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

This Compliance Guideline is provided to establishments producing meat, poultry and processed egg products for use when they are selecting a commercial or private laboratory to analyze establishment microbiological samples. This guidance document should be particularly useful to very small operations in selecting a microbiological testing laboratory. FSIS previously issued this guidance in March 2012 with a request for comments. In response to the comments it received, FSIS has revised the guidance to:

- Clarify that laboratories that meet ISO 17025 accreditation would also meet the guidelines provided by FSIS in this guidance document;
- Compile a Web-based list of methods that have been externally validated for the detection of foodborne pathogens and included information and a hyperlink to this list [1];
- State that proficiency testing (PT) should be performed on a regular basis (two to three times annually) and that PT may be used to evaluate the laboratories' accuracy, precision, and efficiency. PT may also be used as a means to evaluate individual analyst competency;
- Add more questions on PT requirements to the Laboratory Assessment Checklist for establishments to ask laboratories when evaluating if a laboratory is capable of producing accurate and reliable results;
- State that negative controls may be helpful in some circumstances. For example, as a negative control, laboratories may spike one or more samples with non-target bacteria that produce a distinctly different result from the target bacterium on differential media or confirmatory tests.
- State that, because of safety concerns and to prevent cross contamination, FSIS recommends that a pathogen testing laboratory be segregated from manufacturing areas and that access to the laboratory space is limited.

A summary of comments and responses to the comments is included in the Federal Register notice announcing the availability of this document.

[1]These lists of methods that have been externally validated for the detection of foodborne pathogens are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

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Chapter 1. Purpose

FSIS is issuing this guidance document to provide criteria to establishments producing meat, poultry and processed egg products for selecting a commercial or private microbiological testing laboratory to analyze establishment samples. FSIS recognizes that the AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals is a useful technical reference for laboratory staff, and particularly as guidance for laboratories seeking to implement the ISO 17025 requirements. FSIS has included a citation for this reference in the body of this guidance document (see page 18). This FSIS document, in contrast to the Association of Analytical Communities (AOAC) document, was developed to assist industry plant managers and support staff in assessing and selecting their laboratory services at no extra charge. While FSIS acknowledges there is some technical overlap for these documents, the FSIS document provides language and content that is specific to a non-technical industry audience.

A commercial laboratory refers to an outside or off-site contracting testing laboratory, while a private laboratory refers to an establishment's own in-house or on-site laboratory. Throughout this document, the term laboratory will be used to mean both types of laboratories. When outside laboratories analyze establishment samples, it is the responsibility of the regulated establishment to ensure that microbiological testing methodologies and practices meet their food safety needs. Establishments that select a laboratory that does not apply appropriate testing methods or effective Quality Control/Quality Assurance (QC/QA) practices may not receive reliable or useful testing results. FSIS-regulated establishments may perform microbiological testing (or contract with an outside laboratory) for various reasons, including, but not limited to the following:

- To fulfill regulatory requirements (9 CFR 310.25, 381.94, 430.4, 590.580);
- To support on-going verification of the establishment's HACCP plan (9 CFR 417.4(a)(2);
- To support decisions made in the establishment's hazard analysis (9 CFR 417.5(a)(1) and 417.5(a)(2);
- To evaluate the effectiveness of the establishment's sanitation program (9 CFR 416.14); or
- To comply with customers' purchase specifications or requirements.

Ultimately, it is the responsibility of the regulated establishment to ensure that microbiological testing meets its food safety needs. Establishments should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance, including this document, on the FSIS Web site. It is the establishment's responsibility to understand the implication of the results from the laboratory for their program and plan corrective actions accordingly. The establishment should not assume that an unexpected result is incorrect. Re-sampling or retesting a sample is typically not an appropriate action.

Because of safety/security concerns and to prevent cross contamination, FSIS strongly recommends that a pathogen testing laboratory be segregated from manufacturing areas, and that access to the laboratory space be limited. Pathogen testing laboratories should:

- Follow requirements for Biosafety Level II laboratory operation as outlined in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) available at: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf;
- Restrict access to the laboratory to trained staff; and
- Ensure the laboratory is operating under the supervision of a qualified microbiologist or equivalent.

NOTE: Establishments can (and often do) analyze samples for non-pathogenic organisms such as *Listeria* spp., generic *E. coli* and aerobic plate counts (APC).

