Laboratory Approval Program - Export

1. Purpose

The purpose of this document is to outline the requirements for the Laboratory Approval Program for Export of Meat and Poultry Products for analysis of chemical residues, microorganisms, and parasites in meat and poultry products offered for certification by United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) for export. This document describes the technical competency and quality management requirements a laboratory must demonstrate to be a USDA-approved laboratory.

The Laboratory Approval Program (LAP) is administered by the Laboratory Approval Service (LAS) Branch. The LAS is part of the Agricultural Marketing Service (AMS), Science and Technology (S&T) Program, Laboratory Approval and Testing Division (LATD).

The LAS approves, or accredits, laboratories to perform testing services in support of domestic and international trade. At the request of industry, other Federal Agencies, or foreign governments, the LAS develops and administers programs to verify that the analysis of food and agricultural products meet country and customer-specific requirements and that the testing of products marketed is conducted by qualified and approved laboratories.

2. Scope

This LAP is for a laboratory seeking to obtain and maintain its status as a USDA-approved laboratory for analysis of meat and poultry products for chemical residues, microorganisms, and parasites specified by trade agreements. This LAP verifies technical and quality control competencies of a laboratory for the analysis of meat and poultry products. All aspects of a laboratory's quality management system (business processes) are applicable and are critical for ensuring the defensibility of the analytical results produced under the LAP.

This LAP directly supports several USDA programs, described below, associated with country specific requirements described in the FSIS Export Library.

2.1. USDA Programs:

a) FSIS European Union Additional Residue Testing Program

b) USDA Never Fed Beta Agonists Program

c) USDA Pork for the European Union Program

d) USDA Poultry Export Verification Program

e) USDA Porcine Export Verification Programs

f) FSIS Prevention and Control of Trichinella

f-1) FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products

f-2) 9 CFR 149, Voluntary Trichinae Certification Program

Laboratory Approval Program - Export

Approval is granted by analyte group, described below, and not by country as organized by the FSIS Export Library.

2.2. Analyte groups:

a) Chemical residue – Antibiotics (AB)

b) Chemical residue – Beta agonists (BA)

c) Chemical residue – Heavy Metals (HM)

d) Chemical residue – Pesticides (PC)

e) Chemical residue – Resorcylic acid lactones (RC)

f) Chemical residue – Steroids (SR)

g) Microorganisms – *Salmonella* (SLM)

h) Microorganisms – *Listeria monocytogenes* (LM)

i) Microorganisms – Aerobic Plate Count (APC)

j) Parasite – *Trichinella spiralis* (TS)

3. Table of Contents

4. Glossary of Terms

AB	Antibiotics
AMS	Agricultural Marketing Service
AOAC	AOAC International
APC	Aerobic Plate Count (i.e., Total Plate Count (TPC))
BA	Beta agonists
BAM	Bacteriological Analytical Manual, FDA
CFR	Code of Federal Regulations
CCV	Continuing Calibration Verification
CLG	Chemistry Laboratory Guidebook, FSIS
CVM	Center for Veterinary Medicine, FDA
EU	European Union
EPA	Environmental Protection Agency, US
FSIS	Food Safety Inspection Service
FDA	Food and Drug Administration
HM	Heavy Metals
ICV	Independent Calibration Verification
ILAC	International Laboratory Accreditation Cooperation
IS	Internal Standard
ISO/IEC	International Organization for Standardization/ International Electrotechnical Commission.
LAP	Laboratory Approval Program
LAS	Laboratory Approval Service
LATD	Laboratory Approval and Testing Division
LIB	Laboratory Information Bulletin, FDA
LM	*Listeria monocytogenes*
MLG	Microbiology Laboratory Guidebook, FSIS
MSW	Microbiologically Suitable Water
PAM	Pesticide Analytical Manual, FDA
PC	Pesticides
PM	Program Manager
PT	Proficiency Test(ing)
RC	Resorcylic acid lactones
S&T	Science & Technology Program
SLM	*Salmonella*
SR	Steroids
TPC	Total Plate Count
TS	*Trichinella spiralis*
US	United States
USDA	United States Department of Agriculture

5. References

The following articles are referenced in this document. For the dated references, they only apply to the edition cited. For the undated references, the latest edition of the referenced document (including any amendments) applies.

5.1. Laboratory Approval Program

5.1.1. LAP-PR.05, Laboratory Approval Program – General Policies and Procedures.

5.1.2. LAP-PR.06, Laboratory Approval Program – Fees.

5.2. Quality Assurance Standards:

5.2.1. ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories (2005 or 2017).

