the Federal inspection program, the State programs need to have product sampling and laboratory methods with capabilities and safeguards that are “at least equal to” FSIS’s sampling and methods. Hence, the State MPI programs should update and maintain their laboratory microbiological and chemical detection methods so they are “at least equal to” the applicable FSIS guidebook methods.

FSIS has integrated ongoing documents and on-site reviews of the applicable analytical methods in its annual comprehensive review of State MPI programs. Based on these reviews, FSIS will determine whether a participating State MPI testing program is “at least equal to” the corresponding FSIS testing program.

FSIS plans to begin using the criteria in this guidance as part of the Federal Fiscal Year (FY) 2014 review cycle. Each State MPI program needs to submit its FY 2014 self-assessment by November 15, 2013. FSIS will evaluate whether the information submitted by a State as part of the FY 2014 assessment meets the criteria in this guidance.

III. Criteria for “At Least Equal To” Laboratory Methods

To achieve and maintain “at least equal to” laboratory methods, each State MPI program should meet the criteria in the following three areas: (1) Program Sampling and Reporting, (2) Laboratory Quality Assurance Programs, and (3) Laboratory Testing Methods.

Sampling methods should provide analytical results “at least equal to” corresponding FSIS testing programs. Each State program should provide documentation through self-assessment and on-site review to FSIS that demonstrate that its program includes the following:

1) Program Sampling and Reporting

The sampling methodology, including the matrices and tools used, is effective for generating meaningful and consistent data.

- The program ensures sample integrity and identity. Laboratories that analyze samples for State MPI programs should maintain procedures to ensure that samples are not compromised within the laboratory. These procedures should include a documented chain of custody as well as traceability to the sample, equipment, and critical supplies used to analyze the sample.

- The program demonstrates confidence in test results and does not re-sample or re-test pathogen-positive and non-compliant products.
- Official test results are reported directly to the State MPI program in a timely manner.

2) Laboratory Quality Assurance (QA) Programs

State MPI program laboratories, or contract laboratories, should have an appropriate quality assurance (QA) program “at least equal to” the program maintained by FSIS laboratories to ensure the reliability and integrity of analytical results. State MPI program laboratories, or contract laboratories, should ensure that each laboratory meets the criteria outlined in the attached *FSIS MPI Program Laboratory Quality Management System Checklist*.

Laboratory QA program assessment consists the following:

- Documented program of quality control procedures and ensure that these procedures are followed.
- Properly trained personnel, suitable facilities and equipment, and verified, calibrated, and maintained equipment in a manner consistent with international norms (e.g. European co-operation for Accreditation (EA) 04/10 or Analytical Laboratory Accreditation Criteria Committee (ALACC) guidance).
- Appropriate proficiency testing schemes for food analysis.
- Use of validated method protocols.
- Reporting and recordkeeping capabilities that can clearly track and link a test result to the correct establishment.

3) Laboratory Testing Methods

Standard methods are available in the USDA FSIS Microbiology Laboratory Guidebook (MLG), USDA FSIS Chemistry Laboratory Guidebook, FDA Bacteriological Analytical Manual, International Organization for Standardization (ISO) Methods, and Association of Analytical Communities (AOAC) Official Methods of Analysis. Methods used in support of the State MPI program should be validated for the product type sampled. State MPI programs should provide documentation necessary to explain the methods used and the scientific basis for their (or the other testing laboratory's) selection. Such documentation should include detailed testing method protocols, supplemental testing procedures, and evidence of method validation for microbiology methods and sustained proficiency testing for chemistry methods. Method assessment by FSIS considers the following:

Microbiology

- Methods of analysis have been designed to detect the lowest possible level of stressed pathogens from meat, poultry, and environmental samples (e.g., the method includes an enrichment step).
- Methods of analysis have been validated through an experimental study. When methods have been modified, it may be necessary to conduct a supplemental validation. For validation studies conducted outside AOAC, Association Française de Normalisation (AFNOR), the French national organization for standardization, or similar organizations, please refer to “FSIS Guidance for Evaluating Test Kit Performance. 10/15/10” at the following link:

http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES

- Methods of analysis detect the same target pathogens as the corresponding FSIS MLG method. That is, alternative methods should be inclusive for strains defined as positive by the biochemical, genetic, and serological confirmation tests described in the MLG.
- Methods of analysis use appropriately sized test portions or sampling methodology and frequency for samples that offer enhanced opportunity for detecting foodborne pathogen contaminations. For information on the test portions used for FSIS testing programs, refer to FSIS laboratory method protocols available from the *FSIS Microbiology Laboratory Guidebook* website at the following link: <http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook>
- If additional non-validated confirmatory tests are performed by the laboratory, those tests should not be relied upon to invalidate the previous results.
- Shipping enrichments to a second confirmatory laboratory should be avoided.

