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 (LAP-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

LAP-Export is for a laboratory seeking to obtain and maintain status as a USDA-approved laboratory for analysis of chemical residues, microorganisms, and parasites in meat and poultry products for FSIS export certification and FSIS residue monitoring programs. LAP-Export verifies technical and quality control competencies of a laboratory to meet the testing requirements laid out in the FSIS Export Library. All aspects of a laboratory's quality management system (business processes relative to the scope of approval) are applicable and are critical for ensuring the defensibility of the analytical results produced under the LAP.

2.1 Approval is granted for the 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 – Aerobic Plate Count (APC)

h) Microorganisms – *Listeria monocytogenes* (LM)

i) Microorganisms – *Salmonella* (SLM)

j) Parasite – *Trichinella spiralis* (TS)

k) Others – as added to the FSIS Export Library

2.2 Administration of the Program supports USDA Programs:

a) Export Verification Program for Pork to the Russian Federation: Administered by AMS for FSIS for approving companies as eligible suppliers of porcine meat and meat products complying with the requirements outlined in QAD1030V procedure. LAS approves laboratories to perform qualified analysis for the USDA Tetracycline Residue Testing Program and Microbiological Testing Program. See Annex §19.

b) EU Additional Residue Testing Program: Administered by FSIS as an official control for monitoring compliance of slaughter establishments approved for export of poultry, meat and/or offal to the EU to ensure the absence of regulated or prohibited chemical residues as laid out in Council Directive EC 96/23. LAS approves laboratories to perform qualified analysis. See Annex §16.

c) EU Animal Casing Residue Monitoring Program: Administered by FSIS for FDA as an official control for monitoring compliance of establishments approved to export animal casings into the EU to ensure absence of prohibited chemical residues listed in Table 2 of Regulation EU 37/2010. LAS approves laboratories to perform qualified analysis. See Annex §16.

d) Never Fed Beta Agonists Program: Administered by AMS for verifying and monitoring companies that request approval to claim (for marketing purposes) livestock and beef and pork products have never been fed beta agonist growth hormones. LAS maintains a list of suitable screening methods to use for verification testing and approves laboratories to perform qualified conformation analysis. See Annex§17 and §19.

e) Non-Hormone Treated Cattle to the European Union: Administered by AMS for FSIS for verifying slaughter establishments comply with the FSIS-Program for Certifying Non-Hormone Treated Cattle to the European Union. LAS approves laboratories to perform qualified analysis for the EU Additional Residue Testing Program. See Annex §16.

f) Pork for the European Union Program: Administered by AMS for FSIS for verifying slaughter establishments comply with the FSIS Guideline-Program for Certifying Pork Intended for Export to the European Union. LAS approves laboratories to perform qualified analysis for the EU Additional Residue Testing Program. See Annex §16.

g) Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork: Administered by FSIS for companies required to prevent *Trichinella* contamination in porcine meat and meat products. LAS administers the AMS Trichinae Analyst Program and Proficiency Test (PT) Program for laboratories to certify and be approved to perform qualified analysis. See Annex §16, §18, and §19.

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4 Glossary of Terms

APC	Aerobic Plate Count (i.e., Total Plate Count (TPC))
BA	Beta agonists
BAM	Bacteriological Analytical Manual, FDA
CCV	Continuing Calibration Verification
CLG	Chemistry Laboratory Guidebook, FSIS
CVM	Center for Veterinary Medicine, FDA
EC	European Commission
EU	European Union
EURL	European Union Reference Laboratories
EPA	Environmental Protection Agency, US
EV	Export Verification
FSIS	Food Safety Inspection Service
FDA	Food and Drug Administration
HM	Heavy Metals
ICV	Independent Calibration Verification
ILAC	International Laboratory Accreditation Cooperation
IPP	Inspection Program Personnel (FSIS)
ISTD	Internal Standard
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission.
LAP	Laboratory Approval Program
LAP-Export	LAP for Export of Meat and Poultry Products
LAS	Laboratory Approval Service
LATD	Laboratory Approval and Testing Division
LIB	Laboratory Information Bulletin, FDA
LM	*Listeria monocytogenes*
MLG	Microbiology Laboratory Guidebook, FSIS
MMRP	Minimum Method Performance Requirement
MSW	Microbiologically Suitable Water
PAM	Pesticide Analytical Manual, FDA
PC	Pesticides
PM	Program Manager
PT	Proficiency Test
RC	Resorcylic acid lactones
RPA	Reference Point of Action
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

5.1 The following are referenced in this document. Dated references apply to the edition cited and undated references apply to the latest edition published (including any amendments).

5.2 Laboratory Approval Program:

a) LAP-PR.05. Laboratory Approval Program – General Policies and Procedures.

b) LAP-PR.06. Laboratory Approval Program – Fees.

c) USDA AMS LATD LAS Website: https://www.ams.usda.gov/services/lab-testing/lab-approval.

5.3 Quality Assurance Standards:

a) ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories.

b) USDA AMS Laboratory Standards of Practice.

5.4 USDA Requirements:

a) USDA FSIS Export Library

5.5 Chemical Residue Methodology:

a) AOAC Official Methods of Analysis

b) USDA FSIS Chemistry Laboratory Guidebook (CLG)

c) US FDA Laboratory Information Bulletins (LIB)

d) US FDA Pesticide Analytical Manual (PAM)

e) US Environmental Protection Agency (EPA) Methods

5.6 Microbiology Methodology:

a) AOAC Official Methods of Analysis

b) USDA FSIS Microbiology Laboratory Guidebook (MLG)

c) US FDA Bacteriological Analytical Manual (BAM)

5.7 Trichinella Methodology:

a) 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.

b) Gajadhar, Alvin Al, Karsten Joeckler, Pascal Boireau, Patrizia Rossi, Brad Scandrett, and H. Ray Gamble. International Commission on *Trichinellosis*. Recommendations for quality assurance in digestion testing programs for *Trichinella.* Food and Waterborne Parasitology. 16 (2019) e00059.

5.8 European Regulations (Residue Control Programs):

a) EC 96/23. Council Directive (EC) 96/23 of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC.

b) EU 37/2010. Commission Regulation (EU) 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

c) EU 2019/1871. Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC.

d) EU 2021/808. Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC.

e) EURL Guidance on Minimum Method Performance Requirements (MMPRs) for Specific Pharmacologically Active Substance in Specific Animal Matrices. September 2020.

5.9 Additional Resources:

a) Eurachem Guides.

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

c) Guidelines for the Validation of Microbiological Methods for the FDA Foods Program, 3rd Edition. US FDA Foods Program Regulatory Science Steering Committee. October 17, 2019.

d) Guidelines for the Validation of Chemical Methods for the FDA Foods Program, 3rd Edition. US FDA Foods Program Regulatory Science Steering Committee. October 17, 2019.

e) Mass spectrometry for confirmation of the identity of animal drug residues. Guidance for Industry #118. Final Guidance. US FDA Center for Veterinary Medicine. May 1, 2003.

GENERAL REQUIREMENTS

6 Laboratory Approval Program Administrative Procedures

6.1 A laboratory seeking admission to the LAP must fulfill the requirements and follow the process described in the program 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, and appeals.

6.2 This program is administered on an annual, calendar year, basis.

6.3 The program procedure, *LAP-PR.06, Laboratory Approval Program – Fees*, explains the fees for service.

6.4 The administrative procedures are available on the LAS website or by contacting the LAP-Export Program Manager (PM) for the current version.

7 Summary of General Program Requirements

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

a) meet all program requirements relevant to the scope of approval;

b) comply with mandatory laboratory quality assurance practices based on the ISO 17025 standard (See §8);

c) use test method(s) approved by AMS (See §10);

d) validate / verify methods prior to use and ensure the validation / verification data package is available for review upon request (See §11);

e) evaluate analyst competency and maintain satisfactory status (See §12);

f) participate in PT programs and maintain satisfactory status (See §12);

g) 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 (See §5.2.a);

h) notify the PM within 30 days of significant changes relevant to the laboratory's approval status and/or ability to meet the Program's requirements including, but not limited to, legal, organizational, or ownership status; laboratory policies, procedures, and resources; change in key managerial personnel and contact persons; and validation / verification of adequate method performance after a significant change in method, equipment, facilities, working environment, or location. It is at the discretion of LAS

whether an onsite visit/audit is required to evaluate any significant change that a laboratory undergoes (See §5.2.a).

i) be available for a biennial (every other year) re-assessment audit, have actual sample(s) ready to demonstrate its competency of performing the test method, and comply with requests for documents and records before and during the audit (See §5.2.a);

j) respond to each nonconformance found with record of investigation, root cause analysis, and correction or, if warranted due to time, a corrective action plan within 30 calendar days of being reported (See §5.2.a);

k) resolve each nonconformance in a timely manner, whether identified by a LAS audit, another organization, or internally (See §5.2.a);

l) pay all program fees by the due date on the billing invoice (See §5.2.b).

8 Mandatory Quality Assurance Practices

8.1 Implement quality assurance and quality control procedures to ensure a validated and qualified analysis, prove competence and ensure defensible data.

8.2 Maintain formal accreditation to the ISO 17025 standard granted by a third-party that is a member of the International Laboratory Accreditation Cooperation (ILAC). See §15.2 for exception).

8.3 Maintain each method approved for the LAP on third-party accreditation scope of approval.

8.4 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 (See §5.2.a).

8.5 Maintain records for at least three years (See §5.2.a).

9 Country Specific Analyte and Testing Limit

9.1 Know customer's destination market for the product tested to ensure appropriate testing requirements are met.

9.2 Know where to access the country specific export requirements outlined in the FSIS Export Library (See §5.4.a).

9.3 Subscribe to the FSIS' email subscription service to keep up with changes at https://service.govdelivery.com/accounts/USFSIS/subscriber/new.

10 Method Selection

10.1 Use analytical testing methods approved by AMS.

10.2 Use method fit for purpose based upon the needs of the customer and consistent with specified requirements.

10.3 Use methods as validated; for the purposes of this Program, consider methods with collaborative studies, specifically those published by USDA FSIS, US FDA BAM, US FDA PAM, US EPA, and AOAC, as validated methods (See §5.5 and 5.6)

10.4 Refer to sections below for approved methods and other technical requirements:

a) Chemical residue (See §13)

b) Microorganisms (See §14)

c) Parasite (*Trichinella spiralis)* (See §15)

d) European Union (See §16)

e) China (See §17)

f) Argentina, Barbados, Chile, Peru, Singapore (See §18)

g) Russia & Belarus (See §19)

10.5 Request an exception, as needed, to use screening only methods by:

a) Submitting a request to and gaining approval from the PM,

b) Identifying how presumptive positive results are addressed,

c) Maintaining a documented plan for how results are confirmed if requested by the customer.

10.6 Use a subcontractor, as needed, by:

a) Selecting another approved laboratory in this Program; informing the PM of the selection; and ensuring certificate of analysis clearly identifies results from that subcontractor, or

b) Organizing and paying the fees for LAS to assess the subcontractor's ability to meet the relevant program requirements.

11 Demonstration of Method Performance by Validation and Verification Evaluation

11.1 Demonstrate the sample testing method(s) is competently and proficiently performed prior to using it for testing and reporting results by using a validation / verification process, where:

a) Validation is the process of demonstrating that a method is suitable for its intended purpose,

b) Verification is the process of demonstrating a validated method can be performed to the same level of performance determined during the validation, and

c) It is recognized there are multiple ways to demonstrate performance; therefore, the Program does not designate a specific protocol. See §5.9 for resources towards developing a suitable validation / verification plan.

11.2 Demonstrate that variations or modifications to a validated method (e.g., different matrix, different analyte, etc.) are fit-for-purpose.

11.3 Prepare a Method Validation Data Package to record that the procedure has been demonstrated as fit for use.

a) Consolidate pertinent information into an integrated and auditable data package to support the objective's conclusion that includes at least the following: a cover statement containing the conclusion of the validation / verification process, test method procedure, relevant statistics (e.g., linearity, accuracy, precision, measurement uncertainty, etc.), and traceable data (raw and summarized).

b) Send the validation / verification package to the PM for review and approval.

c) Ensure validation / verification data package is readily available at the laboratory for as long as the method is utilized, plus three years past the date of last reported results.

d) Ensure official record of approval for method is maintained and readily available.

12 Analyst Competency and Proficiency Testing

12.1 Analyst Competency

a) Ensure each key analyst responsible performing the method(s) participates in a competency evaluation, at least annually, and maintains satisfactory status.

12.2 Laboratory Analytical Proficiency:

a) Evaluate proficiency for each method at least annually.

b) Use PT program relevant to the approved method in terms of analyte, concentration range, and matrix on scope of approval—where possible from an ISO 17043 PT provider.

c) Document and implement a PT program to include comparison of results with other laboratories (inter-laboratory) and/or other analysts (intra-laboratory) where available; or a defined program that uses an appropriate collection of data used to demonstrate process control and validity of results when an appropriate ISO 17043 PT program is not available.

d) Review PT report and initiate the corrective action process when unsatisfactory results are observed. When Z scores are used, unsatisfactory results and actions to take are defined as follows:

$\|z\| \geq 3$	Initiate 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. Investigate to determine the cause and take action as needed.

12.3 Submit to the PM:

a) Documented proficiency program for review for initial approval.

b) Subsequent changes to the previous PT program(s).

c) Copy of PT report with analyst name, and PT identifier within 30 days of receipt.

d) Record of corrective action response for unsatisfactory results within 30 days of receiving the PT report.

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The following sections include requirements organized by scope; and are in addition to the requirements outlined above.

TECHNICAL REQUIREMENTS

13 Technical Requirements for Chemical Residues

13.1 This section covers requirements for analysis of chemical residues in addition to the requirements described in §6-12. The chemical residue groups include antibiotics (AB), beta agonists (BA), heavy metals (HM), pesticides (PC), resorcylic acid lactones (RC), and steroids (SR).

13.2 Method Selection:

a) Use confirmatory methods.

13.3 Quality Controls:

13.3.1 Use quality controls to demonstrate that testing is performed correctly and factors that could negatively impact the results are mitigated.

13.3.2 Take immediate action prior to continuing testing or reporting results when any quality control does not perform as expected.

13.3.3 Define and justify what constitutes a batch of samples.

13.3.4 Include quality controls with each batch of samples.

13.3.5 Include minimum quality controls of: Matrix Blank, Matrix Spike, Calibration Standard, and Continuing Calibration Verification. Include additional controls called for in the method, as applicable.

13.3.6 LAS interpretation of each quality control and its purpose is defined.

Note: It is not a requirement for the laboratory to use the same term for each type of control as long as the correct control is used for the correct purpose.

a) Reagent Blank: Sample containing only the reagents taken through the entire procedure. Use to determine absence of significant interference due to reagents or equipment used in the analysis. Use as a negative control. Optional if a matrix blank is used.

b) Matrix Blank: Substance that closely matches the samples being analyzed with regard to matrix components. Ideally, the matrix blank does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to test the samples. Use to determine the absence of significant interference due to matrix, reagents, and equipment used in the analysis.

c) Matrix Spike: Aliquot of a sample prepared by adding a known amount of analyte(s) to a specified amount of matrix and subjected to the entire analytical procedure. Use to establish if the method is appropriate for the analysis of a specific analyte(s) in a particular matrix. Also referred to as a Laboratory Fortified Matrix.

d) Incurred Sample: Sample that contains the analyte(s) of interest, which were not derived from laboratory fortification but from sources such as exogenous exposure or endogenous origin. Use as known positive.

e) Calibration Standard: Solution containing known amount or concentration of analyte. Without further indication, calibration standard(s) is usually prepared by adding the analyte(s) of interest in neat solvent/solution. A "matrix-matched calibration standard(s)" is prepared by adding analyte(s) of interest in matrix blank. Use to establish a reference for identification and/or quantification for measuring/detection system.

f) Continuing Calibration Verification (CCV): Solution of known concentration, typically at or near the midpoint of the calibration curve. Use to evaluate instrument stability throughout the sequence.

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

h) Internal Standard (ISTD): Chemical(s), different than analyte(s) of interest, added to every sample at the known concentration, at a specified stage, to facilitate quantitation. The chemical selected should have similar physio-chemical properties as those of the analyte of interest and, where possible, be isotopically labeled. Use to correct for matrix effects, incomplete spike recoveries, etc. Optional, however, it is a best practice to incorporate this control.

13.4 Quality Measures:

13.4.1 Evaluate quality controls to identify acceptability of data, trends, and potential problems.

13.4.2 Take immediate action prior to continuing testing and/or reporting results for any quality measure not performing as expected.

13.4.3 Evaluate quality measures including, but not limited to, calibration curve, calibration stability, spike recovery, and control charting.

13.4.4 Calibration Curve: Use to quantify concentration of unknown samples.

a) Use the same type of calibration solutions used for method validation (e.g., solvent, matrix-matched, etc.).

b) Use the same type of calibration curve (i.e., regression equation) used for method validation.

c) Ensure calibration range brackets the range of the result and includes the level of concern.

d) Ensure calibration curve contains four or more non-zero concentrations; and that a non-linear curve contains five or more non-zero concentrations.

e) Distribute the calibration points as to not bias the curve.

f) Ensure R^2 value is equivalent to or better than the reference method. If the R^2 of the reference method is unattainable then ensure the attainable R^2 is clearly documented in the procedure.

13.4.5 Calibration Stability: Use CCV data to evaluate instrument stability throughout the batch.

a) Collect CCV data points at a minimum, at the beginning of a batch, the end of the batch and throughout a batch with a typical frequency of every 10 (± 2) injections.

b) Calculate recovery of CCV data point.

c) Evaluate against the set performance criteria defined in the method.

13.4.6 Spike Recovery: Use to compare measured concentration to expected concentration to evaluate method performance against defined performance criteria.

a) Calculate recovery for the method as written. For example, if the method prescribes using deuterated internal standards or matrix-matched calibration standards, then the reported analyte recoveries should be calculated according to those procedures. Recovery is typically expressed as a percentage.

b) Evaluate recovery against the set performance criteria defined in the method or qualified by the laboratory's quality control policies and procedures.

13.4.7 Control Charting: Use to track performance over time and serve as an indicator if the analytical process is out of control and needs investigation or correction.

a) Plot recovery for each matrix spike analyzed.

b) Plot for the method regardless of analyst or instrument used.

c) Evaluate whether results are acceptable using defined method performance criteria.

13.4.8 Official Certificate of Analysis/Report:

a) Meet the specified requirements of the customer.

b) Provide a limit of detection or quantification.

c) Address correction for recovery.

d) Address measurement uncertainty.

e) Go to §16.6.1 for additional requirements for the EU Additional Residue Testing Program and the EU Animal Casing Residue Testing Program.

14 Technical Requirements for Microorganisms

14.1 This section covers requirements related to analysis of microorganisms in addition to the requirements described in §6-12. The microorganism groups include Aerobic Plate Count (APC), *Listeria monocytogenes* (LM), and *Salmonella* (SLM).

14.2 Method Selection:

a) Use confirmatory methods.

b) Request an exception, as needed, to use screening only methods (See §10.5).

14.3 Quality Controls:

14.3.1 Use controls to demonstrate testing is performed correctly and factors that could negatively impact the results are mitigated.

14.3.2 Take immediate action prior to continuing testing and or reporting results when any quality control does not perform as expected.