Chapter 2. Laboratory Selection and Evaluation Criteria

When evaluating the services provided by a microbiological testing laboratory, it is important for the establishment to ensure that the candidate laboratory to be able to perform the analyses and report results using methods that meet the establishment's needs. Building a working relationship and initiating conversation consistent with these guidelines will help ensure that the establishment selects an appropriate laboratory. The evaluation criteria and recommended questions found in this document will assist establishments in making a determination that the results they receive from the laboratory are reliable and accurate. These criteria include what FSIS considers essential to understanding whether a laboratory is capable of producing acceptable results. For ease of use, a checklist of recommended questions for assessing laboratories is available in Appendix I. In addition, FSIS inspection personnel will use similar criteria to evaluate laboratory results during the verification of a food safety system such as a Hazard Analysis Critical Control Point (HACCP) system verification or a Food Safety Assessment (FSA). The criteria provided in this document include:

A. Personnel qualifications;

B. Sample receipt and handling, sample integrity maintenance, identity and chain of custody;

C. Quality assurance management system;

D. Method selection and implementation; and

E. Reporting of results and establishment's interpretation of results.

The selected laboratory should not subcontract any portion of the analyses to another laboratory without permission of the establishment management and proof that the subcontract laboratory meets this guidance. The establishment management should also verify that the conditions under which a sample is shipped to a subcontract or second laboratory for testing do not adversely affect the follow-up analysis.

Each section of this document provides general information, questions to ask the laboratory manager, and items to be taken into consideration before selecting a laboratory. This information should be helpful for evaluating which laboratory best fits the needs of an establishment. For further assistance, additional information is available under the References listed in this document (page 18).

Questions to ask Laboratory Manager

1. Does the Laboratory Manager have an advanced degree (PhD or MS) or a 4-year degree in biology, chemistry, microbiology, food or medical technology, or other relevant science with at least 12 semester hours of course work in microbiology, or at least 4 years of experience working in a public health, medical, food, or other related laboratory?

2. Do the Laboratory analysts/technicians have a 4-year degree, or an associate degree in biology, microbiology, or relevant science with at least 10 semester hours of microbiology, or 2 years of working experience?

3. Does the Laboratory have records (certificates) documenting successful participation in applicable proficiency testing programs within the past year?

4. Can the Laboratory provide documentation demonstrating that all laboratory personnel meet the necessary education, training, and competency requirements?

A. Personnel Qualifications

KEY POINTS:

- The laboratory should have a policy and system in place for documenting and maintaining records on the background of laboratory management and analysts, which include their education, experience, and training, to establish analyst competency for a specific testing method.

- All laboratory personnel should be well versed in food microbiology, analytical methods of food sampling, and foodborne pathogens such as *Campylobacter, Salmonella, Listeria monocytogenes, E. coli* O157:H7, and non-O157 Shiga Toxin-Producing *Escherichia coli* (STEC) in meat, poultry, and processed egg products. Analysts should be trained on new or revised methods before they perform the

method on establishment samples. Analysts should then demonstrate ongoing competency annually for each method performed. Laboratories may use laboratory proficiency testing (PT) as a means to evaluate the individual analyst's initial and ongoing competencies to perform a method. Other options to demonstrate analyst competency include control charting and analyzing in-house blinded training or check samples.

- All relevant internal and external training should be documented for each staff member and records must show completed performance verifications.

B. Sample Receipt and Handling

KEY POINTS:

- The laboratory should have a documented system, such as a Standard Operating Procedure (SOP), for ensuring the integrity of samples during transportation and upon receipt, including discard criteria for unacceptable samples.
- The laboratory should have a system for tracking samples after they have been received and accepted for analysis including procedures for maintaining the identity and integrity of the sample throughout storage, analysis, and reporting of test results.
- The laboratory should have a system for tracing a test result to the correct sample.

Sample Receipt, Handling, Integrity Maintenance, Identity, and Chain of Custody

General Principles:

Collecting and analyzing samples involves multiple steps, all of which must be successfully performed and documented to maintain the identity and integrity of the sample. It is important for the establishment to be able to collect and ship samples properly. On-site assistance or information on proper sample collection (aseptic techniques) and shipment of samples by the laboratory to the establishment is also important. The final result of the analysis will be neither accurate nor meaningful if a laboratory has not implemented procedures to prevent mishandling of samples or alteration of records. Procedures for maintaining sample integrity are particularly important when samples need to be transported from the establishment to an off-site laboratory (e.g., by a delivery service such as FedEx or courier) where they may not be under the direct control of the establishment or the laboratory for a period of time.

Things to Look For:

1. Sample integrity: The laboratory should have procedures in place to ensure sample integrity is maintained. These procedures should include:

- Documenting sample custody during all stages of testing, from receipt of samples to reporting of results;
- Determining whether samples have been shipped and held at inappropriate temperatures, and ensuring that such samples are not analyzed; and
- Preventing contamination from other samples or the environment.

2. Sample identity: The laboratory should have procedures to ensure that the history of any sample received by the laboratory is documented. Each sample should be labeled with permanent ink or another permanent labeling system. Each sample should be assigned a unique identifier that is associated with the sample from collection to test report.

3. Chain of custody: A chain-of-custody (COC) document is often used to demonstrate that the sample is always under the control of the establishment or the laboratory. COC documents record the circumstances under which the responsibility of the sample is transferred. They include the time, date, name, and signature of the individuals that are transferring the sample and a description of the sample, including the sample's unique identifier. The COC supports both the sample integrity and the accuracy of the test results. A Laboratory Information Management System (LIMS) is often utilized by laboratories to capture and store this COC information electronically.

4. Preparation and shipment of the sample: Non-intact samples should be placed in a sterile primary container (e.g. sterile Whirlpack bag) designated for collecting samples and shipped in a box containing cooling packs to maintain the proper temperature. Food samples in intact retail packs do not have to be placed in sterile containers but should be placed in a secondary container such as a sealed plastic bag. Shipping boxes should be sealed to prevent unauthorized access to the sample.

5. Sample receipt: The laboratory should maintain a sample log-in book, computer file, or other permanent recordkeeping system with an accessible format to document the following:

- Samples are inspected upon receipt and their condition is recorded;
- Samples are evaluated against the laboratory's discard policy; and
- Unacceptable samples are discarded and not analyzed.

C. Quality Assurance Management System

KEY POINTS: The laboratory should, on a regular basis (at least 2 to 3 times annually), evaluate its competency through participation in proficiency testing (PT) programs for

each method performed. The laboratory should maintain PT records with sufficient information to show that the method was performed like a routine sample.

For all samples, the testing laboratory should have routine controls with each batch of samples, including a positive control inoculated with the analytes of interest, a sterility control, and (optionally) a non-target analyte "negative" control. The laboratory should not report results to establishments unless the controls support acceptable test performance. In addition, all laboratory equipment should be adequately maintained and routinely calibrated according to the appropriate guidance.

General Principles:

Quality assurance (QA) is defined as a program designed to ensure timely and reproducible results that are useful to customers through the minimization of human error. Quality control (QC) is defined as a procedure intended to verify that a system, such as a laboratory method, is working correctly. The International Organization for Standardization (ISO) (http://www.iso.org/iso/home.htm) developed internationally-accepted quality standards for laboratory management, ISO/IEC (International Electrotechnical Commission) Standard 17025 *General requirements for the competence of testing and calibration laboratories*, focusing on QA and QC principles. Laboratories receive external audits to demonstrate compliance with the ISO standard. Although accreditation is not a specific requirement, accreditation provides increased confidence in the accuracy and quality of the test results produced by a laboratory.

Note that FSIS laboratories are audited by an external assessment body to demonstrate compliance with the ISO 17025 Standard and the *AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals*, available at: http://www.aoac.org/accreditation/faq2.htm. Whether or not a laboratory is accredited under ISO 17025, the Analytical Laboratory Accreditation Criteria Committee (ALACC) document is a helpful reference, available at: http://www.a2la.org/requirements/17025_FOOD_MICRO_REQ.pdf. This document provides guidance on the frequency of equipment maintenance, calibration, and monitoring the performance of equipment during the course of analysis (*i.e.*, performance verification). Alternatively, the *European Co-Operation for Accreditation (EA) 04/10*, Accreditation for Microbiology Laboratories provides similar guidance and is available at: http://www.european-accreditation.org/n1/doc/ea-4-10.pdf.

The above accreditation schemes cover all the topics mentioned in this guidance document. Laboratories that meet the guidance provided in the above mentioned accreditation schemes would meet the guidelines provided in this document. All laboratories that test samples from FSIS-regulated establishments should have QA and QC programs and should be able to describe these programs to their customers. At a minimum, QA and QC programs implemented by laboratories should cover written procedures and data collection tools, sample traceability/chain of custody, equipment maintenance and calibration, validated testing methods, PT, and analysis controls.

Things to Look For:

1. Written QA Program: The laboratory should have policy and procedure documents describing the analytical and quality activities performed in the laboratory. Analysts should only have access to the current revisions of these documents. Laboratory personnel should periodically review these QA program documents for continued suitability.

2. Proficiency testing (PT) programs: PT provides evidence of laboratory competency to produce credible analytical results in a method. PT programs are designed to critically evaluate the accuracy, precision, and efficiency of the laboratory. The laboratory should regularly evaluate their laboratory competency through a PT program. PT programs are administered by an outside organization on a routine (e.g., annual, semi-annual, or thrice-annual) basis. In a PT program, the outside organization sends the laboratory a set of food samples, with each sample either inoculated or free of the microorganism of interest. The laboratory analyzes the samples and submits its results for assessment. The outside organization evaluates the returned results against the target value and provides the laboratory a report stating whether the laboratory has successfully met the criteria set by the organization administering the PT program.

Questions to ask Laboratory Manager

1. Does the laboratory have a written Quality Assurance Program?
2. On review and verification of laboratory PT results, were all results for the past year found to be acceptable?
3. Has the performance of the method been evaluated for use in the laboratory?
4. Are the sample type, test portion, analyte, and test method captured on the laboratory's sample worksheet?
5. Does the laboratory always run positive and sterility controls at the same time as the samples?
6. Are the laboratory results approved by the laboratory director or manager before the results are released to the customer?
7. Are the calibration, operation, and maintenance of all equipment verified to be performed in accordance with international recommendations?

3. Data collection tools: The laboratory's sample worksheets should contain sufficient information to verify the proper interpretation of the test for the final result. Worksheets should be prepared by the laboratory on a daily basis to record observations, calculations, and traceable information. These and other data collection tools should contain sufficient information to facilitate the identification of factors that may affect the accuracy of the result, such as media preparation. The worksheets should record the following (as applicable):

- Method protocol name or number;
- Analysts performing the method;
- Unique identifier (internal laboratory number) ;
- Start and completion dates;
- Measurements from relevant equipment such as temperature from ovens, incubators, water baths, autoclaves;
- Incubation or running times;
- Lane or injection order;
- Equipment used;
- Lot number (or traceable identification) for media, reagents, standards, and controls used in the procedure;
- Sample weights;
- Measurements, such as pH and water activity;
- Calculations performed during the procedure;
- Any other relevant observation, such as the size, color, and consistency of colonies on microbiological media;
- Unexpected observations; and
- Results from samples and controls.

4. Controls: The laboratory should run controls with each batch of samples, and the sample results should not be reported unless the controls indicate acceptable test performance. Controls are defined as samples that are intended to verify that the method is performed correctly and produces accurate results. Microbiological controls include:

    - One or more positive controls, which are food samples inoculated with a well-characterized strain that is the target of the method. The positive control result verifies that the method, all media and reagents, and the analyst are capable of achieving the correct result at the time of analysis when the organism of interest is present. Also, laboratories use positive controls to evaluate whether the food sampled interferes with the detection of the target microorganism. Care must be taken to avoid cross-contamination between the positive control and the other samples. One way that laboratories may verify that positive sample results are not caused by cross-contamination is by using an easily identifiable positive control such as one that contains an antibiotic resistance or a fluorescence strain.
    - A sterility control is a type of control where prepared media are not inoculated with any control organism. Laboratories use the sterility control

to verify that all media and reagents, as well as the analyst, are not contributing contamination that could have an impact on the test result. The sterility control should always be negative and there should be no evidence of microbial growth.

- Additional negative controls may be helpful in some circumstances. As an example, laboratories may spike one or more samples with non-target bacteria that produce a distinctly different result from the target bacterium on differential media or confirmatory tests. Such a negative control can be inoculated at the beginning of the analysis or applied later in the analysis for specific biochemical, genetic or serological confirmation tests.

NOTE: Some test kits have controls built into the test. These controls should be analyzed along with the samples and method controls to verify that the kit performs according to manufacturer specifications. Results derived from control samples can be used to identify the source of problems.

Controls demonstrate the following to the customer:

- The entire method is performing as expected;
- The specific media and reagent lots are performing as expected;
- The analyst is performing all steps of the analysis correctly; and
- There is a basis for documenting that the test results are valid and accurate.

Because controls are important to demonstrate that the method was effective, they should be analyzed concurrently with every batch of samples, and the results from the controls should be recorded. Importantly, an unexpected result may indicate that the method is not performing effectively; therefore, the validity of sample results should be evaluated by the laboratory. The laboratory QA system should not allow the result to be reported to the customer until the issue is resolved.

In addition, the laboratory should employ controls to perform lot and batch acceptance on test kits, reagents and culture media. Sterility, selectivity and the ability to support growth of target analytes should be assessed prior to using the product on customer samples.

5. Environmental Monitoring: The laboratory should implement an effective environmental monitoring program to mitigate risk of cross contaminating sample portions. Air monitoring for density of airborne microorganisms and sponge samples of work surfaces such as bench tops, stomachers, balances, and analytical instruments, for the analytes of interest are appropriate activities. The laboratory should investigate positive results to identify cross contamination of positive samples and should follow up with necessary disinfectant of work surfaces and necessary follow up testing.

6. Equipment: The laboratory should have policies and procedures in place to ensure that all equipment and software used for testing, calibration, and sampling are uniquely identified, capable of achieving the required accuracy, and comply with the method specifications. The laboratory should have procedures to ensure that equipment is used properly, maintained, and performance calibrated according to the manufacturer's recommendations, and that defective equipment is removed from the service area and clearly labeled as "out of service."

Questions to ask Laboratory Manager

1. Does the laboratory use an analytical method described in the FSIS-MLG?
2. Has the enrichment and screening method used by the laboratory to detect the target microorganism of interest, been validated and approved by an organization such as AOAC, AFNOR, ISO, NordVal, MicroVal, FDA, FSIS, or other? If yes, specify the organization.
3. Has the method used by the laboratory to confirm the target microorganism of interest been approved by an organization such as AOAC, AFNOR, ISO, NordVal, MicroVal, FDA, FSIS, or other? If yes, specify the organization.
4. Is the sample collected representative of the production lot?
5. Is the test portion representative of the entire sample collected? If yes, is it similar to the sample size provided for in the FSIS-MLG?
6. Has the method been validated for the matrix of interest (food or environmental swabs) and the test portion size?
7. Have any changes been made by the laboratory to the validated method? If yes, request additional scientific supporting documents.

D. Method Selection and Implementation

KEY POINTS: Methods should be specific or fit for the intended purpose to detect the target microorganism in the sample. Methods for detecting foodborne pathogens should be designed to be adequately sensitive to detect low levels of injured cells to prevent false negative results. The method should be capable of detecting the target pathogen, as it is defined in the corresponding FSIS Microbiology Laboratory Guidebook (MLG) protocol. Confirmation methods should be specific for target organisms, so that cross reactions with closely related microorganisms or analytes do not occur. The method should be validated using a scientifically robust study by a recognized entity, as outlined in the FSIS validation guidance document for test kit manufacturers and laboratories.

Internationally recognized independent organizations, including AOAC, AFNOR (Association Française de Normalisation, the French national organization for standardization), MicroVal, and NordVal organize validation studies on behalf of clients.

Any modifications introduced to a validated method should also be validated using a scientifically robust study. Sample size should be comparable to those employed by FSIS, if applicable. For more guidance from FSIS on validation studies please refer to

"FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods".

NOTE: Laboratories that are accredited and use the same analytical methods, procedures, and sample sizes as those used by FSIS laboratories and described in FSIS's Microbiology Laboratory Guidebook (FSIS-MLG) are deemed to have met the laboratory selection and evaluation criteria described in this chapter (Chapter 2).The FSIS-MLG is posted on the FSIS Web site at: http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook

General Principles:

All analytical methods described in the FSIS-MLG have been scientifically validated and are considered fit for their intended purpose. Thus, laboratories that analyze samples using specific instructions in the FSIS-MLG, or that have met the above evaluation criteria and are able to use the methods, would meet the evaluation criteria for laboratory selection.

Validation: Laboratories may also use other validated testing methods that differ from the methods described in the FSIS-MLG. Validation as used in this document refers to a laboratory study to evaluate the performance characteristics of a testing method. Validation is typically performed by regulatory agencies or companies that develop test kits.

In most cases, validation studies are designed to compare the performance of a new method (referred to as an "*alternative*" method) against an older, well-characterized method (referred to as a "*reference*" method). For the intended conditions of use, the performance characteristics of the new method and the well-characterized method should be statistically indistinguishable. FSIS has also provided guidance for industry to consider when validating new microbiological methods or modifications to existing methods for foodborne pathogens. . See guidance document for more information, available at: http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES

Following validated testing protocols: Establishments should verify that their laboratories follow all steps in a validated method protocol. Modifications to validated methods (whether FSIS-MLG or alternative methods) often compromise the effectiveness of the test.

Verification: The laboratory should demonstrate on-going competence in performing the method at their facility, which would include participating in proficiency testing programs.

In summary, establishments should determine whether a laboratory is using validated methods to test their samples, whether the methods are fit for their intended purpose, whether those methods are comparable to the methods used by FSIS (if applicable), and whether the methods have been modified from their initial validated procedure. By

following these guidelines and using methods that are validated, establishments and laboratories can ensure that the results are reliable and fit for their purpose. If an establishment does not choose to use methods that have been validated, FSIS may question the support for decisions made in their hazard analysis.

Things to Look For:

1. Validated methods: The laboratory should only use validated test methods to analyze samples. Validation studies can be performed either in single or multiple laboratories. However, multiple laboratory validation studies are preferable because these studies evaluate the "ruggedness" (comparable test performance in different laboratories with different equipment and personnel), and therefore, the likelihood that the test will have acceptable performance is greater if it has been successfully validated in multiple laboratories.

2. Fit for intended purpose: Validation by a recognized independent organization does not support that the method is appropriate for any and all situations. The laboratory and the establishment should also make a determination that the method is fit for the intended purpose. That is, the method:

- Has been validated in foods or matrices representative of those likely to be sampled at the establishment;

NOTE: Links to AOAC-RI Performance Tested Methods and AOAC Official Methods of Analysis are provided in the Reference section below. Manufacturers of microbiological testing products, including pathogen screening tests, often provide useful information on the validation of their products.

- Has been validated to analyze the desired test portions; and

- Has been validated to detect the microorganisms of concern as identified by the establishment.

Additionally, laboratories and establishments should consider the following intrinsic factors:

- Detection: methods intended to detect the presence of foodborne pathogens should be capable of detecting low levels (approaching one cell per test portion) of injured cells;

- Raw food: the presence of fat and competitive microbiota and other factors can affect test sensitivity;

- Ready- to-Eat (RTE) food: the sensitivity of methods intended for RTE food samples can be affected by properties of the product including added salt, low pH, and low water activity (in the case of dried products such as jerky); and

- Environmental surface: microbial load and the presence of detergents and sanitizers typically used in RTE-producing establishments can affect method sensitivity.

3. Use of FSIS-comparable methods: If the laboratory does not use a method described in the FSIS-MLG, the analytical methods used by the laboratory should be comparable to the methods used by FSIS. For example, for products that are tested for the foodborne pathogens *E. coli* O157:H7, non-O157 STECs, *Salmonella*, *Campylobacter*, or *Listeria monocytogenes*, the establishment should ensure that the sampling and testing methods are comparable to the appropriate FSIS methods used for these specific organisms as described in the MLG. Specifically, the methods should:

- Be validated by a recognized independent organization using an appropriate cultural method as a reference, such as the FSIS-MLG method. Alternatively, a validated method from a scientifically robust study using the FSIS method as a reference is acceptable but should be evaluated by FSIS. FSIS recommends submitting questions regarding the suitability of a method to askFSIS at: http://askfsis.custhelp.com; and
- Be capable of analyzing a test portion similar to the FSIS test portion in terms of size and food type. The MLG provides information about the current analytical portion for each particular analysis. The test portion is the portion of the collected sample that is actually tested by the laboratory.

4. Modifications to Validated Methods: If the laboratory has introduced modifications to a validated analytical method, the modifications should be validated using a scientifically robust study. FSIS has encountered situations where laboratories have made significant modifications to a validated method without determining how the modification would affect test performance. Changes that should be validated include:

- Increased test portion size;
- Altered ratio of sample to enrichment broth;
- Different enrichment broth;
- Modification to established enrichment;
- Reduced enrichment time;
- Different enrichment temperature; and
- Different food sample.