FSIS guidance for evaluating microbiological testing methods can be found in FSIS Directive 5100.1 Rev. 3 Attachment 1 “*Evaluation of Microbiological Methods Used by Establishments*” at the following link:

http://www.fsis.usda.gov/wps/wcm/connect/868cc16e-8dae-48e2-a3c4-898d77f4a0a0/Attachment1_5100.1Rev3_Methods.pdf?MOD=AJPERES

Food Chemistry

- Methods of analysis should be capable of measuring food chemistry components as a percentage of sample weight. Moisture, protein, fat, and salt should be included. FSIS conducts limited food chemistry analysis of products at official establishments when in-plant inspection personnel believe the product is misbranded.
- Acceptable methods of analysis are available on the *FSIS Chemistry Laboratory Guidebook* website at the following link:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook>
- AOAC Official Methods of Analysis for food chemistry are also acceptable.
- Alternative methods for food chemistry analysis are acceptable, provided they measure the same components with sufficient accuracy. Evidence to support use of an alternative method would include proficiency-testing data generated by the State MPI laboratories or contract laboratories laboratory completing the analysis.
- The FSIS Accredited Laboratory Program (ALP) provides proficiency-testing services for food chemistry. For further information, visit the following link:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/accredited-laboratories/accredited-laboratories>

Residue

- Information on in-plant screening of residues in meat and poultry products is available at the following link: http://www.fsis.usda.gov/wps/wcm/connect/c2329ec8-a3fc-4581-8302-dd71aa66e0a8/Compliance_Guide_At_Least_Equal_to_Residue_Testing_122112.pdf?MOD=AJPERES

IV. Submission of Laboratory Methods

To initiate the review process, State MPI programs should submit their current laboratory methods on or before November 15, 2013, as part of the FY 2014 self-assessment submissions. In subsequent years, State MPI programs should submit a list of their current laboratory methods and copies of new or revised methods as part of the self-assessment submission process.

In the submission, State MPI program Directors should divide the document submissions into Microbiology methods, Chemistry methods, and QA records. All three sections should be submitted electronically to the FSIS Outlook mailbox: Statelabinquiry@fsis.usda.gov

If hard copies must be submitted, please mail them to the following address:

Director, USDA, FSIS, OPHS, Laboratory Quality Assurance Staff
950 College Station Road
Athens, Georgia 30605
Phone: (706) 546-3559

FSIS also recommends that States submit a completed *FSIS MPI Program Laboratory Quality Management System Checklist* available at the following link: <http://www.fsis.usda.gov/wps/wcm/connect/b31678b7-0822-4081-bc9a-bf483403851f/State-MPI-Lab-Quality-Mgmt-Sys-Checklist.pdf?MOD=AJPERES> or similar information for each laboratory performing MPI-related analyses.

Records related to FSIS on-site reviews should be submitted to the FSIS Outlook mailbox.

NOTE: State laboratories that are accredited to ISO 17025 with all applicable methods under their scope of accreditation may provide their current certificates of accreditation in lieu of the QA checklist. While use of contract laboratories to meet analytical requirements is acceptable, the contract laboratory should meet the same requirements as described for State MPI program laboratories.

The State MPI program laboratories and their contract laboratories are subject to periodic on-site reviews by FSIS to evaluate the QA program in comparison to written submissions and to verify the accuracy and implementation of the laboratory methods.

V. Additional Information

Questions regarding laboratory methods can be submitted through [AskFSIS](http://askfsis.custhelp.com/) using the following link: <http://askfsis.custhelp.com/>

When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **Laboratory Methods**

Question Field: **Enter your question with as much detail as possible.**
Product Field: Select **General Inspection** from the drop-down menu.
Category Field: Select **Cooperative State Inspection Programs** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only**

When all fields are complete, press the **Submit** button.

VI. References

“At Least Equal to” Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Residue Testing

http://www.fsis.usda.gov/wps/wcm/connect/c2329ec8-a3fc-4581-8302-dd71aa66e0a8/Compliance_Guide_At_Least_Equal_to_Residue_Testing_122112.pdf?MOD=AJPERES

“At Least Equal To” Guidelines For State Meat And Poultry Cooperative Inspection Program

http://www.fsis.usda.gov/wps/wcm/connect/e257c4af-2a5e-4b50-8e5e-3e8da94af949/At_Least_Equal_to_Guidelines.pdf?MOD=AJPERES

Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory March 2012

http://www.fsis.usda.gov/wps/wcm/connect/3d0c3ebb-f09d-494d-9830-ecf4c8435bf7/Guidance_Selecting_Micro_Testing_Lab.pdf?MOD=AJPERES

FSIS Analytical Chemistry Laboratory Guidebook

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/chemistry-laboratory-guidebook/>

FSIS Microbiology Laboratory Guidebook

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook>