Animal Food Regulatory Program Standards

U.S. Department of Health and Human Services
Food and Drug
Administration Office of
Regulatory Affairs

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OMB Control No. 0910-0760
Expiration Date: XX-XX-XXXX

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Background

In the U.S., federal, state, local, tribal, and territorial (SLTT) regulatory agencies ensure the safety of ANIMAL FOOD. The Food and Drug Administration (FDA) and state PROGRAMS are responsible for ensuring that ANIMAL FOOD moving within their jurisdiction is safe, wholesome, and/or labeled properly. These responsibilities can include conducting inspections and regulatory activities that help ensure ANIMAL FOOD manufactured, processed, packaged, held, and distributed within their jurisdictions are safe and in compliance with applicable laws and regulations. State PROGRAMS primarily perform inspections under their own regulatory authority. Some state PROGRAMS conduct inspections of ANIMAL FOOD establishments under contract with FDA. Because jurisdictions may overlap, FDA and state PROGRAMS collaborate and share resources to protect ANIMAL FOOD. To better facilitate a partnership among regulatory authorities, state PROGRAMS should achieve IMPLEMENTATION with the Animal Food Regulatory Program Standards (AFRPS).

The implementation of seamless partnerships between FDA and SLTTs enable programs with comparable regulatory public health systems, as trusted partners, to rely on, coordinate with, and leverage one another's work, data, and actions to meet the public health goal of a safe national food supply. The FDA and the Association of American Feed Control Officials (AAFCO) are members of the Partnership of Food Protection (PFP). The vision for an Integrated Food Safety System (IFSS) was developed in 2009[1]. One of the foundational principles of an IFSS is the IMPLEMENTATION and uniform application of model standards so that federal and SLTT regulatory agencies conduct regulatory activities under the same set of standards. Prior to 2010, the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the Manufactured Food Regulatory Program Standards (MFRPS) were examples of such model standards. However, the VNRFRPS and MFRPS were developed for human food only and did not apply to ANIMAL FOOD. As further development on the IFSS progressed, there was a recognized need to develop standards for ANIMAL FOOD state PROGRAMS. One of the key recommendations that came from the 2010 50-State workshop ("A United Approach to Public Health") was the development of standards for ANIMAL FOOD state PROGRAMS. Standards provide a consistent, underlying foundation that is critical for uniformity across federal and SLTT agencies to ensure the credibility of all programs under an IFSS.

The Food Safety Modernization Act (FSMA) provides further support for developing AFRPS. FSMA was signed into law in January 2011 and calls for enhanced partnerships and integration with federal and SLTT agencies. The mutual reliance called for by FSMA will allow FDA to leverage capacity, inspections, and data collected by other agencies to support regulatory activities and further enhance the idea of an IFSS.

In 2011, FDA and AAFCO entered into a partnership to develop the AFRPS and was initially launched in January 2014. These standards are designed to promote uniformity and consistency among ANIMAL FOOD state PROGRAMS. This is consistent with the principles of the FSMA and the fundamental goal of AAFCO and FDA to provide a mechanism for developing and implementing uniform and equitable statutes, regulations, and standards to enhance the protection of the nation's ANIMAL FOOD supply.

[1] Link to the current PFP vision documents available at https://www.pfp-ifss.org/about/pfp-vision1/.

Introduction

The AFRPS establishes a uniform foundation for the design and management of state PROGRAMS responsible for the regulation of ANIMAL FOOD. Through IMPLEMENTATION of the AFRPS, a state PROGRAM is able to achieve and maintain programmatic improvements that help ensure the safety and integrity of the U.S. ANIMAL FOOD supply. IMPLEMENTATION of the AFRPS is voluntary. A state PROGRAM'S IMPLEMENTATION of the AFRPS helps ensure a uniform and consistent approach to ANIMAL FOOD regulation among jurisdictions including the sharing of information and the coordination of resources.

The AFRPS is composed of eleven standards that serve as an objective framework to evaluate and improve components of a state PROGRAM. The standards cover the state PROGRAM'S REGULATORY FOUNDATION, training program, inspection program, auditing program, ANIMAL FOOD-related
illnesses or death and emergency response, compliance and enforcement program, outreach program, planning and resources, laboratory services, sampling program, and assessment and improvement of standard IMPLEMENTATION.

Each standard is laid out in the following format to ensure uniformity: Purpose (x.1), Requirement Summary (x.2), Program Elements (x.3), Outcome (x.4), and Documentation (x.5). The program elements describe the best practices of a high-quality state PROGRAM. Required program elements and documentation requirements for IMPLEMENTATION are found in the Program Elements (x.3) and Documentation (x.5) sections for each standard. Terms in all capital letters correspond to a defined term in the Definition section of the document. The term "should" is used sometimes in the AFRPS. Program elements and corresponding conditions described as "should" are best practices but are optional and not required to IMPLEMENT a standard. To IMPLEMENT the AFRPS, the state PROGRAM must IMPLEMENT all eleven standards. "Notes" are used sometimes to provide clarification, alternatives, and guidance that the state PROGRAM may use to help IMPLEMENT the AFRPS. "Notes" do not contain program elements and thus will not be subject to an FDA verification assessment.

Each standard has appendices designed to assist the state PROGRAM in achieving and maintaining IMPLEMENTATION. State PROGRAMS are not obligated to use the appendices provided in the AFRPS. Other manual or electronic generated forms, worksheets, and templates may be used if all program elements are present.

Each standard has a corresponding self-assessment worksheet (Appendix x.1). The state PROGRAM uses the self-assessment worksheets to determine if the program elements are, or remain, fully met, partially met, or not met. The self-assessment worksheets are used to develop a strategic improvement plan for IMPLEMENTATION of standards.

The state PROGRAM maintains CURRENT AND FIT-FOR-USE documents required in the standards to verify IMPLEMENTATION for the purposes of a verification assessment. The AFRPS is not intended to address the performance appraisal processes that an agency may use to evaluate individual employee performance.

FDA uses the AFRPS as a tool to promote and verify the development of a high-quality ANIMAL FOOD regulatory PROGRAM, which includes a process for continuous improvement based upon quality management systems. The AFRPS assists both FDA and the states in fulfilling their regulatory obligations. State PROGRAMS enrolled in the AFRPS under an FDA funding vehicle are expected to develop and IMPLEMENT a strategic improvement plan to demonstrate that they are moving toward IMPLEMENTATION and to participate in FDA assessments. State PROGRAMS are encouraged to build systems that are sustainable and IMPLEMENT plans that result in the standards being maintained.

The collection of information is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The OMB control number is 0910-0760.

Definitions

Animal Food: Used to represent the definitions for: (1) food and animal feed in the Federal Food, Drug, and Cosmetic Act (FD&C Act) sections 201(f) and 201(w), (2) for animal food in Title 21 of the Code of Federal Regulations (CFR) section 507.3 (21 CFR 507.3), and (3) for animal feed in the AAFCO Official Publication (AAFCO OP).

Contact Hour: One CONTACT HOUR equals 60 minutes.

Corrective Action: Action to correct a DEVIATION from the program elements of a standard.

Current and Fit-for-Use: "Current" indicates that documentation is signed and dated in accordance with state PROGRAM procedures that meet criteria in the most current standard. "Fit-for-use" is a quality term used to indicate that a product or service fits the customer's defined purpose for that product or service. Documentation may be electronic or hard copy.

Curriculum: A plan which includes documented specific coursework and field training for both inspection and sample collection.

Deviation: Non-fulfillment of a program element.

Document Control: Ensures that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

Emergency: An unforeseen or sudden occurrence requiring immediate action to protect against substantial risk to animal and/or public health, and that involves the safety, efficacy, and security of the ANIMAL FOOD supply.

Enforcement Strategy: Plans of action designed to prioritize and achieve enforcement goals and are developed by the state PROGRAM based on critical and chronic violations and violators and contain guidelines for selecting enforcement tools.

Equivalent: State law directly references the relevant FD&C Act provision or federal regulation.

Equivalent in Effect: State law has the same regulatory effect as the relevant FD&C Act provision or federal regulation.

Implement/Implementation: Means a state PROGRAM has a particular program element, system, or program as required in the Program Elements and Documentation sections of the AFRPS; and can demonstrate the use of that particular program element, system, or program.

Joint Field Training Inspection: An inspection conducted jointly by the FDA and/or state personnel for the purposes of training or enforcement. A joint inspection may be used to provide training during an inspection of an establishment which may either be trainer led or trainee led.

No Authority: Responsibility for enforcing a relevant FD&C Act provision or federal regulation lies with another program or agency and not the state PROGRAM. There is such a state law, but it does not apply to the state's PROGRAM.

Not Equivalent: There is no state law EQUIVALENT to the relevant FD&C Act provision or federal regulation, or the federal and state laws address the same matter but are inconsistent and do not have the same regulatory effect.

Outreach Activity: A spontaneous or planned activity where the state PROGRAM provides materials or information that relates to ANIMAL FOOD topics to industry stakeholders, academia, other regulators, or consumers. Materials or information may include but is not limited to brochures, pamphlets, printed materials, websites, or other items.