If any modifications are introduced to a validated method, the method should be re-validated using a scientifically robust study and comparing it with a reference cultural method. These studies are performed by regulatory bodies or internationally recognized independent validation organizations.

E. Reporting of Results and Establishment's Interpretation of Results

KEY POINTS: A Certificate of Analysis (COA) or a laboratory report details data consistent with FSIS reporting results. The information provided in these reports may vary for each laboratory. FSIS recommends that establishments know what data are included in the laboratory's sample report or COA before selecting the lab.

General Principles:

Test results should be reported in a manner consistent with the principles of quality assurance to provide useful information and to minimize human error. Laboratory reports or COAs issued for production lots should contain the following information, which is consistent with test result reports prepared by FSIS laboratories:

- Result (including the units of measurement, e.g. cfu/g, cfu/sq. in., MPN/g);
- Description of sample;
- Unique identifier of sample (internal laboratory number);
- Location of sample collection or type of product tested;
- Date of sample collection;
- Date of analysis;
- Date of result report;
- Name of method (cite AOAC, AFNOR, ISO number, if applicable);
- Name, title, and signature of individual preparing the result;
- Interpretation of results (acceptable or unacceptable); and
- Name, title, date and signature of individual reviewing result and authorizing its release.

Things to Look For:

The laboratory's QA system should address how the combination of test results (screening vs. confirmation results) are interpreted and reported. All presumptive positive results identified by a rapid screening method should be reported. For laboratories that perform analysis of egg product samples (PEPRLab program), all presumptive positive results from official surveillance samples should also be confirmed using one of three cultural confirmed methods (AMS Laboratory Methods for Egg

Products – Section I ('93 rev.) and Section VII ('94 rev.), FSIS MLG online, Chapter 4, and FDA Bacteriological Analytical Manual (BAM) online, Chapter 5). Once analysis is started on a sample, the analysis should be completed. If the analysis is terminated before completion, the analyst should document why the analysis was not completed. The QA system should also ensure that test results that do not meet internal laboratory standards are not reported.

NOTE: It is the establishment's responsibility to interpret the results for its own food safety system.

Chapter 3. What Data Should an Establishment Have Readily Available for FSIS Personnel?

The establishment management is responsible for testing that is conducted on its behalf and should communicate with the laboratory manager to ensure that the methods used by the laboratory are fit for purpose. The method should be validated to test the product the establishment produces. In some circumstances, such as during an outbreak investigation or FSA, FSIS will evaluate methods using similar criteria and may request additional supporting documentation from the establishment. Under the HACCP regulations, the results of any testing that is performed by an establishment that may have an impact on the establishment's hazard analysis are subject to FSIS review and are to be available to FSIS personnel. Therefore, FSIS has access to testing records and testing data related to HACCP, prerequisite programs, and good manufacturing procedures. FSIS also has access to records of testing conducted for the establishment's business customers that could bear on the hazard analysis. Furthermore, FSIS has access to supporting documentation associated with this testing, including method protocols. Data on testing methods and results that are subject to FSIS review include, but are not limited to the following:

- Testing protocol for requested analyses, including modification necessary to meet the needs of the establishment program;

- Evidence of method validation;

- Establishment's sampling plan, including purpose, type, and frequency of sampling;

- Correspondence between the establishment and laboratory, including acknowledgement from the laboratory that it meets the criteria established in this guidance (for example, including a completed laboratory assessment checklist);

- Chain of Custody (COC) documentation when samples are needed to be transported from the establishment to an off-site laboratory (e.g. by a delivery service such as FedEx or courier) where they may not be under the direct control of the establishment or the laboratory for a period of time;

- Microbiological test results and reports;

- Interpretation of results (acceptable/unacceptable) for use by the establishment such as applying results to determine process control or following HACCP (Hazard Critical Control Points) plan, or integrating results in conjunction with SOP;

- Corrective actions related to test results, such as laboratory error, unacceptable sample temperature or failed PT;

- Data and supporting documentation associated with testing; and

- Testing associated with prerequisite programs and with good manufacturing procedures.

References

1. Ask FSIS Questions and Answers. Available at: http://askfsis.custhelp.com

2. AOAC Official Methods of Analysis search engine at: http://www.eoma.aoac.org/

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APPENDIX I.