5.2.2. USDA AMS Laboratory Standards of Practice.

5.3. Agency Requirements

5.3.1. USDA FSIS Export Library

5.4. Chemical Residue Methodology

The sources listed are links to collections of current available methods commonly used and cited in §13.

5.4.1. USDA FSIS Chemistry Laboratory Guidebook (CLG)

5.4.2. AOAC Official Methods of Analysis

5.4.3. US FDA Laboratory Information Bulletins (LIB)

5.4.4. US FDA Pesticide Analytical Manual (PAM)

5.4.5. US EPA Methods

5.5. Microbiology Methodology

The sources listed are links to collections of current available methods commonly used and cited in §14.

5.5.1. USDA FSIS Microbiology Laboratory Guidebook (MLG)

5.5.2. US FDA Bacteriological Analytical Manual (BAM)

5.5.3. AOAC Official Methods of Analysis

5.6. Trichinella Methodology

5.6.1. EU 2015/1375. Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for Trichinella in meat (Codification). Official Journal of the European Communities, L212: 7-34.

5.7. Method Validation Guidance Resources and others

These references are mentioned as guidance documents to aid a laboratory's development of their own method validation procedure and good laboratory practices.

5.7.1. Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (2002/657/EC). Official Journal of the European Communities, L221: 8-36.

5.7.2. Eurachem Guides

5.7.3. Good Laboratory and Clinical Practices, Techniques for the Quality Assurance Professional, edited by P.A. Carson and N.J. Dent, 1990.

5.7.4. Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition. US FDA, FDA Foods and Veterinary Medicine Science and Research Steering Committee, May 19, 2015.

5.7.5. Guidelines for the Validation of Chemical Methods for the FDA CVM Program, 2nd Edition. US FDA. FDA Foods and Veterinary Medicine Science and Research Steering Committee, May 19, 2015.

5.7.6. ITC. International Commission on Trichinellosis. Guidelines. Recommendations for Quality Assurance in Digestion Testing for *Trichinella*.

5.7.7. Mass spectrometry for confirmation of the identity of animal drug residues. Center for Veterinary Medicine (CVM), Guidance for Industry #118.

6. Laboratory Approval Program Administrative Procedures

A laboratory seeking admission to the Laboratory Approval Program must fulfill the requirements and follow the process described in the LAP procedure, LAP-PR.05, Laboratory Approval Program – General Policies and Procedures. This procedure describes the process for application, assessment audits, acceptance, maintaining program status, suspension, withdrawal, dismissal, appeals, and fees.

This program is administered on an annual, calendar year, basis. The LAP procedure, LAP-PR.06, Laboratory Approval Program – Fees explains the fees for service.

The administrative procedures are available on the LAS website, or contact the LAS Export Program Manager (PM) for the current version of the procedure.

7. Summary of General Program Requirements

The laboratory must comply with all requirements set forth in this document in order to be compliant with the LAP. For the laboratory to maintain in good standing, each year it must:

7.1. meet all program requirements relevant to the scope of approval;

7.2. comply with mandatory laboratory quality assurance practices based on the ISO 17025 standard (see §8);

7.3. use test method(s) approved by AMS, and the validation and verification data package must be available for review upon request (see §10 and 11);

7.4. evaluate analyst competency and maintain satisfactory status (see §12);

7.5. participate in proficiency testing programs and maintain satisfactory status (see §12);

7.6. communicate regularly with the PM to share vital information regarding the laboratory and make all information relevant to the LAP available to PM upon request. Notify the PM within 30 days of significant changes relevant to:

7.6.1. laboratory policies and procedures;

7.6.2. change in key managerial personnel, contact persons;

7.6.3. validation and verification of adequate method performance after a significant change in location, equipment, facilities, or working environment;

It is at the discretion of LAS whether an onsite visit/audit is required to evaluate any significant change that a laboratory undergoes.

7.7. ensure LAS performs a biennial (every other year) re-assessment audit during which the laboratory must have a sample (i.e., appropriate matrix and condition that would be received from customer) ready to demonstrate its competency of performing the test method. Additionally, the laboratory must comply with requests for documents/records before and during the audit;

7.8. respond to each nonconformance found during an audit and documented in the audit report. The response must include an investigation and root cause analysis. Correction or corrective action must be planned and/or completed within 30 calendar days of receiving the report;

7.9. resolve each nonconformance in a timely manner, whether identified by a LAS auditor, another organization, or internally;

7.10. pay all program fees by the due date on the billing invoice.

8. Mandatory Quality Assurance Practices

The laboratory must implement quality assurance and quality control procedures to ensure a validated and qualified analysis, prove competence and ensure defensible data. LAS uses the ISO 17025 standard to evaluate all laboratory quality systems regardless of accreditation status. A nonconformance identified during a LAS assessment audit may be cited to the ISO 17025 standard.

8.1. The laboratory is required to maintain formal accreditation to the ISO 17025 standard granted by a third-party that is a member of the International Laboratory Accreditation Cooperation (ILAC). There is one type of *Trichinella spiralis* laboratory that is exempt from maintaining formal accreditation (see §15).

8.2. The laboratory must have each method approved under the LAP on their ISO 17025 scope of accreditation.

9. Determine analyte and testing limit requirement

The laboratory must be aware of their customer's destination market for the product tested to ensure appropriate testing requirements are met. Country specific export requirements are outlined in the FSIS Export Library, which is frequently updated. The laboratory may subscribe to the FSIS' email subscription service as an easy way to keep up with changes.

10. Method Selection

The laboratory is to use a method fit for purpose based upon the needs of the customer and consistent with specified requirements (see §13-15).

10.1. The method must be approved for use in the program by the PM.

10.2. The laboratory may request to employ screening methods where screening methods are exclusively distinct from confirmative methods. The approval for screening methods only will be clearly stated on the scope of approval.

10.3. If the laboratory only has screening methods on their scope of approval, they must have a documented plan for how results will be confirmed if requested by the customer.

10.4. The laboratory may sub-contract a confirmatory analysis to another laboratory if:

a) the sub-contracted laboratory is an approved laboratory in this Program; or

b) the contracting laboratory bears the cost of a LAS assessment of the sub-contracted laboratory's ability to meet the relevant program requirements.

11. Demonstration of Method Performance by Validation and Verification Evaluation

The laboratory must demonstrate it can competently and proficiently perform the selected method prior to using it for testing and reporting results. Method validation is the process of demonstrating that a method is suitable for its intended purpose, and method verification is the process of demonstrating a validated method can be performed to the same level of performance determined during the validation.

11.1. The method selected must be appropriately validated to define its performance characteristics. Methods, with collaborative studies, specifically those published by USDA FSIS, US FDA BAM, US FDA PAM, US EPA, and AOAC are considered validated methods. If used as written, covered by the original validation, no additional validation is needed. Usage of these methods need only be verified (see §11.3).

11.2. Changes to a method as written (e.g., different matrix, different analyte, etc.) must be validated and approved for use by the PM.

11.3. The laboratory must demonstrate its competency to perform the method prior to testing and reporting results by performing a method verification study.

11.4. The laboratory must perform method validations and verifications in accordance with their documented procedures to the extent necessary to meet the needs of the given application.

Note: It is recognized there are multiple ways to demonstrate competency of performing an analytical method; therefore, the LAP does not designate a specific protocol. See §5.7 for a selection of references recommended to aid development of a suitable procedure and test design.

11.5. The laboratory must record each method validation and verification in the form of an auditable data package. The package is to contain all pertinent information supporting the objective's conclusion and at a minimum, include the test procedure, relevant statistics (e.g., linearity, accuracy, precision, measurement uncertainty, etc.), and traceable data (raw and summarized).

11.6. The laboratory must keep the validation and verification data package readily available for as long as the method is utilized, plus three years past the date of last reported results.

12. Analyst Competency and Proficiency Testing (PT)

The laboratory must demonstrate analyst competency and laboratory analytical proficiency.

12.1. Analyst Competency

Each analyst responsible for performing the method(s) must participate in a competency evaluation, at least annually, and maintain satisfactory status.

12.2. Laboratory Analytical Proficiency

Use of PT programs from an ISO 17043 PT provider is preferred.

12.2.1. The laboratory must comply with their ISO 17025 accreditation body's requirements.

12.2.2. The laboratory must evaluate proficiency for each method at least annually.

12.2.3. If an ISO 17043 PT program is not used, the laboratory must document and implement a PT program to include:

a) comparison of results with other laboratories (inter-laboratory), where available; or

b) a defined program that uses an appropriate collection of data used to demonstrate process control and validity of results.

12.2.4. The laboratory must initiate and follow their corrective action process to perform an investigation, root cause analysis, and correction or corrective action within 30 days for each unsatisfactory result.

When Z scores are used in a report, unsatisfactory results and action to take are defined as follows:

$\|z\| \geq 3$	An immediate corrective action investigation on the part of the laboratory to establish root cause.
$2 \leq \|z\| \leq 3$	Evaluate the context of other scores obtained in the same test and other PTs over time. Investigated to determine the cause and take action as needed.

12.2.5. The laboratory must provide the PM:

a) documented proficiency program for review for initial approval or PT program change;

b) proficiency results (i.e. final report and laboratory identifier) within 30 days of receiving the report; and

c) record of an investigation, root cause analysis, and correction or corrective action planned and/or completed within 30 calendar days of receiving the report for each unsatisfactory result for review by PM.

13. Technical Requirements for Chemical Residues

This section covers specific requirements related to analysis of chemical residues in addition to the requirements described in §1-12. The chemical residue groups include: antibiotics (AB), beta agonists (BA), heavy metals (HM), pesticides (PC), resorcylic acid lactones (RC), and steroids (SR). Other residue groups may be considered if proscribed in the FSIS Export Library. Contact the PM for assistance with interpreting the analytical requirements listed in the FSIS Export Library.

13.1. Method Selection

The laboratory must have confirmatory methods on their scope of approval as chemistry residue results must be confirmed for reporting.

13.2. Quality Controls

The laboratory must utilize controls to demonstrate testing is performed correctly and factors that could negatively impact the results are mitigated. If any quality control does not perform as expected, immediate action must be taken prior to any samples being tested and/or sample results reported.

13.2.1. Method Quality Controls:

a) The laboratory must define and justify what constitutes a batch of samples.

b) The laboratory must include quality controls with each batch of samples.

c) The minimum quality controls required, but not limited to, matrix blank, matrix spike, reagent blank, calibration standard, and continuing calibration verification.

13.2.2. Quality Control Definitions:

LAS interpretation of each quality control and its purpose is defined. Note: It is not a requirement for the laboratory to use exactly the same terms for each type of control as long as they use the correct control for the correct purpose.

a) Matrix Blank (negative control): known reference material or sample previously determined to contain a known, negligible, amount of target analyte. Use to evaluate sample matrix interferences and confirm true negative.

b) Matrix Spike (positive control, fortified): matrix blank with known quantity of spiked analyte. This sample must go through the entire method. Use to evaluate recovery (extraction efficiency) at any quantifiable concentration, verify sensitivity using a concentration near the detection limit, accuracy, precision, and robustness of the method resulting from changes in sample matrix. (Note: The recovery of spiked analyte may not be equivalent to the recovery from naturally incurred analytes.)

c) Known Positive (positive control, incurred): sample that is known to be positive through prior analysis and confirmation.

d) Reagent Blank (negative control): sample made up of only the reagents used in testing the samples that goes through the entire procedure. Use to determine potential contamination within the process and to monitor instrument noise. A matrix blank may be used in lieu of a reagent blank.

e) Calibration Standard: analyte of known concentration used to establish a reference base to measure.

f) Continuing Calibration Verification (CCV): solution of known concentration, typically at or near the midpoint of the calibration curve. Use to monitor instrument stability throughout the sequence. At a minimum, a batch of samples must be bracketed between CCV samples. For each batch, the frequency of CCV usage throughout a batch must be defined, with a typical frequency of every 10 (± 2) injections.

g) Independent Calibration Verification (ICV): solution of known concentration that is from a different manufacturer, same manufacturer but different lot, separate preparation using same reference standards used to calibrate, preparation by different personnel, etc. Use to evaluate the accuracy of a reference material and/or accuracy of preparation techniques. It is a best practice to incorporate this control.

h) Internal Standard (IS): a chemical(s), different than analyte(s) of interest, added to every sample at the known concentration, at a specified stage, to facilitate quantitation. Use to monitor analyte signal variability throughout a batch to correct for matrix effects, incomplete spike recoveries, etc. Analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard should have a similar physio-chemical properties to those of the analyte of interest. Use deuterated standards where possible. It is a best practice to incorporate this control.

13.3. Quality Measures

The laboratory must evaluate the quality controls for acceptability of data, trends, and potential problems. If any of the quality controls do not perform as expected, immediate action must be taken prior to samples being tested and/or reported.

13.3.1. Quality measures that must be evaluated include, but not limited to, calibration curve, calibration stability, percent recovery (matrix spike), and control charting.

13.3.2. Calibration Curve: The calibration curve is to be made up of standards at various known concentrations to enable quantification of unknown samples.

a) The calibration solutions must be the same type as used to validate the method (e.g., solvent, matrix-matched, etc.).

b) The calibration curve (i.e., regression equation) must be the same type as used to validate the method.

c) The calibration range is to bracket the range of reported result and include the level of concern.

d) The calibration curve must have four or more non-zero concentrations. A non-linear curve must have five or more non-zero concentrations.

e) The R^2 must be equivalent to or better than the reference method. If the R^2 of the reference method is unattainable the attainable R^2 must be clearly documented in the procedure.

13.3.3. Calibration Stability: Use CCV data to evaluate instrument stability throughout the batch. The CCV data, expressed as percent recovery, must be within the set performance criteria defined in the method or qualified by the laboratory's quality control policies and procedures.

13.3.4. Percent Recovery (Matrix Spike): Compare expected concentration to measured concentration to evaluate extraction performance against defined performance criteria. The percent recovery must be within the set performance criteria defined in the method or qualified by the laboratory's quality control policies and procedures.

13.3.5. Control Charting. Track performance over time and serve as an indicator if something in the analytical process is out of control and needs investigation or correction.

a) Plot % recovery for each matrix spike analyzed. Plot for the method regardless of analyst or instrument used to evaluate overall performance of the method. Acceptable % recovery range is determined by method specific defined performance criteria. Investigate and take action as needed for each data point outside the acceptable range and per the laboratory's quality control policies and procedures.

Note: Additional, optional, control charting methods can be used to evaluate other variables of the testing procedure. For example, a plot by analyst evaluates an individual analyst's performance compared to other analysts. Or, a plot by instrument evaluates individual instrument performance, and can help identify instrument problems.

13.4. Official Certificate of Analysis/Report

13.4.1. The analytical report must meet the requirements of the customer.

13.4.2. Provide a limit of detection or quantification.

13.4.3. Specify if corrected or not corrected for recovery.

13.4.4. Specify the measurement uncertainty or indicate that it is available upon request.

14. Technical Requirements for Microorganisms

This section covers specific requirements related to analysis of microorganisms in addition to the requirements described in §1-12. The microorganism groups include: *Salmonella* (SLM), *Listeria monocytogenes* (LM), and Aerobic Plate Count (APC). Other microorganisms may be considered if proscribed in the FSIS Export Library. Contact the PM for assistance with interpreting the analytical requirements listed in the FSIS Export Library.

14.1. Method Selection

14.1.1. The laboratory may have screening methods, exclusively distinct from confirmative methods, on their scope of analysis.

14.1.2. The laboratory must clearly identify how it will address presumptive positive results (see §10).

14.1.3. If selecting an unvalidated method to test for pathogenic microorganisms, the validation must include a comparison against a reference cultural method. Cultural confirmation includes the use of biochemical and serological tests to verify proper detection of the organism.

14.2. Quality Controls

The laboratory must utilize quality controls to demonstrate testing is performed correctly and factors that could negatively impact the results are mitigated. If any quality control does not perform as expected, immediate action must be taken prior to any samples being tested and/or sample results reported.

14.2.1. Method Quality Controls:

a) The laboratory must define and justify what constitutes a batch of samples.

b) The laboratory must include quality controls with each batch of samples and be set up in the same manner.

b-1) Quantitative Methods: The minimum quality controls required, but not limited to are, Positive control or Matrix Spike, and a Sterility Control (medium/negative control).

b-2) Qualitative methods: The minimum quality controls required, but not limited to are, Positive control or Matrix Spike; and a Sterility Control (medium/negative control).

14.2.2. Environmental Monitoring Quality Controls:

a) The laboratory must perform environmental monitoring at a schedule determined by the laboratory and set up at the time of sample setup.

b) The minimum quality controls required, but not limited to are, Surface Swabbing and Air Quality Plate testing.

14.2.3. Quality Control Definitions:

LAS' interpretation of each quality control and its purpose is defined. Note: It is not a requirement for the laboratory to use exactly the same terms for each type of control as long as they use the correct control for the correct purpose.

a) Sterility Control (medium/negative control): an uninoculated medium used for the analysis to verify sterility of medium and consumables used.

b) Positive Control: medium inoculated with target control culture organism to ensure growth of organism. Inoculate at a low concentration for qualitative methods and a known concentration for quantitative methods in the countable range.

c) Matrix Blank: appropriate matrix that has been shown to be free of target pathogens for qualitative methods and have no or low levels of aerobic bacteria for quantitative methods.

d) Matrix Spike: Matrix Blank inoculated with control organism and prepared alongside samples being tested with the purpose of identifying possible interferences that may inhibit growth. Inoculate at a low concentration for qualitative methods and a known concentration for quantitative methods in the countable range.

e) Air Quality Plate: used to ensure the laboratory environment does not contain contaminants that would negatively impact the test, used alongside quantitative tests.

f) Surface Swabbing: used to validate laboratory surfaces are free of contamination of pathogens of interest.

14.3. Quality Measures

The laboratory must evaluate quality controls to identify acceptability of data, trends, and potential problems. If any quality controls do not perform as expected, immediate action must be taken prior to samples being tested and/or reported.

14.3.1. Medium, Reagents, and Commercial Test Kits

a) Chemicals, medium, immunoreagents, and commercial test kits must not be used past their expiry date without verification that they are still suitable for their intended purpose and use.

b) Each batch of medium must be tested for sterility and growth promotion/inhibition characteristics before use. A laboratory may be approved to verify suitability at time of use if the process, including how to handle nonconforming medium and when results can be reported, is clearly documented.

c) When pH is measured, record the final pH and traceability information for the measurement device and reagents used.

14.3.2. Microbiologically Suitable Water (MSW) requirements.

Only water free from traces of dissolved metal, bactericidal, and inhibitory compounds must be used to prepare culture medium, reagents, and dilution blanks. Inhibitor free water is referred to as microbiologically suitable water (MSW). The following verifications must be performed on the water source, at the frequency specified (at a minimum), to ensure that the water is inhibitor free. Records of must be kept.

a) Weekly (or prior to use): >2.0 MΩ-cm resistance at 25ºC, or <2.0 µS-cm conductivity at 25°C.

b) Monthly: Total Residual Chlorine must be < 0.1 mg/L and APC must be < 1,000 colony forming unit (cfu/mL).

c) Annually: Heavy Metals (Cd, Cr, Cu, Ni, Pb, and Zn-single) must be < 0.05 mg/L and Heavy Metals (total) must be < 0.10 mg/L.

14.4. Official Certificate of Analysis/Report

14.4.1. The analytical report must meet the requirements of the customer.

14.4.2. For unconfirmed positive result, report as “presumptive positive.”

14.4.3. For APC, if enumeration is less than countable range (cfu/g), report as less than the limit of the countable range.

15. Technical Requirements for Parasite (*Trichinella spiralis*)

This section covers specific requirements related to analysis of *Trichinella spiralis* (TS) in addition to the requirements described in §1-12.

15.1. Mandatory Quality Assurance Practices

15.1.1. An independent 3rd-party laboratory must maintain an ISO 17025 accreditation and have the approved method on their scope of accreditation.

15.1.2. A laboratory located onsite a slaughter facility with FSIS oversight is exempt from maintaining accreditation; however, they are expected to meet the general quality assurance requirements (see §8).

15.2. Method Selection

15.2.1. The approved method is "Magnetic stirrer method for pooled sample digestion" as given in Annex I – Chapter 1 of EC 2015/1375.

15.2.2. The laboratory must be capable of identifying 3 larvae per gram (LPG).

15.3. Documented Testing Procedure Requirements

The laboratory must have a documented procedure(s) describing how samples are handled from shipping to reporting results. The following must be specifically addressed:

15.3.1. Sample Handling: sample must not be subjected to freezing temperatures at any point (e.g., shipping, receipt, storage, etc.), and when shipped must be shipped for next day delivery.

15.3.2. Sample Identification: each individual sample must be uniquely identified, and each pooled sample must be uniquely identified.

15.3.3. Sample Preparation:

a) Meat sample must be ground to an appropriate size, similar to ground meat from the grocery store, but not to a milk shake or paste like consistency.

b) Meat sample must be at room temperature before addition to the digest solution.

15.3.4. Solution Preparation:

a) Pepsin must be added to a dilute HCl solution to prevent deactivation of the pepsin.

b) Pepsin activity must be verified for each lot when received, and yearly thereafter, to ensure sufficient digestion is achieved.

c) Digestion solution and digest meat ratio must be according to the method (at the ratio of 1:20, meat:solution).

d) After digestion, less than 5% meat must be remaining on the 180 µm sieve.