Outreach Event: An OUTREACH EVENT which the state PROGRAM hosts, co-hosts, or is an invited presenter such as seminars, workshops, conferences, trainings, or meetings that relate to ANIMAL FOOD topics and that support communication and information exchange among industry stakeholders, academia, other regulators, or consumers.

Preventive Action: Action to prevent the recurrence of a DEVIATION requiring a CORRECTIVE ACTION.

Program: An operational unit in a regulatory agency that is responsible for the regulatory oversight of ANIMAL FOOD.

Qualified Field Inspection Auditor: An individual who is recognized by the state's PROGRAM as having field experience and communication skills necessary to audit inspectors/investigators.

Qualified Field Inspection Trainer: An individual who is recognized by the state's PROGRAM as having field experience and communication skills necessary to train inspectors/investigators.

Regulatory Foundation: The statutes, regulations, rules, ordinances, or other regulatory requirements that govern the operation of an ANIMAL FOOD establishment.

Regulatory Testing Laboratory: A laboratory that conducts measurements and analyses on food or ANIMAL FOOD and associated physical samples, which result in qualitative or quantitative analytical findings that may be used as a basis for regulatory action.

Sample Analysis Schedule: A schedule of analyses based on the sampling plan developed in cooperation with the REGULATORY TESTING LABORATORY performing routine services to ensure compatibility with REGULATORY TESTING LABORATORY capabilities and capacities.

Start Date: Date employee is hired or reassigned in or into the ANIMAL FOOD state PROGRAM as the beginning date for training timelines.

STANDARD 1
Regulatory Foundation

1.1 Purpose

This standard describes the program elements used by a state PROGRAM to effectively evaluate and review the REGULATORY FOUNDATION to regulate ANIMAL FOOD.

1.2 Requirement Summary

The state PROGRAM establishes an evaluation of its legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect samples, and take regulatory actions under state law to ensure the safety and security of ANIMAL FOOD.

This includes an evaluation of how the state's legal authority and regulatory provisions correspond to the sections of the FD&C Act and CFR specified in Appendix 1.2.

1.3 Program Elements

1.3.1 Evaluation of Legal Authority

The state PROGRAM conducts an evaluation to determine whether the state's legal authority and regulatory provisions are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to the specified sections of the current FD&C Act and CFR Title 21, and completes Appendix 1.2, or an equivalent form.

Note: In conducting such an evaluation, the state PROGRAM should consult with its legal counsel when state law or regulation does not provide for incorporation of subsequent revisions of the FD&C Act and CFR, the revision date of the CFR is unknown, or the federal law or regulation is partially written into state law or regulation.

1.3.2 Regulatory Foundation Evaluation

The state PROGRAM has a procedure that includes:

1.3.2.1 Reviewing the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:

1.3.2.1.1 Apply to the regulation of ANIMAL FOOD.
1.3.2.1.2 Delegate authority to the state agency.
1.3.2.1.3 Describe the state agency's administrative procedure for establishing its authority and incorporating rules by reference.

1.3.2.2 Timeframe for the review.

1.4 Outcome

The state PROGRAM utilizes the evaluation its REGULATORY FOUNDATION to protect animal and public health by ensuring the safety and security of ANIMAL FOOD.

1.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

1.5.1 Appendix 1.1: Self-Assessment Worksheet.

1.5.2 Appendix 1.2: Regulatory Foundation Worksheet.

1.5.3 Procedure for reviewing appropriate statutes, regulations, rules, ordinances, and other prevailing regulatory requirements.

1.5.4 The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of ANIMAL FOOD, (2) delegate authority to the state agency, and (3) describe the state agency's administrative procedure for establishing its authority and incorporating rules by reference.

STANDARD 2
Training Program

2.1 Purpose

This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD training program.

2.2 Requirement Summary

The state PROGRAM establishes a training program that ensures that all inspectors complete coursework, field training, and continuing education to effectively perform their assignments and responsibilities.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The state PROGRAM has a documented training plan that includes training and continuing education, as defined by the state PROGRAM, that includes:

2.3.1.1.1 Description of each inspection type.
2.3.1.1.2 CURRICULUM for each inspection type.

2.3.1.2 For inspectors with greater than five years of experience at the date of the initial self-assessment or at the inspectors START DATE, where their training documentation is not available, the state PROGRAM:

2.3.1.2.1 Documents an evaluation of the inspector's performance and experience to determine if additional training is needed.
2.3.1.2.2 Maintains proper supporting documents to verify successful completion of the requirement, if previous coursework is completed before the inspectors START DATE and utilized to meet coursework requirements.

2.3.1.3 The state PROGRAM maintains records documenting the training completed by all inspectors on Appendix 2.2, or an equivalent form.

2.3.2 Basic ANIMAL FOOD Inspector Training

2.3.2.1 Timeframe

The state PROGRAM requires a basic inspector to successfully complete the basic coursework within 24 months from the START DATE.

2.3.2.2 Coursework

Basic inspector training consists of basic coursework in the following subject areas:

2.3.2.2.1 Animal and Public Health Principles
2.3.2.2.2 Animal Food Defense
2.3.2.2.3 Basic Animal Nutrition
2.3.2.2.4 Basic Ingredients, Processing, and Technology

2.3.2.2.5 Basic National Incident Management System and Incident Command System (ICS)
2.3.2.2.6 Communication
2.3.2.2.7 Current Statutes, Regulations, and Policies
2.3.2.2.8 Inspections, Compliance, and Enforcement
2.3.2.2.9 Labeling
2.3.2.2.10 Professionalism
2.3.2.2.11 Risk Awareness
2.3.2.2.12 Safety
2.3.2.2.13 Sample Collection

2.3.2.3 Field Training

The state PROGRAM requires basic field training to complement the basic coursework. The basic field training specifies the following:

2.3.2.3.1 The procedure for JOINT FIELD TRAINING INSPECTIONS.
2.3.2.3.2 The number of JOINT FIELD TRAINING INSPECTIONS that are conducted in establishments that represent the state PROGRAM inventory and the type of basic work that will be performed by the inspector.
2.3.2.3.3 List the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS on Appendix 2.3, or an equivalent form.
2.3.2.3.4 The QUALIFIED FIELD INSPECTION TRAINER verifies the field training checklist of competencies in the field for each inspection type.
2.3.2.3.5 The inspector completes the minimum basic field training requirements for the inspection type, prior to performing independent work.

2.3.3 Advanced ANIMAL FOOD Inspector Training

2.3.3.1 Timeframe

The state PROGRAM requires an advanced inspector to successfully complete the advanced coursework within 60 months from the START DATE.

2.3.3.2 Coursework

Advanced inspector training consists of advanced coursework in the following subject areas but not limited to:

2.3.3.2.1 Advanced Ingredients, Processing, and Technology
2.3.3.2.2 Advanced Inspections, Compliance and Enforcement
2.3.3.2.3 Advanced Labeling
2.3.3.2.4 Animal Illness and Death Investigation
2.3.3.2.5 Current Statutes, Regulations, and Policies
2.3.3.2.6 Epidemiology
2.3.3.2.7 Microbiological Pathogens

2.3.3.2.8 Traceback and Traceforward Investigations

2.3.3.3 Field Training

The state PROGRAM requires advanced field training to complement the advanced coursework. The advanced field training specifies the following:

2.3.3.3.1 The procedure for JOINT FIELD TRAINING INSPECTIONS.
2.3.3.3.2 The number of JOINT FIELD TRAINING INSPECTIONS that are conducted in establishments that represent the state PROGRAM inventory and the type of advanced work that will be performed by the inspector.
2.3.3.3.3 List the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS on Appendix 2.3, or an equivalent form.
2.3.3.3.4 The QUALIFIED FIELD INSPECTION TRAINER verifies the field training checklist of competencies in the field for each inspection type.
2.3.3.3.5 The inspector completes the minimum advanced field training for the inspection type, prior to performing independent work.

2.3.4 Continuing Education

The state PROGRAM requires that each basic and advanced inspector participate in continuing education. The continuing education specifies the following:

2.3.4.1 Each inspector receives 20 CONTACT HOURS of continuing education every 36 months.
2.3.4.2 The 36-month continuing education interval starts, as defined by the state PROGRAM, when the required CURRICULUM is complete.
2.3.4.3 Documentation accompanies each activity submitted for continuing education.

2.4 Outcome

The state PROGRAM utilizes the training program to ensure inspectors have the knowledge, skills, and abilities to effectively inspect ANIMAL FOOD establishments, conduct investigations, gather evidence, collect samples, and take enforcement actions.

2.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

2.5.1 Appendix 2.1: Self-Assessment Worksheet.
2.5.2 Training Plan.
2.5.3 Appendix 2.2: Inspector Training Record.
2.5.4 Appendix 2.3: Field Training Competencies.
2.5.5 Documents verifying successful completion of required coursework.
2.5.6 Documentation for continuing education.

STANDARD 3
Inspection Program

3.1 Purpose

This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD inspection program.

3.2 Requirement Summary

The state PROGRAM establishes a risk-based inspection program to determine compliance with ANIMAL FOOD laws. This includes procedures to handle recalls, consumer complaints, and complaints resulting from state PROGRAM inspection activities.

3.3 Program Elements

3.3.1 Risk-Based Inspection Program

3.3.1.1 The state PROGRAM has a procedure to define and maintain a current inventory of ANIMAL FOOD establishments whose activities fall under the state PROGRAM'S jurisdiction and authority.

3.3.1.2 The state PROGRAM has a procedure for risk categorization of ANIMAL FOOD establishments using the three minimum required factors for defining risk categories:

3.3.1.2.1 Types of ANIMAL FOOD and ANIMAL FOOD products.
3.3.1.2.2 Types of processing.
3.3.1.2.3 Compliance history of the establishment.

3.3.1.3 Based on risk categorization of an ANIMAL FOOD establishment, inspections are:

3.3.1.3.1 Prioritized.
3.3.1.3.2 Assigned frequencies.
3.3.1.3.3 Allocated resources.

3.3.2 Inspection Procedure

The state PROGRAM has procedures for inspecting ANIMAL FOOD establishments that require the inspectors to:

3.3.2.1 Review the ANIMAL FOOD establishment's history and determine the scope of the inspection.
3.3.2.2 Present appropriate credentials and written Notice of Inspection to the ANIMAL FOOD establishment's owner, operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; confirm inspection authority and establish FDA jurisdiction, if applicable.
3.3.2.3 Follow the safety protocols required by the ANIMAL FOOD establishment and the state PROGRAM.

3.3.2.4 Follow the biosecurity protocols required by the ANIMAL FOOD establishment and the state PROGRAM.
3.3.2.5 Use appropriate equipment and forms needed to conduct inspections.
3.3.2.6 Recognize the relative risk categorization of the ANIMAL FOOD establishment based on the risk-based inspection program.
3.3.2.7 Conduct comprehensive inspection activities, appropriate for the level of risk, focused on the establishment's products and processes determined to be of higher risk.
3.3.2.8 Assess employee activities critical to the safe manufacturing, processing, packaging, handling, holding, and distribution of ANIMAL FOOD.
3.3.2.9 Properly evaluate the potential that conditions, practices, processes, components, or labeling could cause the product to become adulterated, contaminated, or misbranded.
3.3.2.10 Recognize significant non-compliant conditions or practices and document findings consistent with state PROGRAM procedure.
3.3.2.11 Distinguish between significant and insignificant observations and isolated incidents versus trends.
3.3.2.12 Review, evaluate, and verify that the appropriate ANIMAL FOOD establishment records, plans, programs, and/or procedures are established, maintained, and/or implemented.
3.3.2.13 Collect adequate evidence and documentation to support inspection observations in accordance with state PROGRAM procedures.
3.3.2.14 Verify deficiencies identified during the previous inspections have been addressed.
3.3.2.15 Conduct activities in a professional manner.
3.3.2.16 Use effective interviewing techniques.
3.3.2.17 Explain findings clearly and adequately throughout the inspection.
3.3.2.18 Alert the ANIMAL FOOD establishment's owner, operator, or agent in charge when an immediate corrective action is necessary.
3.3.2.19 Document findings accurately, clearly, legibly, and concisely on the applicable forms and provide a copy to the ANIMAL FOOD establishment's owner, operator, or agent in charge.
3.3.2.20 Answer questions and provide information as appropriate.
3.3.2.21 Submit inspection report, samples where applicable, and supporting evidence and documentation within designated timeframes consistent with state PROGRAM procedure.

3.3.3 Recall System

The state PROGRAM has procedures to handle recalls that includes:

3.3.3.1 Receiving
3.3.3.2 Tracking
3.3.3.3 Evaluating recall notifications
3.3.3.4 Closing
3.3.3.5 Maintaining records
3.3.3.6 Performing recall effectiveness checks, as applicable

3.3.4 Consumer Complaints

The state PROGRAM has a procedure to handle consumer complaints that includes:

3.3.4.1 Receiving
3.3.4.2 Tracking
3.3.4.3 Evaluating
3.3.4.4 Answering
3.3.4.5 Closing
3.3.4.6 Maintaining records

3.3.5 Complaints Resulting from State PROGRAM Inspection Activities

The state PROGRAM has a procedure to handle industry complaints resulting from state PROGRAM inspection activities that includes:

3.3.5.1 Receiving
3.3.5.2 Evaluating
3.3.5.3 Maintaining records

3.4 Outcome

The state PROGRAM utilizes the risk-based ANIMAL FOOD inspection program to significantly minimize or prevent the occurrence of ANIMAL FOOD adulteration, contamination, and misbranding.

3.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

3.5.1 Appendix 3.1: Self-Assessment Worksheet.
3.5.2 An inventory of ANIMAL FOOD establishments.
3.5.3 Procedure for defining and maintaining the state PROGRAM'S current inventory of ANIMAL FOOD establishments.
3.5.4 Procedure for categorizing ANIMAL FOOD establishments based on risk, including the inspection frequency assigned to each defined risk-based category.
3.5.5 Procedures for inspecting ANIMAL FOOD establishments.
3.5.6 Procedures for recall system.
3.5.7 Procedure for consumer complaints.
3.5.8 Procedure for industry complaints about state PROGRAM inspection activities.

STANDARD 4
Audit Program

4.1 Purpose

This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD audit program.

4.2 Requirement Summary

The state PROGRAM establishes an audit program to document and evaluate the effectiveness of the state PROGRAM'S inspections and sample collections. This includes two components: (1) a field audit component, which is an on-site performance evaluation of inspection and sample collection procedures and (2) a report audit component, which is a performance evaluation of the inspection and sample collection reports, to verify they are consistently performed according to established performance factors.

4.3 Program Elements

4.3.1 Audit Program

The state PROGRAM has procedures for conducting four types of audits:

4.3.1.1 Field inspection audits as described in 4.3.3
4.3.1.2 Field inspection report audits as described in 4.3.4
4.3.1.3 Sample collection audits as described in 4.3.5
4.3.1.4 Sample collection report audits as described in 4.3.6

Note: In general, each type of audit is composed of multiple performance factors. The performance factors are evaluated during an audit and then used to calculate an individual's audit score. The audit score determines the audit rating, which is recorded as "acceptable" or "needs improvement". Using the individual audits, the state PROGRAM calculates a performance factor score for each performance factor and a cumulative score for each type of audit. The state PROGRAM uses the audit scores, performance factor scores, and calculated scores to recognize trends in the field inspection and sample collection programs. The trends are used to identify specific areas that need improvement and to take CORRECTIVE ACTION to improve areas.

4.3.2 Audit Program Review

The state PROGRAM conducts a review of the performance factor scores and cumulative scores for each of the four types of audits at least every 12 months.

4.3.3 Field Inspection Audit

The state PROGRAM conducts field inspection audits using a QUALIFIED FIELD INSPECTION AUDITOR to verify that inspections are consistently performed according to the state's PROGRAM procedures.

4.3.3.1 Frequency

4.3.3.1.1 Conduct a minimum of two field inspection audits of each inspector every 36 months.

4.3.3.1.2 Select field inspections for audits that reflect the inspector's assignments and responsibilities.

4.3.3.2 Performance Factors

Evaluate performance factors listed in the inspection procedure as described in 3.3.2 and as listed in Appendix 4.2, or an equivalent form.

4.3.3.3 Performance Documentation

4.3.3.3.1 Record the rating of each performance factor, audit score, and audit rating for each field inspection audit on Appendix 4.2, or an equivalent form. State PROGRAMS may use the current Appendix C found in FMD-76 in lieu of Appendix 4.2.

4.3.3.3.2 Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.3, or an equivalent worksheet.

4.3.4 Field Inspection Report Audit

The state PROGRAM conducts field inspection report audits to verify that inspectional findings are consistently reported according to the state PROGRAM'S procedures.

4.3.4.1 Frequency

Review a random selection of field inspection reports to be audited based on the number of inspections completed in 12 months of performance using Table 1.

Table 1 Field Inspection Report Audit Requirements

# of Inspections in 12 Months	Min # Reports Required	Max # Reports Required
Less than 20 reports	All	All
20 – 400 reports	20	20
More than 400 reports	5% reports	50

4.3.4.2 Performance Factors

Evaluate the performance factors listed in Appendix 4.4, or an equivalent form.

4.3.4.3 Performance Documentation

4.3.4.3.1 Record the rating of each performance factor, audit score, and audit rating for each inspection report audit on Appendix 4.4, or an equivalent form.

4.3.4.3.2 Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.5, or an equivalent worksheet.

4.3.5 Sample Collection Audit

The state PROGRAM conducts sample collection audits using a QUALIFIED FIELD INSPECTION AUDITOR to verify that sample collections are consistently performed according to the state PROGRAM'S procedures.

4.3.5.1 Frequency

4.3.5.1.1 Conduct a minimum of two sample collection audits of each inspector every 36 months.

4.3.5.1.2 Select sample collections for audits that reflect the inspector's assignments and responsibilities.

4.3.5.2 Performance Factors

Evaluate the performance factors listed in the sample collection procedure as described in 11.3.2 and as listed in Appendix 4.6, or an equivalent form.

4.3.5.3 Performance Documentation

4.3.5.3.1 Record the rating of each performance factor, audit score, and audit rating for each sample collection audit on Appendix 4.6, or an equivalent form.

4.3.5.3.2 Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.7, or an equivalent worksheet.

4.3.6 Sample Collection Report Audit

The state PROGRAM conducts sample collection report audits to verify that sample collection documentation is consistently performed according to the state PROGRAM'S procedures.

4.3.6.1 Frequency

Review a random selection of sample collection reports to be audited based on the number of samples collected in 12 months of performance based using Table 2.

Table 2 Sample Collection Report Audit Requirements

# of Samples Collected in 12 Months	Min # Reports Required	Max # Reports Required
Less than 40 reports	All	All
40 – 800 reports	40	40
More than 800 reports	5% of reports	70

4.3.6.2 Performance Factors

Evaluate the performance factors listed in Appendix 4.8, or an equivalent form.

4.3.6.3 Performance Documentation

4.3.6.3.1 Record the rating of each performance factor, audit score, and audit rating for each sample collection report audit on Appendix 4.8, or an equivalent form.

4.3.6.3.2 Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.9, or an equivalent worksheet.

4.3.7 Corrective Action Plan

The state PROGRAM documents CORRECTIVE ACTIONS as described in 9.3.2 for each of the four types of audits when any of the following conditions are met:

4.3.7.1 An inspector receives an overall audit rating of "needs improvement" (audit score below 80 percent) for an individual audit.

4.3.7.2 A state PROGRAM has a performance factor score (as a result of all audits in 12 months of performance) below 80 percent for a single performance factor.

4.3.7.3 A state PROGRAM has a cumulative score (as a result of all audits in 12 months of performance) below 80 percent.

4.4 Outcome

The state PROGRAM utilizes the audit program to evaluate its inspection and sample collection activities for effectiveness, to recognize trends, and to document CORRECTIVE ACTIONS, when necessary.

4.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

4.5.1 Appendix 4.1: Self-Assessment Worksheet.
4.5.2 Procedure for conducting four types of audits.
4.5.3 Appendix 4.2: Field Inspection Audit Form.
4.5.4 Appendix 4.3: Field Inspection Audit Worksheet.
4.5.5 Appendix 4.4: Field Inspection Report Audit Form.
4.5.6 Appendix 4.5: Field Inspection Report Audit Worksheet.
4.5.7 Appendix 4.6: Sample Collection Audit Form.
4.5.8 Appendix 4.7: Sample Collection Audit Worksheet.
4.5.9 Appendix 4.8: Sample Collection Report Audit Form.
4.5.10 Appendix 4.9: Sample Collection Report Audit Worksheet.

STANDARD 5
Animal Food-Related Illnesses or Death and Emergency Response

5.1 Purpose

This standard describes the program elements used by a state PROGRAM to effectively detect, identify, and respond to ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.2 Requirement Summary

The state PROGRAM establishes a system to conduct EMERGENCY response to ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.3 Program Elements

5.3.1 Animal Food-Related Illnesses or Deaths and Emergencies Procedure

5.3.1.1 The state PROGRAM has a procedure to gather information to identify incidents of ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.3.1.2 The state PROGRAM has a procedure to communicate with the appropriate agencies or departments that investigate ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.3.1.3 For ANIMAL FOOD-related illnesses or deaths and EMERGENCIES, the state PROGRAM has a procedure to:

5.3.1.3.1 Determine the appropriate response.
5.3.1.3.2 Initiate the response.
5.3.1.3.3 Complete the response.

5.3.2 Emergency Event Management

For ANIMAL FOOD-related EMERGENCIES, the state PROGRAM manages the event using:

5.3.2.1 An Incident Command System, or
5.3.2.2 An official action plan[2].

The official action plan includes:

5.3.2.2.1 Containment
5.3.2.2.2 Communication
5.3.2.2.3 Control
5.3.2.2.4 Correction and/or Corrective Actions
5.3.2.2.5 After-action protocols

[2] An example of an official action plan can be found in the AAFCO Emergency Response Preparedness Guidance Document (AAFCO Official Publication).

5.3.3 Animal Food-Related Illnesses or Deaths and Emergencies Notification Procedures

5.3.3.1 The state PROGRAM maintains a current list of relevant agencies and emergency contacts that is reviewed and updated at least every 12 months.

5.3.3.2 The state PROGRAM has a procedure to rapidly notify government agencies, departments, and appropriate parties of relevant findings.

5.3.3.3 The state PROGRAM has a procedure to rapidly notify law enforcement agencies when intentional ANIMAL FOOD contamination or ANIMAL FOOD-related terrorism is suspected or threatened.

5.3.3.4 The state PROGRAM has a procedure for:

5.3.3.4.1 Releasing information to the public.

5.3.3.4.2 Coordinating media information with other jurisdictions to reduce the impact of ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.4 Outcome

The state PROGRAM utilizes the EMERGENCY response system to work with government agencies, departments, and appropriate parties to gather and share information to reduce ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

5.5.1 Appendix 5.1: Self-Assessment Worksheet.

5.5.2 Procedure to gather information to identify incidents of ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.5.3 Procedure to communicate with agency/departments.

5.5.4 Procedure to determine the appropriate response, initiate the response, and complete the response for ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.

5.5.5 Procedure using an Incident Command System or an official action plan.

5.5.6 Emergency contact list.

5.5.7 Procedure to rapidly notify government agencies, departments, and appropriate parties of relevant findings.

5.5.8 Procedure to rapidly notify law enforcement agencies when intentional ANIMAL FOOD contamination or ANIMAL FOOD-related terrorism is suspected or threatened.

5.5.9 Procedure for releasing information to the public and coordinating media information with other jurisdictions.

STANDARD 6
Compliance and Enforcement Program

6.1 Purpose

This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD compliance and enforcement program.

6.2 Requirement Summary

The state PROGRAM establishes a compliance and enforcement program with ENFORCEMENT STRATEGIES to achieve compliance with ANIMAL FOOD laws. This includes an annual evaluation of the ENFORCEMENT STRATEGIES to identify potential improvements or modifications.

6.3 Program Elements

6.3.1 Compliance and Enforcement Program

6.3.1.1 The state PROGRAM has a documented compliance and enforcement program that contains ENFORCEMENT STRATEGIES.

6.3.1.2 The state PROGRAM selects an appropriate enforcement tool using the following six factors:

6.3.1.2.1 Compliance history
6.3.1.2.2 Responsiveness
6.3.1.2.3 Scope
6.3.1.2.4 Nature of the Violation
6.3.1.2.5 Impact of the Violation
6.3.1.2.6 Resources

6.3.1.3 The state PROGRAM has a documented description for all factors.

6.3.1.4 The state PROGRAM has documented relative conditions with an assigned numerical weight for all factors.

6.3.1.5 The state PROGRAM has a documented enforcement matrix designed to incorporate the relative conditions of each factor and the application of enforcement tools.

6.3.2 Performance Review

The state PROGRAM has a procedure for conducting an evaluation of its ENFORCEMENT STRATEGIES at least every 12 months to:

6.3.2.1 Determine if the state PROGRAM'S ENFORCEMENT STRATEGIES were successful in achieving compliance.
6.3.2.2 Identify potential improvements or modifications of the ENFORCEMENT STRATEGIES, if any.
6.3.2.3 Determine if the enforcement priorities remain the same or require modification.

6.4 Outcome

The state PROGRAM utilizes the compliance and enforcement program to achieve compliance with ANIMAL FOOD laws.

6.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

6.5.1 Appendix 6.1: Self-Assessment Worksheet.

6.5.2 ENFORCEMENT STRATEGIES.

6.5.3 The ENFORCEMENT STRATEGIES factors including the description, relative conditions, and associated numerical weight for each.

6.5.4 Enforcement matrix.

6.5.5 Procedure for conducting an evaluation of the ENFORCEMENT STRATEGIES.

6.5.6 Evaluation of the ENFORCEMENT STRATEGIES at least every 12 months.

STANDARD 7
Outreach Program

7.1 Purpose

This standard describes the program elements used by a state PROGRAM to effectively conduct an ANIMAL FOOD outreach program.

7.2 Program Elements

The state PROGRAM established an outreach program with OUTREACH ACTIVITIES or OUTREACH EVENTS to inform ANIMAL FOOD industry stakeholders, academia, other regulators, or consumers about ANIMAL FOOD topics.

7.3 Requirement Summary

7.3.1 Outreach Methods

The state PROGRAM identifies the methods that will be used for outreach to inform ANIMAL FOOD industry stakeholders, academia, other regulators, or consumers about ANIMAL FOOD topics.

7.3.2 Outreach Plan

The state PROGRAM has a documented outreach plan at least every 12 months that supports the state PROGRAM mission and that includes:

7.3.2.1 Objectives of an outreach plan.
7.3.2.2 Target populations.
7.3.2.3 The types of outreach (including OUTREACH ACTIVITIES or OUTREACH EVENTS).

7.3.3 Outreach Events

The state PROGRAM documents and evaluates OUTREACH EVENTS using Appendix 7.2, or an equivalent form.

7.4 Outcome

The state PROGRAM utilizes an outreach plan to inform ANIMAL FOOD industry stakeholders, academia, other regulators, or consumers about ANIMAL FOOD topics.

7.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

7.5.1 Appendix 7.1: Self-Assessment Worksheet.
7.5.2 Outreach plan.
7.5.3 Appendix 7.2: Outreach Event Overview and Evaluation.

STANDARD 8
Program Planning and Resources

8.1 Purpose

This standard describes the program elements used by a state PROGRAM to effectively conduct the ANIMAL FOOD work planning and resources evaluation.

8.2 Requirement Summary

A state PROGRAM establishes a workplan to support its inspection and sample collection programs.

This includes an evaluation of resource needs for completing the workplan and to IMPLEMENT and maintain the AFRPS.

8.3 Program Elements

8.3.1 Workplan

The state PROGRAM has a documented workplan that includes the:

8.3.1.1 Inspection plan

8.3.1.1.1 Number of inspections
8.3.1.1.2 Type of inspection
8.3.1.1.3 Risk category of establishment or product
8.3.1.1.4 Frequency

8.3.1.2 Sample plan

8.3.1.2.1 Number of samples
8.3.1.2.2 Type of samples

8.3.1.3 Timeframe that the workplan is applicable.

8.3.2 Workplan Procedure

8.3.2.1 The state PROGRAM has a procedure for evaluating the workplan that includes:

8.3.2.1.1 Conducting evaluations of the workplan at least every 12 months.
8.3.2.1.2 Evaluating alignment with state PROGRAM objectives and resources.

8.3.2.2 The state PROGRAM has a procedure for identifying and evaluating its resources to accomplish the workplan within the applicable timeframe.

Note: The resource evaluation should include staffing, equipment, and funding needed to support the inspection and sample collection activities identified in the workplan.

Note: The resources needed to train and audit field staff, to support laboratory services, compliance and enforcement program, outreach program, and to respond to ANIMAL FOOD-related illnesses, deaths, or EMERGENCIES should be determined by the state PROGRAM. The administrative functions needed to support all state PROGRAM areas should be considered when determining state PROGRAM resources.

8.3.2.3 The state PROGRAM develops a formula and calculates the number of staff needed to accomplish the state PROGRAM'S ANIMAL FOOD workplan based on staff assignments, responsibilities, and work hours.

Note: The state PROGRAM should have adequate staff to inspect the state PROGRAM'S ANIMAL FOOD inventory and to conduct sample collections established in its workplan.

8.3.3 Equipment

The state PROGRAM establishes and maintains a list of the equipment required for inspections and sample collections.

8.3.4 Resource Review

8.3.4.1 The state PROGRAM conducts a baseline evaluation of the resources required to IMPLEMENT the AFRPS, including the program elements and the documentation requirements in the standards to determine whether the state PROGRAM has:

8.3.4.1.1 Adequate staff
8.3.4.1.2 Equipment
8.3.4.1.3 Funding

8.3.4.2 The state PROGRAM completes subsequent resource evaluations to determine the resources necessary for the state PROGRAM to partially meet, fully meet, or maintain IMPLEMENTATION of the program elements and documentation requirements within three years of the previous evaluation.

8.3.4.3 The state PROGRAM records the evaluation on Appendix 8.2, or an equivalent form.

8.4 Outcome

The state PROGRAM utilizes the workplan to support its inspection and sample collection programs. The state PROGRAM evaluates the resources needed to support both the state PROGRAM and the IMPLEMENTATION and maintenance of the AFRPS.

8.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

8.5.1 Appendix 8.1: Self-Assessment Worksheet.

8.5.2 Workplan.

8.5.3 Procedure for evaluating the workplan.

8.5.4 Procedure for identifying and evaluating its resources to accomplish the workplan within the applicable timeframe.

8.5.5 Formula used to calculate the number of staff needed to accomplish the state PROGRAM'S ANIMAL FOOD workplan based on the state PROGRAM staff assignments, responsibilities, and work hours.

8.5.6 List of required equipment for inspection and sample collection.

8.5.7 Appendix 8.2: Resources for Implementation of Animal Food Regulatory Program Standards.

STANDARD 9
Assessment and Improvement

9.1 Purpose

This standard describes the program elements used by a state PROGRAM to effectively evaluate and demonstrate IMPLEMENTATION with each of the program standards.

9.2 Requirement Summary

The state PROGRAM establishes a baseline evaluation utilizing the self-assessment worksheets completed for each standard. This includes using the results to create a strategic improvement plan that aids the state PROGRAM in IMPLEMENTING the program elements of each standard.

9.3 Program Elements

9.3.1 State Program Baseline Evaluation

The state PROGRAM conducts a baseline evaluation using the self-assessment worksheets from each standard to determine if a standard is fully met, partially met, or not met.

9.3.2 Strategic Improvement Plan

The state PROGRAM develops a strategic improvement plan to IMPLEMENT the program elements or documentation requirements of each standard. The strategic improvement plan includes the following, as applicable:

9.3.2.1 The program element or documentation requirement of the standard that was not met.
9.3.2.2 Improvements or CORRECTIVE ACTIONS needed to IMPLEMENT the program element or documentation requirement of the standard.
9.3.2.3 The cause for any DEVIATIONS requiring CORRECTIVE ACTIONS when the state PROGRAM was previously in IMPLEMENTATION with the program element or documentation requirement of a standard.
9.3.2.4 The PREVENTIVE ACTION taken to prevent future similar DEVIATIONS when the state PROGRAM was previously in IMPLEMENTATION with the program element or documentation requirement of the standard that was corrected.
9.3.2.5 Projected completion date for each improvement or CORRECTIVE ACTION.
9.3.2.6 Personnel responsible.
9.3.2.7 Date completed.

9.3.3 Strategic Improvement Plan Review

The state PROGRAM reviews and updates at least every 12 months the

9.3.3.1 following: The self-assessment worksheets.
9.3.3.2 The strategic improvement plan.

9.3.4 Document Control Procedure

9.3.4.1 The state PROGRAM has a procedure for DOCUMENT CONTROL that ensures all guidance and procedures required by the standards are CURRENT AND FIT-FOR-USE.

9.3.4.2 The state PROGRAM maintains a master document list of all documents subject to this procedure to demonstrate they are CURRENT AND FIT-FOR-USE.

9.3.5 Record Retention

The state PROGRAM retains records required under x.5 of each standard for the three previous years, or per the state PROGRAM'S record retention policy.

9.4 Outcome

The state PROGRAM utilizes the strategic improvement plan to achieve and maintain IMPLEMENTATION of the required program elements and documentation requirements for all standards.

9.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

9.5.1 Appendix 9.1: Self-Assessment Worksheet.
9.5.2 Strategic Improvement Plan.
9.5.3 Procedure for Document Control.
9.5.4 Master Document List.

STANDARD 10
Laboratory Services

10.1 Purpose

This standard describes the program elements used by a state PROGRAM to effectively utilize REGULATORY TESTING LABORATORY services.

10.2 Requirement Summary

The state PROGRAM establishes access to REGULATORY TESTING LABORATORY services that provide accurate, timely, reliable, and defensible analytical data.

10.3 Program Elements

10.3.1 Laboratory Support

10.3.1.1 The state PROGRAM maintains a list of analytical services the REGULATORY TESTING LABORATORY provides for the state PROGRAM.

10.3.1.2 The state PROGRAM has a documented formal agreement with the REGULATORY TESTING LABORATORY that conducts routine analytical services unless under the same administrative agency.

10.3.2 Laboratory Sample Integrity Procedure

The state PROGRAM has procedures developed by the REGULATORY TESTING LABORATORY to maintain the integrity of the samples sent to the REGULATORY TESTING LABORATORY for analytical testing that includes:

10.3.2.1 Sample receipt.
10.3.2.2 Preservation.
10.3.2.3 Storage.
10.3.2.4 Retention.
10.3.2.5 Disposal.
10.3.2.6 Chain of custody.
10.3.2.7 Report of analysis.
10.3.2.8 Methods to communicate information between the state PROGRAM and REGULATORY TESTING LABORATORY.

10.3.3 Laboratory Quality Assurance Program

The state PROGRAM utilizes REGULATORY TESTING LABORATORIES that:

10.3.3.1 Are accredited by a recognized accreditation body to ISO/IEC 17025:2017[3], or current version, or
10.3.3.2 Implement and comply with the AAFCO Quality Assurance/Quality Control guidelines, or
10.3.3.3 Implement and comply with the ISO/IEC 17025:2017, or current version.

[3] A recognized accreditation body must be signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

10.4 Outcome

The state PROGRAM utilizes valid and defensible REGULATORY TESTING LABORATORY data to protect animal and public health and to enforce ANIMAL FOOD laws.

10.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

10.5.1 Appendix 10.1: Self-Assessment Worksheet.

10.5.2 A list of all analytical services provided by the REGULATORY TESTING LABORATORY for the state PROGRAM.

10.5.3 A formal agreement with REGULATORY TESTING LABORATORYIES that provide routine analytical services unless the laboratory is under the same administrative agency.

10.5.4 Procedure to maintain the integrity of the samples sent to the REGULATORY TESTING LABORATORY.

10.5.5 ISO Accredited Laboratory: ISO/IEC 17025:2017, or current version, Certificate and Scope of Accreditation, or documentation for non-ISO REGULATORY TESTING LABORATORIES.

STANDARD 11
Sampling Program

11.1 Purpose

This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD sampling program.

11.2 Requirement Summary

The state PROGRAM established a sampling program to determine compliance with ANIMAL FOOD laws. This includes a sampling plan, sample collection procedures, and procedures for completing the sample collection report.

11.3 Program Elements

11.3.1 Sampling Plan

The state PROGRAM has a documented sampling plan, at least every 12 months, for collecting surveillance, compliance, investigational, regulatory samples, or other samples[4].

11.3.1.1 The state PROGRAM and REGULATORY TESTING LABORATORY jointly develops and amends the sampling plan, at least every 12 months, for performing routine analytical services to allow for advanced planning and scheduling of work.

11.3.1.2 The sampling plan includes the:

11.3.1.2.1 Availability or coordination of analytical support.
11.3.1.2.2 Sample priorities.
11.3.1.2.3 SAMPLE ANALYSIS SCHEDULE.

The SAMPLE ANALYSIS SCHEDULE includes the:

11.3.1.2.3.1 Types of ANIMAL FOOD to be analyzed.
11.3.1.2.3.2 Number of samples to be collected.
11.3.1.2.3.3 Estimated timeframe for collection.
11.3.1.2.3.4 Types of analyses to be performed.

11.3.2 Sample Collection Procedure

The state PROGRAM has procedures for collecting, storing, and transporting samples that includes:

11.3.2.1 Following safety precautions on ANIMAL FOOD labels.
11.3.2.2 Following the state PROGRAM'S safety protocols for collecting samples.
11.3.2.3 Using appropriate method, sample collection procedures, and equipment to collect the sample.
11.3.2.4 Sealing the sample to initiate chain of custody.

[4] Regulatory samples may be used to support inspection observations.

11.3.2.5 Maintaining and documenting sample integrity, security, and chain of custody.
11.3.2.6 Issuing receipt[5] for the sample.
11.3.2.7 Handling[6], packaging, and shipping samples to prevent compromising the condition of the sample.
11.3.2.8 Delivering or shipping samples to the appropriate REGULATORY TESTING LABORATORY within designated timeframes.

11.3.3 Sample Collection Report

The state PROGRAM has a procedure for completing the sample collection report that includes the:

11.3.3.1 Identification of sample collector.
11.3.3.2 Date of the sample collection.
11.3.3.3 Product identification.

The product identification includes the:

11.3.3.3.1 Name.
11.3.3.3.2 Lot numbers or any other codes referencing manufacture identification.

11.3.3.4 Description of product.
11.3.3.5 Method of collection and any special techniques used to collect sample.
11.3.3.6 Lot sampled.
11.3.3.7 Lot size.
11.3.3.8 Location where sample was collected.
11.3.3.9 Name and address of responsible party, guarantor, possessor, or distributor.
11.3.3.10 Sample type (example: surveillance, compliance, investigational, regulatory, or other).
11.3.3.11 Analysis requested, if applicable.
11.3.3.12 Collection or reproduction of product label, including customer-formula label.
11.3.3.13 Receiving and distribution information.

11.4 Outcome

The state PROGRAM utilizes the sampling program to align sampling resources to collect, store, transport, and document samples to achieve compliance with ANIMAL FOOD laws.

[5] Receipt could include cost of sample and method of payment.

[6] Includes storing sample.

11.5 Documentation

The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:

11.5.1 Appendix 11.1: Self-Assessment Worksheet.
11.5.2 Sampling plan.
11.5.3 Sampling collection procedure.
11.5.4 Procedure for completing the sample collection report.

Appendix 1.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
1.3.1 Evaluation of Legal Authority		
Does the state PROGRAM conduct an evaluation to determine whether the state's legal authority and regulatory provisions are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to the specified sections of the current FD&C Act and CFR Title 21, and completes Appendix 1.2, or an equivalent form?		
1.3.2 Regulatory Foundation Evaluation		
Does the state PROGRAM have a procedure that includes:		
1. Reviewing the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:		
1.1 Apply to the regulation of ANIMAL FOOD?		
1.2 Delegate authority to the state agency?		
1.3 Describe the state agency's administrative procedure for establishing its authority and incorporating rules by reference?		
2. Timeframe for the review?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 1.2: Regulatory Foundation Worksheet

***Instructions*:** Determine if state laws and regulations are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to the specified sections of the current FD&C Act and CFR Title 21.

A state law or regulation may have the same regulatory effect as the relevant FD&C Act provision or federal regulation if either a single state law or regulation has the same regulatory effect as the federal statute or regulation, or when multiple laws of that state are combined and deemed EQUIVALENT IN EFFECT to a single federal statute or regulation.

If there is no state law or regulation EQUIVALENT to the relevant FD&C Act provision or federal regulation or the federal and state laws or regulations address the same matter but are inconsistent and do not have the same regulatory effect, please select NOT EQUIVALENT.

Select NO AUTHORITY if regulatory responsibility for a FD&C Act provision or federal regulation falls under the jurisdiction of another agency.

If the state has laws and regulations pertinent to the regulation of ANIMAL FOOD for which there are no comparable relevant FD&C Act provision or federal regulation, these laws or regulations should be listed on Appendix 1.2 or equivalent form.

For those laws and regulations for which the state PROGRAM does have authority, record the state law or regulations and the date it was incorporated. The Notes section can be used to detail differences between state and federal laws and regulations.

Note: The FD&C Act reference links direct you to the relevant U.S. Code section number. For a cross reference of FD&C Act and U.S. Code sections please visit FDA's website: *https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act*

State Agency _____

FD&C Act	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
201	Definitions (f), (g), (k), (m), (s), (v) and (w)				
301	Prohibited acts (a), (b), (c), (d), (e), (f), and (k)				
303*	Penalties				
304**	Seizure				
401	Definitions and standards for food				
402	Adulterated food (a)-(c)				
403	Misbranded food (a)-(n)				
404	Emergency permit control				
406	Tolerances for poisonous ingredients in food				
408	Tolerances and exemptions for pesticide chemical residues				
409	Food Additives				
501	Adulterated drugs and devices (ONLY: 501(a)(2)(B) and 501(a)(6))				
504	Veterinary feed directive drugs				
512	New animal drugs (ONLY: 512(a)(2))				
701	Regulations and hearings				
704	Inspection				

CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
1	General enforcement regulations (ONLY §1.20-1.23, Subpart L (§1.500-1.514), Subpart M (§1.600-1.695), and Subpart O (§1.900-1.934))				
7	Enforcement policy (ONLY §7.1-7.13 and 7.40-7.59)				
70	Color additives (ONLY §70.20-70.25)				
73	Listing of colors exempt from certification (ONLY §73.1-73.615)				
74	Listing of color additives subject to certification (ONLY §74.101-74.706)				
81	General specifications and general restrictions for provisional color additives for use in foods, drugs, and cosmetics				
82	Listing of certified provisionally listed colors and specifications (ONLY §82.3-82.706)				
225	Current good manufacturing practice for medicated feeds				
226	Current good manufacturing practice for Type A medicated articles				
500.23	Thermally processed low-acid foods packaged in hermitically sealed containers (refers to 21 CFR 113 and 21 CFR 507)				

CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
500.24	Emergency permit control (refers to 21 CFR 108 - ONLY §108.25-108.35)				
500.29	Gentian violet for use in animal feed				
500.45	Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed				
500.50	Propylene glycol in or on cat food				
500.80 – 500.92	Regulation of carcinogenic compounds used in food-producing animals				
501	Animal food labeling				
502	Common or usual name for non-standardized animal foods				
507	Current good manufacturing practice, hazard analysis, and risk-based preventive controls for food for animals				
509	Unavoidable contaminants in animal food and food-packaging material				
510	New animal drugs (ONLY Subpart D - Records and Reports)				
558	New animal drugs for use in animal feeds				

CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
570	Food additives (EXCEPT §570.6, §570.15, and §570.17)				
573	Food additives permitted in feed and drinking water of animals				
579	Irradiation in the production, processing, and handling of animal feed and pet food				
582	Substances generally recognized as safe				
584	Food substances affirmed as generally recognized as safe in feed and drinking water of animals				
589	Substances prohibited from use in animal food or feed				

Instructions: List any state laws and/or regulations used by the state PROGRAM that are pertinent to the regulation of ANIMAL FOOD for which there are no comparable relevant FD&C Act provision or federal regulation (examples: tolerance for mycotoxins, fluorine, or noxious weeds in ANIMAL FOOD).

Additional State Authorities (optional):

Additional notes and comments:

Assessment Completed By:

Name _____ **Date** _____

Appendix 2.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
2.3.1 Training Plan and Training Records		
1. Does the state PROGRAM have a documented training plan that includes training and continuing education, as defined by the state PROGRAM, that includes:		
1.1 Description of each inspection type?		
1.2 CURRICULUM for each inspection type?		
2. For inspectors with greater than five years of experience at the date of the initial self-assessment or at the inspectors START DATE, where their training documentation is not available, does the state PROGRAM:		
2.1 Document an evaluation of the inspector's performance and experience to determine if additional training is needed?		
2.2 Maintain proper supporting documents to verify successful completion of the requirement, if previous coursework is completed before the inspectors START DATE and utilized to meet coursework requirements?		
3. Does the state PROGRAM maintain records documenting the training completed by all inspectors on Appendix 2.2, or an equivalent form?		

Program Elements	Yes/No	Notes
2.3.2 Basic ANIMAL FOOD Inspector Training		
1. Timeframe		
Does the state PROGRAM require a basic inspector to successfully complete the basic coursework within 24 months from the START DATE?		
2. Coursework		
Does the basic inspector training consist of basic coursework in the subject areas listed in 2.3.2.2.1 – 2.3.2.2.13?		
3. Field Training		
Does the state PROGRAM require basic field training to complement the basic coursework? Does the basic field training specify the following:		
3.1 The procedure for JOINT FIELD TRAINING INSPECTIONS?		
3.2 The number of JOINT FIELD TRAINING INSPECTIONS that are conducted in establishments that represent the state PROGRAM inventory and the type of basic work that will be performed by the inspector?		
3.3 List the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS on Appendix 2.3, or an equivalent form?		
3.4 The QUALIFIED FIELD INSPECTION TRAINER verifies the field training checklist of competencies in the field for each inspection type?		
3.5 The inspector completes the minimum basic field training requirements for the inspection type, prior to performing independent work?		

Program Elements	Yes/No	Notes
2.3.3 Advanced ANIMAL FOOD Inspector Training		
1. Timeframe		
Does the state PROGRAM require an advanced inspector to successfully complete the advanced coursework within 60 months from the START DATE?		
2. Coursework		
Does the advanced inspector training consist of advanced coursework in the subject areas listed in 2.3.3.2.1 – 2.3.3.2.8, but not limited to?		
3. Field Training		
Does the state PROGRAM require advanced field training to complement the advanced coursework? Does the advanced field training specify the following:		
3.1 The procedure for JOINT FIELD TRAINING INSPECTIONS?		
3.2 The number of JOINT FIELD TRAINING INSPECTIONS that are conducted in establishments that represent the state PROGRAM inventory and the type of advanced work that will be performed by the inspector?		
3.3 List the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS on Appendix 2.3, or an equivalent form?		
3.4 The QUALIFIED FIELD INSPECTION TRAINER verifies the field training checklist of competencies in the field for each inspection type?		
3.5 The inspector completes the minimum advanced field training for the inspection type, prior to performing independent work?		

Program Elements	Yes/No	Notes
2.3.4 Continuing Education		
Does the state PROGRAM require that each basic and advanced inspector participate in continuing education? Does the continuing education specify the following:		
1. Each inspector receives 20 CONTACT HOURS of continuing education every 36 months?		
2. The 36-month continuing education interval starts, as defined by the state PROGRAM, when the required CURRICULUM is complete?		
3. Documentation accompanies each activity submitted for continuing education?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 2.2: Inspector Training Record

A. Basic Animal Food Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience shows adequate training has been completed, mark the Name and Location of Training Column, with "Met via Evaluation."

Inspector Name: **Employment Start Date:**

Subject Areas	Name and Location of Training	Completion Date	Documentation Verifying Completion
Animal and Public Health Principles			
Animal Food Defense			
Basic Animal Nutrition			
Basic Ingredients, Processing, and Technology			
Basic National Incident Management System and Incident Command System (ICS)			
Communication			
Current Statutes, Regulations, and Policies			
Inspections, Compliance, and Enforcement			
Labeling			
Professionalism			
Risk Awareness			
Safety			
Sample Collection			

Appendix 2.2: Inspector Training Record

Instructions: Record the name of the establishment where the joint training inspection took place as well as the competencies covered.

Inspector Name: **Employment Start Date:**

Basic Field Training (Name and Location of Establishment)	Competencies Covered	Completion Date	Verified (Y/N)

Appendix 2.2: Inspector Training Record

B. Advanced Animal Food Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience shows adequate training has been completed, mark the Name and Location of Training Column, with "Met via Evaluation."

Inspector Name: **Employment Start Date:**

Subject Areas	Name and Location of Training	Completion Date	Documentation Verifying Completion
Advanced Ingredients, Processing, and Technology			
Advanced Inspections, Compliance, and Enforcement			
Advanced Labeling			
Animal Illness and Death Investigation			
Current Statutes, Regulations, and Policies			
Epidemiology			
Microbiological Pathogens			
Traceback and Tracefoward Investigations			

Appendix 2.2: Inspector Training Record

Instructions: Record the name of the establishment where the joint training inspection took place as well as the competencies covered.

Inspector Name: **Employment Start Date:**

Advanced Field Training (Name and Location of Establishment)	Competencies Covered	Completion Date	Verified (Y/N)

Appendix 2.2: Inspector Training Record

C. Continuing Education

Instructions: Record the continuing education activity as well as the name and location of the activity.

Inspector Name: **Employment Start Date:**

Type of Activity	Name and Location of Activity	Completion Date	Contact Hours Earned

Appendix 2.3: Field Training Competencies

A. Basic Field Training Competencies

Instructions: List the competencies to be covered in the state PROGRAM'S basic field training and provide a short description.

Competency	Description

Minimum Number of Joint Field Training Inspections Required: _____

Appendix 2.3: Field Training Competencies

B. Advanced Field Training Competencies

Instructions: List the competencies to be covered in the state PROGRAM'S advanced field training and provide a short description.

Competency	Description

Minimum Number of Joint Field Training Inspections Required: _____

Appendix 3.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
3.3.1 Risk-Based Inspection Program		
1. Does the state PROGRAM have a procedure to define and maintain a current inventory of ANIMAL FOOD establishments whose activities fall under the state PROGRAM'S jurisdiction and authority?		
2. Does the state PROGRAM have a procedure for risk categorization of ANIMAL FOOD establishments using the three minimum required factors for defining risk categories:		
2.1 Types of ANIMAL FOOD and ANIMAL FOOD products?		
2.2 Types of processing?		
2.3 Compliance history of the establishment?		
3. Based on risk categorization of an ANIMAL FOOD establishment, are inspections:		
3.1 Prioritized?		
3.2 Assigned frequencies?		
3.3 Allocated resources?		

Program Elements	Yes/No	Notes
3.3.2 Inspection Procedure		
1. Does the state PROGRAM have procedures for inspecting ANIMAL FOOD establishments that require the inspectors to:		
1.1 Review the ANIMAL FOOD establishment's history and determine the scope of inspection?		
1.2 Present appropriate credentials and written Notice of Inspection to the ANIMAL FOOD establishment's owner, operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; confirm inspection authority and establish FDA jurisdiction, if applicable?		
1.3 Follow the safety protocols required by the ANIMAL FOOD establishment and the state PROGRAM?		
1.4 Follow the biosecurity protocols required by the ANIMAL FOOD establishment and the state PROGRAM?		
1.5 Use appropriate equipment and forms needed to conduct inspections?		
1.6 Recognize the relative risk categorization of the ANIMAL FOOD establishment based on the risk-based inspection program?		
1.7 Conduct comprehensive inspection activities appropriate for the level of risk, focused on the establishment's products and processes determined to be of higher risk?		
1.8 Assess employee activities critical to the safe manufacturing, processing, packaging, handling, holding, and distribution of ANIMAL FOOD?		
1.9 Properly evaluate the potential that conditions, practices, processes, components, or labeling could cause the product to become adulterated, contaminated, or misbranded?		

Program Elements	Yes/No	Notes
1.10 Recognize significant non-compliant conditions or practices and document findings consistent with state PROGRAM procedures?		
1.11 Distinguish between significant and insignificant observations and isolated incidents versus trends?		
1.12 Review, evaluate and verify that the appropriate ANIMAL FOOD establishment records, plans, programs, and/or procedures are established, maintained, and/or implemented?		
1.13 Collect adequate evidence and documentation to support inspection observations in accordance with state PROGRAM procedures?		
1.14 Verify deficiencies identified during the previous inspections have been addressed?		
1.15 Conduct activities in a professional manner?		
1.16 Use effective interviewing techniques?		
1.17 Explain findings clearly and adequately throughout the inspection?		
1.18 Alert the ANIMAL FOOD establishment's owner, operator, or agent in charge when an immediate corrective action is necessary?		
1.19 Document findings accurately, clearly, legibly, and concisely on the applicable forms and provide a copy to the ANIMAL FOOD establishment's owner, operator, or agent in charge?		
1.20 Answer questions and provide information as appropriate?		
1.21 Submit inspection report, samples where applicable, and supporting evidence and documentation within designated timeframes consistent with state PROGRAM procedure?		