Laboratory Assessment Checklist

The checklist is intended to assist establishments to determine whether a microbiological laboratory is capable of producing accurate and reliable results. The questions are phrased so that the appropriate response to most questions is "Yes," "No," or not applicable ("NA"). Questions pertaining to services or procedures not routinely used by the establishment should be marked as "NA". A "No" response to any of the questions would not necessarily imply that results from the laboratory are not reliable. The establishment should request additional supporting information or a justification for the "No" response, or contact FSIS through askFSIS at: http://askfsis.custhelp.com, for additional assistance.

Date _____ Laboratory Name _____

Questions	Yes	No	Not Applicable (NA)
Does the laboratory manager have an advanced degree (PhD or MS) or a 4 year degree in biology, chemistry, microbiology, food or medical technology, or other relevant science with at least 12 semester hours of course work in microbiology or at least 4 years of experience working in a public health, medical, food, or other related laboratory?			
Does the laboratory analyst or technician have a 4 year degree, or an associate degree in biology, microbiology, or relevant science with at least 10 semester hours of microbiology, and/or 2 years of working experience?			
Can the laboratory provide documentation demonstrating that all laboratory personnel meet the recommended education, training, and certification requirements above? (See Chapter 2 - A: Personnel Qualifications).			
Is the laboratory analyst trained on a new method and found to be competent before he/she can perform the method on the establishment samples?			
Does the laboratory have records (certificates) documenting the analysts' or technicians' competency, such as participation in a laboratory PT program, analyzing in-house blinded training or check samples?			

Does the laboratory have a written Quality Assurance Program?			
Is the laboratory's Quality Assurance Program periodically reviewed by an external party?			
Questions	Yes	No	Not Applicable (NA)
Does the laboratory have lot acceptance criteria for test kits, reagents and growth media (*i.e.*, does the laboratory assess them for sterility, selectivity, and ability to support growth of target analyte prior to using product on customer samples)?			
On review and verification of laboratory PT results, were all results for the past year found to be acceptable? For any unacceptable PT result, did the laboratory perform an appropriate root cause analysis and implement effective corrective actions?			
If a commercial PT program is unavailable for the target analyte, does the laboratory use blinded in-house check samples to demonstrate laboratory competency"?			
Has the performance of the method been verified for use in the laboratory?			
Does the laboratory subcontract any portion of the analyses to another laboratory? If yes, does the subcontract laboratory meet the recommended criteria found in this document?			
If portions of the analyses are subcontracted to another laboratory, has sample integrity been maintained under the conditions under which the samples are stored and shipped?			
If enrichments have been shipped to a second laboratory for follow-up analysis, what ensures the integrity of these analyses?			
Does the sample have a unique identification number (Sample ID, internal laboratory #) to be able to trace the sample results back to sample receiving and sample collection?			
Does the laboratory have criteria for accepting or discarding samples when samples are received at the laboratory (sample receiving)? (for example: unbroken seals on containers; acceptable temperature for raw ground beef).			

Are the sample type, test portion, analyte, and test method captured on the laboratory's sample worksheet?			
Does the laboratory run control samples (positive, sterility, or negative) at the same time as the samples?			
Questions	Yes	No	Not Applicable (NA)
Does the laboratory sample result reporting tool have the name or initial of the technician or analyst carrying out the analysis?			
Are the laboratory results reviewed by the laboratory director or manager before the results are released to the customer?			
Is equipment maintained, calibrated and performance monitored during the course of analysis (verified) in accordance with international recommendations (ALACC or EA04/10) and also maintained and calibrated as recommended by the manufacturer?			
Has the enrichment or screening method used by the laboratory to detect the target microorganism of interest been approved by an organization such as AOAC, AFNOR, ISO, MicroVal, NordVal, FDA, FSIS, or other? If yes, specify the organization.			
Has the confirmatory method used by the laboratory to confirm the target microorganism of interest been approved by an organization such as AOAC, AFNOR, MicroVal, ISO, NordVal, FDA, FSIS, or other? If yes, specify the organization.			
Is the sample collected representative of the production lot?			
Is the test portion representative of the entire sample collected? If yes, is it similar to the sample size provided for in the FSIS-MLG?			
Has the method been validated for the matrix of interest (food or environmental swabs) and the test portion size?			
Have any changes been made by the laboratory to the validated method?			
If changes have been made to the validated method, does the laboratory have additional scientific supporting documentation to support the modification?			

Does the laboratory's sample report or COA include information on the sample type, analyte, laboratory official who approved results of test?			