15.3.5. Digestion:

a) Ratio must be at least 1:20 meat:solution.

b) Temperature must be maintained between 44 – 46ºC the entire time.

c) Meat sample must be broken up and distributed evenly in the digestion solution.

d) Digestion time must be more than 30 minutes but less than 1 hour.

e) If meat is not digested during the 1-hour period, filter the sample through the sieve, collect the remaining undigested meat, and digest again with fresh digestion solution.

15.3.6. Washing: washing must be performed as many times as needed to have a clear enough solution to distinguish larvae under the microscope.

15.3.7. Equipment: appropriate equipment must be used, and performance must be verified at a specified frequency.

15.3.8. Records: records to maintain must include at least the sample identification, sample pool identification, solution preparation (e.g., lot numbers, weights, volumes, date prepared, analyst identification), temperature of digestion solution during digest, and equipment verification.

15.3.9. Reporting:

a) Results reported must include all information requested by the customer and necessary for the interpretation of the test results. For internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way.

b) The sample report must include at least:

b-1) Title;

b-2) Name and address of the laboratory where test was carried out;

b-3) Name and address of the customer;

b-4) Identification of the method used;

b-5) Sample identification;

b-6) Date of receipt, date of testing, date of issuing report;

b-7) Test results;

b-8) Identification of the person authorizing the test report.

c) Ensure positive samples are reported and additional appropriate notifications are made.

15.4. Demonstration of Method Performance by Validation and Verification Evaluation

15.4.1. The method verification must be performed by a Certified Analyst on staff.

15.4.2. The laboratory must record the method verification in the form of an auditable data package. The package must contain:

a) a copy of the laboratory's testing procedure(s);

b) record of sample receipt and identification;

c) record of chemicals used, and solutions prepared;

d) record of measurement equipment used (e.g., serial number);

e) record of reported results (i.e., test report).

15.5. Quality Measures

The laboratory must evaluate quality controls to identify acceptability of data, trends, and potential problems. If any quality controls do not perform as expected, immediate action must be taken prior to samples being tested and/or reported.

15.5.1. Critical Equipment

a) Balance: Balance must be accurate to at least 0.1 g. Performance must be verified daily, when in use with working weights that fall within the weight range used by the laboratory.

b) Reference Weight & Working Weights: Reference weighs must be verified every 5 years. Working weights must be verified against reference weights at least annually.

c) Thermometer: Thermometers must be accurate to 0.5ºC within the range of use. Performance must be verified at least annually; and verification at freezing and/or boiling points of water is acceptable.

d) Magnetic Hotplate Stirrers: The hotplate must be of sufficient size and heating capacity to maintain a stable temperature, within the targeted range, and maintain sufficient spinning of the stir bar, throughout the digestion.

e) A stereo-microscope: The microscope must have a light source of adjustable intensity and sufficient magnification to identify larvae.

f) Analytical wares: Analytical wares must be **GLASS** to prevent larvae from sticking to the surfaces and of sufficient size to accommodate the analytical step.

g) Petri dish (or equivalent): Must be marked to facilitate tracking areas checked under microscope.

15.5.2. Critical Reagents:

a) Store according to manufacturer's instructions.

b) Pepsin: ~1:10,000 activity. A potential source for pepsin at 1:10,000 activity, granular, is American Laboratories Incorporated, Omaha, NE. Pepsin must be stored in the dark.

c) Hydrochloric acid: at least reagent grade quality.

15.6. Analyst Certification

15.6.1. Analyst must complete AMS training course, including lecture (onsite) and laboratory elements, and successfully analyze a certification sample. Training provided by LAS occurs onsite at the laboratory, materials are provided, and includes an initial proficiency evaluation. Contact the PM to request training.

15.6.2. Analyst must be certified by LAS for the performance of the approved method used by the laboratory. Contact the PM to request analyst certification.

15.6.3. Certification must be maintained through periodic (i.e., quarterly) evaluation (see §12). A record of certification, and continued certification, is provided by the PM.

15.7. Proficiency Testing (PT)

15.7.1. The laboratory must participate in the USDA administered PT program. Contact the PM to request participation.

15.7.2. Analyst independently analyzes, and reports results for the sample set according to the instructions provided on the "Sample Set Results" for supplied with the sample set.

15.7.3. Evaluation:

a) For initial certification, if the first attempt is unsatisfactory, the analyst may have a second attempt. If the second attempt is satisfactory, the analyst is certified. If the second attempt is unsatisfactory, the analyst must undergo additional training and proficiency evaluation.

b) If a certified analyst reports unsatisfactory results, the analysts may make a second attempt. If second attempt is satisfactory, the analyst maintains certification. If the second attempt is unsatisfactory, the analyst is de-certified.