14.3.3 Define and justify what constitutes a batch of samples.

14.3.4 Include controls with each batch of samples and to be set up in the same manner as unknown samples.

14.3.5 Include at a minimum, a Matrix Spike or Positive Control and a Sterility Control (medium/negative control).

14.3.6 Include at a minimum, the environmental monitoring controls of Surface Swabbing and Air Quality Plate Testing at a defined schedule. Ensure they are set up at the time of sample setup.

14.3.7 LAS' interpretation of each quality control and its purpose is defined.

Note: It is not a requirement for the laboratory to use the same terms for each type of control as long as the correct control is used for the correct purpose.

a) Sterility Control (medium/negative control): Uninoculated medium. Use as a negative control to verify sterility of medium and consumables.

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

c) Matrix Spike: Aliquot of sample prepared by adding a known quantity of target analytes to a specified amount of matrix and subjected to the entire analytical procedure. Use to establish if the method or procedure is appropriate for the analysis of a specific analyte in a specific matrix.

d) Air Quality Plate: Uninoculated medium exposed to laboratory air. Use to ensure the laboratory environment does not contain contaminants that may negatively impact the test. Use alongside quantitative tests.

e) Surface Swabbing: Swab of laboratory surfaces. Use to verify laboratory surfaces are free of contamination of pathogens for interest.

14.4 Quality Measures:

14.4.1 Evaluate quality controls to identify acceptability of data, trends, and potential problems.

14.4.2 Take immediate action prior to continuing testing and/or reporting results when any quality measure does not perform as expected.

14.4.3 Ensure chemicals, medium, reagents, immunoreagents, and commercial test kits are not used past their expiry date without conducting a suitability verification for their intended purpose and use.

14.4.4 Ensure each batch of medium is tested for sterility and growth promotion / inhibition characteristics before use (preferable) or at time of use if the process is clearly documented, including how to handle nonconforming medium and when results can be reported.

14.4.5 Record the final pH and identifying information for the measurement device and reagents used where pH is a critical factor to method performance.

14.5 Official Certificate of Analysis/Report

a) Meet the specified requirements of the customer.

b) Report an unconfirmed positive result as “presumptive positive.”

c) Report an APC result as “less than the limit of the countable range (cfu/g)” when enumeration of colonies falls below the minimum countable range.

15 Technical Requirements for Parasite (Trichinella spiralis)

15.1 This section covers requirements related to analysis of *Trichinella spiralis* (TS) in addition to the requirements described in §6-12.

15.2 Mandatory Quality Assurance Practices:

a) Independent 3rd-party laboratory: Maintain an ISO 17025 accreditation and have the approved method on scope of accreditation (See §8).

b) Onsite laboratory at slaughter facility with FSIS oversight: Comply with the general quality assurance requirements (See §8).

15.3 Method Selection:

a) Use "Magnetic stirrer method for pooled sample digestion" as given in Annex I – Chapter 1 of EC 2015/1375 (See §5.7.a).

b) Ensure capability to identify 3 larvae per gram (LPG).

15.4 Method Validation / Verification:

15.4.1 Maintain a documented procedure(s) describing how samples are handled from shipping to reporting results. Specifically address the following:

a) Sample Handling: Do not subject to freezing temperature. When shipped, use next day delivery.

b) Sample Identification: Uniquely identify each sample and each pooled sample.

c) Sample Preparation: Grind meat to size similar to that at the grocery, but not to a milk shake or paste like consistency; bring to room temperature before adding to the pepsin digest solution.

d) Solution Preparation: Make pepsin digestion solution by adding pepsin to a dilute HCl solution to prevent deactivation of the pepsin.

e) Digestion: (1) Digest meat at ratio of approximately 1 g meat to 20 mL digestion solution; (2) Maintain temperature between 44 – 46 ºC; (3) Ensure even distribution of meat in digestion solution; (4) Digest for more than 30 minutes but less than 1 hour; (5) if all meat is not digested during the 1-hour period, filter the sample through the 180 µm sieve to collect the undigested meat and when the remaining meat is more than about 5% of the original sample wash the remaining meat into a new aliquot of digestion solution and repeat the digestion; (6) combine all portions of digestate together for next steps.

f) Washing: Wash as many times as needed to obtain a solution clear enough to identify larvae under the microscope.

g) Equipment: Use appropriate equipment; verify equipment performance at a specified frequency.

h) Records: Maintain records including, but not limited to, 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.

i) Reporting: Provide instructions for data to include in the report (See §15.8) and for addressing notifications required for positive samples.

15.4.2 Ensure method verification is performed by a Certified Analyst on staff.

15.4.3 Record the method verification in the form of an auditable data package including, but not limited to:

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) (See §11.3).

15.5 Critical Equipment:

15.5.1 Balance:

a) Use balance accurate to at least 0.1 g.

b) Verify daily, when in use, with weights that bracket the mass measured.

15.5.2 Weights:

a) Verify working weights against reference weights annually.

b) Verify reference weights every 5 years.

15.5.3 Thermometer:

a) Use thermometer accurate to 0.5 ºC.

b) Verify performance at least annually (e.g., 0 ºC and 100 ºC).

