Laboratory Approval Program for Trichinae Analysis and Analyst Certification

1. Purpose

This document provides the requirements for the Laboratory Approval Program (LAP) for Trichinae Analysis and Analyst Certification Program. This LAP is for laboratories seeking to perform confirmatory analysis of *Trichinella spiralis* in pork which is offered for certification by USDA Food Safety and Inspection Service (FSIS) for export to Chile, European Union, Russia, and Singapore. It also provides the procedures and requirements used for the objective evaluation of a laboratory's analysis program submitted for approval and monitored by the Agricultural Marketing Service (AMS), Science and Technology (S&T) Program, Laboratory Approval and Testing Division (LATD), Laboratory Approval Service (LAS).

2. Scope

This LAP may be used by laboratories that submit their analysis program to LAS for approval, verification, and monitoring. It is limited to the analysis of *Trichinella spiralis* in pork and all aspects of a laboratory's documented quality management system that apply to this analysis.

3. References

3.1 The certification process is designed to conform to the requirements of the EU using the requirements published in the Official Journal of the European Communities, No. L 26/67-77 and No. L 167/34-43. Council Directive 77/96 EEC, dated December 21, 1976.

3.2 Commission Directive of June 7, 1984 amending the Annexes to "Council Directive 77/96/EEC addresses the examination for trichinae (*Trichinella spiralis*) prior to importation from third countries of fresh meat derived from domestic swine."

3.3 On December 2, 1994, the Council Directive 77/96/EEC was amended a third time, and the changes published in the Official Journal of the European Communities, No. L 315/18-20.

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

4. Laboratory Approval Procedures

4.1 Initial Request for Admission: A laboratory seeking approval must send an email/letter to the Program Manager (PM) requesting admission to the program at the following address:

Program Manager – LAP Trichinae Analysis and Analyst Certification
Laboratory Approval & Testing Division
USDA, AMS, S&T
1400 Independence Ave. SW, Room 3533-S
Washington, D.C. 20250-0272
Telephone: (202) 690-0621
Email: LAS@ams.usda.gov

4.2 Submission of Required Information: After providing the initial request for admission into the program, the applicant laboratory must address all program requirements; including fees (see Section 10). The following requirements must be provided to the PM for review:

4.2.1 A signed statement from the Laboratory Director stating that the laboratory will analyze samples using only the methods accepted by AMS.

4.2.2 The laboratory must be located on-site where the product is produced.

4.2.3 Proficiency test (PT) results – When required, laboratories must participate in an external PT program, obtain a satisfactory status, and send the PT reports to the PM.

4.2.4 The program is user-fee supported and all laboratories must pay annual program fees upon receipt of the billing invoice. All fees must be received prior to admission to the program.

4.3 Review of Information Submitted: The PM will review the required information and communicate any concerns or deficiencies. Laboratories must respond, in writing, to the concern or deficiency.

4.4 Analyst Training Course: All analysts must be trained in an AMS sponsored training course, which is held quarterly January-December.

4.4.1 The training course consists of both lecture (including test method) and laboratory.

4.4.2 Upon completion of the training, the analysts must successfully analyze an initial or second set of proficiency check samples in his/her own laboratory to complete his/her certification.

NOTE: The yearly fee covers the training of two analysts each year and quarterly proficiency check samples for all trained analysts up to four per laboratory. If the company has not trained two people during the fee year, the retraining of an analyst can replace one new analyst training slot.

4.5 Issuance of Certificate/Acceptance Letter: AMS will provide a certificate and/or a letter of approval to the laboratory after it meets all program requirements. All certificates should be retained as proof of full accreditation.

5. Maintaining Program Status

5.1 The LAP is managed on a yearly basis (January – December).

5.2 The laboratory must participate in quarterly proficiency check sample programs and meet a satisfactory status.

5.2.1 At quarterly intervals during the year, each analyst will receive six (6) proficiency check samples, which must be analyzed correctly.

5.2.1.1 The samples are prepared and shipped by the technical advisor. Results are sent to the technical advisor for evaluation.

5.2.1.2 If the samples are correctly analyzed, the analysts will receive a letter stating that he/she is retained in the program.

5.2.1.3 If the samples are not correctly analyzed, the technical advisor will ship a second set of samples.

5.2.1.3.1 If this second set is correctly analyzed, the analyst will receive a letter stating that the original set was not analyzed correctly, but the second set was analyzed correctly, and the analyst is retained in the program.
5.2.1.3.2 If both sets of samples (original and the second set) are not correctly analyzed, the analyst will be decertified and denied entry into the program.

5.3 The company/establishment and laboratory must conform to the Council Directive 77/96/EEC of 21 December 1976 on the examination of *Trichinae* (*Trichinella Spiralis*) upon importation from third countries of fresh meat derived from domestic seine.

5.4 The laboratory must inform PM if its approved equipment/methods have been modified. The laboratory must perform method verification study again with acceptable results.

5.5 Upon analyst changes, the laboratory must inform PM. The new analyst must participate in the AMS sponsored training course, see Section 4.4.

5.6 The laboratory must meet all program requirements. PT results **must be made available to PM upon request**.

5.7 The laboratory must pass announced or unannounced yearly onsite audit.
5.7.1 Each laboratory will be visited yearly by the LAS auditor and all aspects of the analysis reviewed.
5.7.2 A written report on the observations made will be sent to the laboratory and to the Food Safety and Inspection Service (FSIS) Deputy Administrator for International Programs.
5.7.3 Laboratory personnel will make any changes or correct any nonconformity listed in the report, and reports those changes to the PM within 30 days of receipt of the report.
5.7.4 Each responsible person described above will be notified in writing when a laboratory complies with recommended changes to comply with program requirements.