15.7.4. Laboratory performs investigation, root cause analysis, and correction or corrective action for unsatisfactory results.

15.8. Official Certificate of Analysis/Report

15.8.1. Reporting of results must satisfy the requirements specified in customer's requirements; and

15.8.2. Include the following information (ISO 17025:2017 § 7.8.2.1), unless the laboratory has a valid reason for not doing so:

a) a title (e.g., “Test Report”, “Certificate of Analysis”);

b) the name and address of the laboratory;

c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;

d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

e) the name and contact information of the customer;

f) identification of the method used;

g) a description, unambiguous identification, and, when necessary, the condition of the item;

h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;

i) the date(s) of performance of the laboratory activity;

j) the date of issue of the report;

k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;

l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;

m) the results with, where appropriate, the units of measurement;

n) additions to, deviations, or exclusions from the method;

o) identification of the person(s) authorizing the report;

p) clear identification when results are from external providers.

16. Revision History

New Rev.	Description of Change	Prepared by
03/27/14	Original	Program Manager
	Related to the Russia Export Library, section "Laboratory testing of meat for ractopamine", this program may be referred to as the "*AMS Laboratory Approval Program for Analysis of Beta Agonists.*" Related to the Russia Export Library, section "Laboratory Approval Program" this program may be referred to as "*AMS Laboratory Approval Program for Poultry Products Destined for Exportation from the United States to Russia.*"	
?	Related to the European Export Library page, the PFEU Program. *FSIS Guideline - Program for Certifying Pork Intended for Export to the EU*. FSIS refers to this program as "*Agricultural Marketing Service's European Meat Export Laboratory Program.*"	Program Manager
2015	Summary to Export Stakeholder Laboratories from Program Manager explaining the consolidation of four programs into one and expands the scope to include requirements for additional countries, specifically the European Union (EU). The single program is centered on specific analyses rather than a specific country so it can more efficiently address multiple-country requirements under on program instead of having a program for each country. The new program will require laboratories to be ISO 17025 accredited and will require onsite audits by LAS. These new requirements bring the program into alignment with international standards and foreign government requirements. Current laboratories that are not ISO 17025 accredited will be given time to come into compliance. On-site audits will be conducted every two years or as needed. 1. The Laboratory Verification Program for Pork to be exported to Russia 2. The laboratory Verification Program for Poultry to be exported to Russia 3. The Laboratory Approval Program for Beta Agonists 4. The Laboratory Approval Program for Trichinae Analysis and Analyst Certification.	Program Manager
12/20/16	Updated fees.	Program Manager
01/28/19	Updated document format, re-organized, and clarified requirements. Feedback from FSIS and laboratories was collected and evaluated during December 2019. §2: Clarified scope to define specific USDA programs the LAP supports, and scope of approval is by analyte and not by country. §3: Added table of contents §4: Added Glossary of terms §5: Reorganized references. Updated and removed outdated versions. §6: Moved all administrative procedures to the LAP-PR.05 document and all fee information to LAP-PR.06 document. §7: Updated summary §8: Added to clarify ISO 17025 and exception requirements. Added ILAC requirement for AB. §9: Added to clarify lab responsibility for understanding the analyte and performance specifications needed. §10: Clarified method selection, confirmation method, and sub-contracted analysis requirements. §11: Clarified method validation and verification requirements. §12: Clarified analyst competency and proficiency test requirements.	Lingsu Zhang, Program Manager Heath McClure, Microbiologist Grace Vaillant, Program Manager

New Rev.	Description of Change	Prepared by
	§13: Clarified technical requirements for chemical residue analysis for method selection, quality controls, quality measures, and reporting. Identification of specific analytes and detection limits were removed to allow for the frequent changes in the FSIS Export Library. §14: Clarified technical requirements for microbiological analysis for method selection, quality controls, quality measures, and reporting. §15: Clarified technical requirements for trichinae analysis for QA practices and exception, approved method, documented testing procedure requirements, method verification, quality measures, analyst certification, proficiency test program, and reporting.	

17. Review / Approvals

LINGSU ZHANG

Digitally signed by LINGSU ZHANG
Date: 2019.01.28 13:21:20 -05'00'

Program Manager - Export
(Review)

GRACE VAILLANT

Digitally signed by GRACE VAILLANT
Date: 2019.01.28 14:12:03 -05'00'

Branch Chief, LAS
(Approve)