15.5.4 Magnetic Hotplate Stirrers: Use hotplate of sufficient size and heating capacity to maintain stable temperature and spinning of the stir bar.

15.5.5 Stereomicroscope: Use microscope having a light source of adjustable intensity and sufficient magnification to identify larvae.

15.5.6 Analytical wares: Use **GLASS** analytical wares, to prevent larvae from sticking to the surfaces, of sufficient size to accommodate the analytical step.

15.5.7 Petri dish (or equivalent): Use dish with markings to facilitate tracking of areas checked under microscope.

15.6 Critical Reagents:

a) Store according to manufacturer's instructions.

b) Use pepsin with ~1:10,000 activity and store in the dark. Verify activity for each lot when received, and yearly thereafter, to ensure sufficient digestion can be achieved.

c) Use hydrochloric acid, at least reagent grade quality.

15.7 Analyst Certification & Proficiency Testing

a) Ensure analyst performing analysis is certified by LAS.

b) Obtain analyst certification from AMS by completing the AMS training course (onsite lecture and hands-on laboratory elements) and demonstrating successful analysis of a certification sample (contact the PM).

c) Maintain analyst certification through periodic (i.e., quarterly) evaluation by participating in the USDA Administered PT program where:

Pass = initial certification is granted; certification is maintained

1st Fail = option to make a second attempt; option to discontinue initial certification / recertification process

2nd Fail = initial certification not granted; certification revoked

d) Maintain record of continued certification (provided by the PM).

15.8 Official Certificate of Analysis/Report

15.8.1 Meet specified requirements of the customer.

15.8.2 Include the following on the test report:

a) Title;

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

c) Name and contact information of the customer;

d) Identification of the method used;

e) Description, unambiguous identification of the item;

f) Date of receipt of the test item;

g) Date(s) of testing;

h) Date of issue the report;

i) Identification of the person(s) authorizing the report;

Laboratory Approval Program - Export

ANNEX

The following sections are a consolidation of the country specific export testing requirements laid out in the FSIS Export Library, USDA Export Verification Programs, and other references.

This is a tool intended to help the laboratory understand the full range of testing and reporting requirements. It is organized with the focus being the laboratory user and Program Administrators.

The information as presented does not supersede or change what is stated in the cited references. If there is a difference between this document and the reference, the reference guidance takes precedence.

Contact the Program Manager for guidance regarding how these requirements are administered.

16 Testing Requirements for European Union

16.1 Apply the requirements in this section in addition to those outlined in §6-12 as applicable to the scope of approval.

16.2 Review the testing requirements outlined in the FSIS Export Library for the European Union.

16.3 Testing Requirement for EU Additional Residue Testing Program:

a) Administered by FSIS for compliance with regulation EC 96/23 (See §5.8.a).

b) Applies to species: bovine, porcine, turkey, and wild boar.

c) Applies to matrices: kidney, kidney fat, muscle, and urine.

d) Applies to chemical residues in Table 16.3-1:

Table 16.3-1. Testing Requirements for the EU Additional Residue Testing Program, for European Union, for bovine, porcine, turkey, and wild boar.

Group	Analyte*	Species	Matrix	Method of Analysis	Action Level (ng/g)
SR	Melengestrol acetate (MGA)	Bovine	Kidney fat	LC-MS/MS	5
	17α-trenbolone acetate 17β-trenbolone acetate	Bovine Porcine	Urine	LC-MS/MS	0.5
RC	Zeranol Taleranol Zearalenone Zearalanone α-zearalenol β-zearalenol	Bovine Porcine	Urine	GC/MS	0.5
BA	Ractopamine	Bovine Porcine Turkey	Muscle	LC-MS/MS	0.1
HM	Cadmium	Bovine Porcine Wild Boar	Muscle	ICP-MS	10 (Cd)
	Lead		Kidney		30 (Pb)
* FSIS Export Library - European Union: Other Requirements, VI. Residue Testing, D. Table 3: EU Analytes and Methods.					

16.4 Testing Requirement for Trichinae:

a) Administered for compliance with regulation EU 2015/1375 (See §5.7.a).

b) Applies to species: domestic porcine and wild boar.

c) Applies to matrices: meat, meat products, and meat preparations containing porcine meat.

d) Applies to the parasite *Trichinae spiralis* (TS).

e) Go to §15 for technical requirements for analysis of Trichinae.

16.5 Testing Requirement for EU Animal Casings Residue Monitoring Program:

a) Administered by FSIS for FDA for compliance with Council Directive EC 96/23 (See §5.8.a).

b) Applies to species: bovine, porcine, and ovine.

c) Applies to matrices: casings (if treated with dry salt), casings (if treated with brine), and brine (with traceability to casings)

d) Applies to chemical residues in Table 16.5-1:

Table 16.5-1. Testing Requirements for EU Animal Casings Residue Testing Program, for European Union, for animal casings and brine.