5.8 The laboratory must pay the program fee on time.

5.9 At any time, if there is concern about a laboratory's ability to meet program requirements, AMS may conduct an onsite audit of the laboratory, at the laboratory's expense.

6. Removal from the Program

6.1 Voluntary Removal: A laboratory may voluntarily remove itself from the program at any time by submitting a written request to the PM.

6.2 Involuntary Removal: A laboratory may be involuntarily removed from the approval program with any one of the following reasons, but not limited to:
6.2.1 Falsification of analytical results.
6.2.2 Failure to use methods and procedures approved by AMS.
6.2.3 Failure to meet analytical requirements.
6.2.4 Failure to correctly analyze quarterly proficiency check samples, the analyst is decertified.

6.2.4.1 A letter will be sent to the owner or manager of the plant/laboratory explaining that the analyst must be retrained before being reinstated in the program. *[**Note**: 1) In general, it is of more value for the PM to travel to the laboratory in question for analyst retraining since PM can observe any activities or procedures that may be causing problems. 2) To provide time for this retraining to take place, a temporary certificate may be issued to the analyst, not to exceed 3 months, so that the running of the plant is not unduly disrupted.]*

6.2.4.2 The analyst may fulfill the retraining requirement by attending the analyst training course, see Section 4.4.

6.2.4.3 After retraining, the analyst will receive proficiency check samples for analysis. If these samples (the first or second sets) are correctly analyzed the analyst will receive a new certificate with a new effective date. If the second set is not analyzed correctly, the analyst will not be recertified.

6.3 It is the responsibility of the FSIS Inspector-In-Charge (IIC) for exported products to determine that the tests are being done to his/her satisfaction.

6.3.1 If the FSIS, IIC has proof that the samples are not being run, or believes that the analyst's work is not reliable enough for him/her to accept the laboratory reports, then it is the IIC's duty to bring the problem to the attention of the FSIS, area supervisor.

6.3.2 The area supervisor may then write a letter to the certification LAP PM and request that the analyst be removed from the program.

6.3.3 The LAP PM will immediately do so, and send letters attesting to this to the plant owner, analyst, and Deputy Administrator for International Programs, FSIS. The analyst will not be permitted back into the program.

***NOTE**: The yearly program fee will not be refunded (whole or prorated), regardless of voluntary removal or involuntary removal.*

7. Readmission to the Program

7.1 A laboratory removed from the program due to falsification of analytical results will be prohibited to reapply.

7.2 A laboratory removed from the program due to failure of analytical requirements must wait, at least six months before it can re-submit a written request to the PM in order to initiate the admission process again.

8. Complaints

All complaints should be brought to the attention of the PM for timely resolution. If the complaint cannot be resolved by the PM to the satisfaction of the complainant, the complaint may be brought to the attention of the Director of the LATD. The contact information for the current Director is as follows:

Kerry R. Smith, Ph.D., Director
Laboratory Approval & Testing Division
USDA, AMS, Science and Technology

1400 Independence Ave. SW, Room 3533-S
Washington, D.C. 20250-0272
Telephone: (202) 690-4089
Email: KerryR.Smith@ams.usda.gov

9. Appeals

9.1 A laboratory that has been involuntarily removed from the program may file a written appeal to the Deputy Administrator of the S&T Program with supporting evidence as to why the laboratory should not be removed from the program. Within 30 days of receipt of the written appeal, the Deputy Administrator shall make a determination and take an action, as deemed appropriate, with respect to the removal. The name, address, and telephone number of the current Deputy Administrator are as follows:

Ruihong Guo, Ph.D., Deputy Administrator
USDA, AMS, Science and Technology
1400 Independence Ave. SW, Room 3543-S
Washington, D.C. 20250-0270
Telephone: (202) 720-8556
Email: Ruihong.Guo@ams.usda.gov

9.2 If the appeal to the Deputy Administrator of the S&T Program cannot be resolved to the satisfaction of a laboratory, an appeal, in writing, may be filed with the Administrator of AMS. Within 90 days of receipt of the written appeal with supporting evidences, the Administrator shall make a determination and take an action, as deemed appropriate, with respect to the removal. The name, address, and telephone number of the current Administrator are as follows:

Anne Alonzo, Administrator
USDA, Agricultural Marketing Service
1400 Independence Ave. SW, Room 3071-S
Washington, D.C. 20250-0201
Telephone: (202) 720-4276

10. Fee Schedule

10.1 LATD sets the program fee for each program based on administrative costs. Program fees are reviewed yearly to determine if they are adequate compared with USDA operational costs.

10.2 The fee for certification is $8,300.00 yearly.

10.3 If a company desires the training of additional analysts or retraining of an analyst (more than the two provided for by the yearly fee); there is an additional charge of $700.00 per trainee.

10.4 The yearly fee is nonrefundable.

11. Technical Requirements

11.1 Test Method

11.1.1 The following acid digestion methods have been accepted into this program:

- Magnetic Stirrer Method for Pooled Sample Digestion (Magnetic Stirrer method) and
- Mechanically Assisted Pooled Sample Digestion Method, Sedimentation Technique (Stomacher method)

11.2 The laboratory has to choose one of the methods, above, to conduct the analysis. *[**Note**: The Magnetic Stirrer method is included in the Trichinella Analyst Training Manual, which is provided in the training session.]*

NOTE: *Trichinella spiralis is a human pathogen that can cause serious disease when ingested. The dose that is commonly thought to cause clinical disease is reported as several hundred parasites. However, as few as two parasites can cause a sub-clinical infection. Laboratory personnel may be exposed to large numbers of Trichinella when performing analysis for this program. Each analyst has been made aware during training of the necessity of safe handling of these parasites.*