Group	Analyte	Species	Method of Analysis	Action Level (ng/g)
	Nitromidazoles and the 5-hydroxy-metabolites			
AB	Dimetridazole*	Bovine Porcine Ovine	LC-MS/MS	1.0**
	Dimetridazole-OH			1.0**
	Metronidazole*			1.0**
	Metronidazole-OH			1.0**
	Ipronidazole			1.0**
	Ipronidazole-OH			1.0**
	Ronidazole*			1.0**
	Nitrofuran metabolites			
AB	Furazolidone: amino-oxazolidinone (AOZ)*	Bovine Porcine Ovine	LC-MS/MS	0.5***
	Furaltadone: 3-amino-5-morpholinomethyl-2-oxazolidinone (AMOZ)			0.5***
	Nitrofurazone: semicarbazide (SEM)			0.5***
	Nitrofurantoin: aminohydantoin (AHD)			0.5***
	Other			
AB	chloramphenicol*	Bovine Porcine Ovine	LC-MS/MS	0.15***

* EU 37/2010, Annex II
** EURL Guidance on Minimum Method Performance Requirements (MMPRs) for Specific Pharmacologically Active Substance in Specific Animal Matrices, September 2020.
*** EU 2019/1871, Reference point for action (RPA)

16.6 Official Certificate of Analysis / Report

16.6.1 EU Animal Casing Residue Monitoring Program and EU Additional Residue Testing Program

a) Submit records of sample analysis in a timely manner to allow U.S. regulatory enforcement actions to be taken.

b) Submit records of sample analysis to USDA in the format requested, to:

1. FSIS Office of International Coordination (internationalcoordination@usda.gov),
2. FSIS Inspection Program Personnel (IPP), and
3. LATD (LAS@usda.gov)

c) Submit records of sample analysis to FDA in the format requested to: FDA Center for Food Safety and Applied Nutrition, Office of International Engagement (FDA-CFSAN-International-Engagement@fda.hhs.gov)

d) Submit records of sample analysis upon request to support the U.S. government annual report to EU. Note: this request may come directly from FSIS.

17 Testing Requirements for China

17.1 Apply the requirements in this section in addition to those outlined in §6-12; as applicable to the scope of approval.

17.2 Review the testing requirements outlined in the FSIS Export Library for China.

17.3 Testing Requirement for Ractopamine Residue Program:

a) Applies to species: porcine.

b) Applies to matrices: muscle, liver, or kidney.

c) Applies to chemical residues in Table 17.3-1:

Table 17.3-1. Testing Requirements for chemical residues, for China, for porcine.

Group	Analyte	Species	Matrix	Method of Analysis	Action Level (ng/g)*
BA	Ractopamine	Porcine	Muscle	LC-MS/MS	0.1
			Kidney or Liver	LC-MS/MS	0.1
* Action level is unspecified for China; therefore, for the Program the action level listed is based on requirements for the approved ractopamine screening kits on the Business Listing of USDA-Approved Methods for Export; and the confirmation requirement for Russia.					

18 Testing Requirements for Argentina, Barbados, Chile, Peru, Singapore

18.1 Apply the requirements in this section in addition to those outlined in §6-12; as applicable to the scope of approval.

18.2 Review the testing requirements outlined in the FSIS Export Library for applicable country: Argentina, Barbados, Chile, Peru, or Singapore.

18.3 Testing requirement:

a) Applies to species: domestic porcine.

b) Applies to matrices:

Argentina - fresh/frozen pork and pork products

Barbados - fresh/frozen and cooked pork and pork products

Chile - pork and pork products

Peru - pork and pork products

Singapore - pork and pork products

c) Applies to the parasite *Trichinae spiralis* (TS).

d) Go to §15 for technical requirements for analysis of Trichinae.

19 Testing Requirements for Belarus & Russia

19.1 Apply the requirements in this section in addition to those outlined in §6-12 as applicable to the scope of approval.

19.2 Review the testing requirements outlined in the FSIS Export Library applicable country: Russia or Belarus.

19.3 Testing Requirement for Poultry:

a) Applies to species: poultry.

b) Applies to matrices: muscle.

c) Applies to chemical residues and microorganisms in Table 19.3-1:

Table 19.3-1. Testing Requirements for chemical residues and microorganisms, for Russia and Belarus, for poultry and turkey.

Group	Analyte	Species	Method of Analysis	Action Level (ng/g)
	Chemical Residues (basic)			
HM	Lead	Poultry Turkey	Various	0.5*
	Arsenic			0.1*
	Organic arsenicals			0.5*
	Cadmium			0.05*
	Mercury			0.03*
PC	HCH (α, β, γ – isomers)	Poultry Turkey	Various	0.1*
	DDT and its metabolites			0.1*
	Dioxins			0.000002 (in fat)*
AB	Chloramphenicol	Poultry Turkey	Various	Not allowed, < 0.0003*
	Tetracycline group			Not allowed, < 0.01*
	Bacitracin			Not allowed, < 0.02*
BA	Ractopamine	Turkey	LC-MS/MS	0.1
	Chemical Residues (Additional)**			
AB	Chloramphenicol	Poultry Turkey	LC-MS/MS	0.1
	Bacitracin			0.28
	Virginiamycin			0.2
	Bambermycin (Flavomycin)			0.2
	Ceftiofur			-
	Enrofloxacin			0.3
	Erythromycin			0.125
	Gentamicin			0.1
	Sulfadiamethoxine			0.1
	Sulfaquinoxzlone			0.1
	Penicillin			0.1
	Tylosin			0.05

Group	Analyte	Species	Method of Analysis	Action Level (ng/g)
	Neomycin			0.2
	Lincomycin			0.5
	Spectinomycin			0.1
	Streptomycin			0.1
	Microorganisms**			
SLM	*Salmonella*	Poultry Turkey	Confirmatory	Negative
LM	*Listeria monocytogenes*			Negative
APC	Aerobic plate count			less than 10^5 CFU/g
* Customs Union Decision 299 ** FSIS Export Library – Russia: K. Laboratory Testing of poultry meat, 6. Laboratory Approval Program *** Sample size for microorganism testing is 25 grams from deep muscle tissue.				

19.4 Testing Requirement for Pork and Pork Products:

a) Applies to species: porcine.

b) Applies to matrices: muscle.

c) Applies to chemical residues in Table 19.4-1, AMS Tetracycline Residue Program in Table 19.4-2, and Microbiological Testing Program in Table 19.4-3.

Table 19.4-1. Testing Requirements for chemical residues, for Russia and Belarus, for pork and pork products.

Group	Analyte	Species	Method of Analysis	Action Level (ng/g)*
BA	Ractopamine	Porcine	LC-MS/MS	0.1
* FSIS Export Library – Russia: Other Requirements. Q. Laboratory testing of pork and pork products for ractopamine.				

Table 19.4-2. Testing Requirements for the AMS Tetracycline Residue Program, for Russia and Belarus, for pork and pork products.

Group	Analysis*	Species	Method of Analysis	Action Level (ng/g)
AB	Chlortetracycline Tetracycline Oxytetracycline	Porcine	LC-MS/MS	10
* USDA Program for Pork to the Russian Federation, QAD 1030V. *USDA Export Verification (EV) Program: Specified Product Requirements for Pork to the Russian Federation.*				

Table 19.4-3. Testing Requirements for the Microbiological Testing Program, for Russia and Belarus, for pork and pork products.

Group	Analysis*, **	Species	Method of Analysis	Action Level
SLM	*Salmonella*	Porcine	Confirmatory	Negative
LM	*Listeria monocytogenes*			Negative
APC	Aerobic plate count			less than 10^5 cfu/g
* USDA Program for Pork to the Russian Federation, QAD 1030V. *USDA Export Verification (EV) Program: Specified Product Requirements for Pork to the Russian Federation.* ** Sample size for microorganism testing is 25 grams from deep muscle tissue; and if deep muscle tissue is unavailable for sampling, a sample must be taken and test conducted on available product, regardless of form.				

20 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. §13: Clarified technical requirements for chemical residue analysis for method selection, quality controls, quality measures, and reporting. Identification of specific	Lingsu Zhang, Program Manager Heath McClure, Microbiologist Grace Vaillant, Branch Chief

New Rev.	Description of Change	Prepared by
	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.	
08/15/22	Program expanded to include testing requirements for the EU Animal Casing Residue Monitoring Program, re-organized content, re-structured sentences to begin with action word, added consolidated country specific testing requirements. Other changes include: §1-2: Reorganized information between the two sections to better fit the section objectives. §2: Placed 'Analyte groups' before information about 'USDA Programs'. Added 'Others – as added to the FSIS Export Library' to the analyte group list to eliminate a redundancy elsewhere in the document. Removed '9 CFR 149' because it was removed from the CFR. Updated and expanded description of USDA export programs. §3: Added an additional section level. Added Tables. §4: Added EC, EURL, EV, IPP, Lap-Export, MMRP, RPA; removed CFR, edited IS to ISTD. §5: Removed ISO 17025:2005 and ITC. Added USDA LAS webpage, Gajadhar et. al., EU 37/2010EU 2019/1871, EU 2021/808, EURL. Updated versions. §8: Added record retention requirement from LAP-PR.05. §10: Added references for sections to go to for analyte and country specific requirements. §13: Adjusted quality control definitions to better align with FDA definitions. Changed 'Percent Recovery (Matrix Spike)' to 'Spike Recovery'. Added citation for reporting requirements for EU Additional Residue Testing Program and EU Animal Casing Residue Testing Program. §14: Consolidated required quality controls for quantitative and qualitative methods. Aligned definitions with FDA definitions. Removed Microbiologically Suitable Water requirement. §15: Edited to be more concise, Removed outdated ISO 17025:2005 report requirements Annex: New §16-19: New	Grace Vaillant Branch Chief

21 Review / Approvals

Lingsu Zhang
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Grace Vaillant
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