Program Elements	Yes/No	Notes
3.3.3 Recall System		
Does the state PROGRAM have procedures to handle recalls that includes:		
1. Receiving?		
2. Tracking?		
3. Evaluating recall notifications?		
4. Closing?		
5. Maintaining records?		
6. Performing recall effectiveness checks, as applicable?		
3.3.4 Consumer Complaints		
Does the state PROGRAM have a procedure to handle consumer complaints that includes:		
1. Receiving?		
2. Tracking?		
3. Evaluating?		
4. Answering?		
5. Closing?		
6. Maintaining records?		

Program Elements	Yes/No	Notes
3.3.5 Complaints Resulting from state PROGRAM Inspection Activities		
Does the state PROGRAM have a procedure to handle industry complaints resulting from state PROGRAM inspection activities that includes:		
1. Receiving?		
2. Evaluating?		
3. Maintaining records?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 4.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
4.3.1 Audit Program		
Does the state PROGRAM have procedures for conducting four types of audits:		
1. Field inspection audits as described in 4.3.3?		
2. Field inspection report audits as described in 4.3.4?		
3. Sample collection audits as described in 4.3.5?		
4. Sample collection report audits as described in 4.3.6?		
4.3.2 Audit Program Review		
Does the state program conduct a review of the performance factor scores and cumulative scores for each of the four types of audits at least every 12 months?		
4.3.3 Field Inspection Audit		
Does the state PROGRAM conduct field inspection audits using a QUALIFIED FIELD AUDITOR to verify that inspections are consistently performed according to the state's PROGRAM procedures?		
1. Frequency		

Program Elements	Yes/No	Notes
1.1 Are a minimum of two field inspection audits of each inspector conducted every 36 months?		
1.2 Do the field inspections selected for audits reflect the inspector's assignments and responsibilities?		
2. Performance Factors		
Are performance factors listed in the inspection procedure as described in 3.3.2 and as listed in Appendix 4.2, or an equivalent form, evaluated?		
3. Performance Documentation		
3.1 Is the rating of each performance factor, audit score, and audit rating for each field inspection audit recorded on Appendix 4.2, or an equivalent form?		
3.2 Are the performance factor scores and a cumulative score for the state PROGRAM calculated on Appendix 4.3, or an equivalent worksheet?		
4.3.4 Field Inspection Report Audit		
Does the state PROGRAM conduct field inspection report audits to verify that inspectional findings are consistently reported according to the state PROGRAM'S procedures?		
1. Frequency		
Is the review a random selection of field inspection reports to be audited based on the number of inspections completed in 12 months of performance using Table 1?		
2. Performance Factors		

Program Elements	Yes/No	Notes
Are the performance factors listed in Appendix 4.4, or an equivalent form, evaluated?		
3. Performance Documentation:		
3.1 Is the rating of each performance factor, audit score, and audit rating for each inspection report audit recorded on Appendix 4.4, or an equivalent form?		
3.2 Are the performance factor scores and a cumulative score for the state PROGRAM calculated on Appendix 4.5, or an equivalent worksheet?		
4.3.5 Sample Collection Audit		
Does the state PROGRAM conduct sample collection audits using a QUALIFIED FIELD AUDITOR to verify that sample collections are consistently performed according to the state PROGRAM'S procedures?		
1. Frequency		
1.1 Are a minimum of two sample collection audits of each inspector conducted every 36 months?		
1.2 Do sample collections selected for audits reflect the inspector's assignments and responsibilities?		
2. Performance Factors		
Are performance factors listed in the sample collection procedure as described in 11.3.2 and as listed in Appendix 4.6, or an equivalent form, evaluated?		
3. Performance Documentation:		

Program Elements	Yes/No	Notes
3.1 Is the rating of each performance factor, audit score, and audit rating for each sample collection audit recorded on Appendix 4.6, or an equivalent form?		
3.2 Are the performance factor scores and a cumulative score for the state PROGRAM calculated on Appendix 4.7, or an equivalent worksheet.		
4.3.6 Sample Collection Report Audit		
Does the state PROGRAM conduct sample collection report audits to verify that sample collection documentation is consistently performed according to the state PROGRAM'S procedures?		
1. Frequency		
Is the review a random selection of sample collection reports to be audited based on the number of samples collected in 12 months of performance based using Table 2?		
2. Performance Factors		
Are the performance factors listed in Appendix 4.8, or an equivalent form, evaluated?		
3. Performance Documentation:		
3.1 Is the rating of each performance factor, audit score, and audit rating for each sample collection report audit recorded on Appendix 4.8, or an equivalent form?		
3.2 Are the performance factor scores and a cumulative score for the state PROGRAM calculated on Appendix 4.9, or an equivalent worksheet?		

Program Elements	Yes/No	Notes
4.3.7 Corrective Action Plan		
Does the state PROGRAM document CORRECTIVE ACTIONS as described in 9.3.2 for each of the four types of audits when any of the following conditions are met:		
1. An inspector receives an overall audit rating of "needs improvement" (audit score below 80 percent) for an individual audit?		
2. A state PROGRAM has a performance factor score (as a result of all audits in 12 months of performance) below 80 percent for a single performance factor?		
3. A state PROGRAM has a cumulative score (as a result of all audits in 12 months of performance) below 80 percent?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 4.2: Field Inspection Audit Form

Field Inspection Audit	
Inspector:	Auditor: Date of Audit:
Establishment Name: Establishment Address:	Type of Inspection: ☐ BSE ☐ GMP ☐ Tissue Residue ☐ Complaint ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:

All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/ (# Acceptable + # Needs Improvement)] x 100*.

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.

I. Pre-Inspection Assessment

1. Did the inspector review the animal food establishment's history and determine scope of the inspection?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector use appropriate equipment and forms needed to conduct the inspection?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

II. Inspection Observations and Performance

1. Did the inspector present appropriate credentials and written Notice of Inspection to the animal food establishment's owner, operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; confirm inspection authority and establish FDA jurisdiction, if applicable?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector follow safety protocols required by the animal food establishment and the state program?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

3. Did the inspector follow the biosecurity protocols required by the animal food establishment and the state program?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

4. Did the inspector recognize the relative risk categorization of the animal food establishment based on the risk-based inspection program?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

5. Did the inspector conduct comprehensive inspection activities, appropriate for the level of risk, focused on the establishment's products and processes determined to be of higher risk?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

6. Did the inspector assess employee activities critical to the safe manufacturing, processing, packaging, handling, holding, and distribution of animal food?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

7. Did the inspector properly evaluate the potential that conditions, practices, processes, components, or labeling could cause the product to become adulterated, contaminated, or misbranded?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

8. Did the inspector recognize significant non-compliant conditions or practices and document findings consistent with state program procedure?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

9. Did the inspector distinguish between significant and insignificant observations and isolated incidents versus trends?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

10. Did the inspector review, evaluate, and verify that the appropriate animal food establishment records, plans, programs, and/or procedures are established, maintained, and/or implemented?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

11. Did the inspector collect adequate evidence and documentation to support inspection observations in accordance with state program procedures?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

12. Did the inspector verify deficiencies identified during the previous inspections have been addressed?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

13. Did the inspector conduct activities in a professional manner?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

III. Oral and Written Communications
1. Did the inspector use effective interviewing techniques? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
2. Did the inspector explain findings clearly and adequately throughout the inspection? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
3. Did the inspector alert the animal food establishment's owner, operator, or agent in charge when an immediate corrective action is necessary? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
4. Did the inspector document findings accurately, clearly, legibly, and concisely on the applicable forms and provide a copy to the animal food establishment's owner, operator, or agent in charge? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
5. Did the inspector answer questions and provide information as appropriate? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
6. Did the inspector submit inspection report, samples where applicable, and supporting evidence and documentation within designated timeframes consistent with state program procedure? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)

IV. General Comments
Enter any general comments or recommendations as a result of this audit.

Name of Auditor _____ Signature of Auditor _____ Date _____

Appendix 4.3: Field Inspection Audit Worksheet

State Program: **Reviewed By:**

Performance Period: **Date:**

Cumulative Score (5):

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
II.10																					
II.11																					
II.12																					
II.13																					
III.1																					
III.2																					
III.3																					
III.4																					
III.5																					
III.6																					
Audit Score (2)																					
																		Subtotal - ***Enter the sum of the totals from all continuation worksheets.***			
																		Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***			

(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.

State Program: **Reviewed By:**

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
II.10																					
II.11																					
II.12																					
II.13																					
III.1																					
III.2																					
III.3																					
III.4																					
III.5																					
III.6																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation worksheets.***																					
Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***																					

(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.

Appendix 4.4: Field Inspection Report Audit Form

Field Inspection Report Audit	
Auditor:	Date of Audit: Date of Inspection:
Establishment Name: Establishment Address:	Type of Inspection: ☐ BSE ☐ GMP ☐ Tissue Residue ☐ Complaint ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:

All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/ (# Acceptable + # Needs Improvement)] x 100*.

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.

I. Organization of the Report

1. Format of the inspection report followed the state program's current procedures.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Required fields on inspection report or related report forms are completed.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Written observations were clear and concise.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Submitted report within timeframes.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

II. Record of Findings
1. Recorded name and title of establishment managers and key personnel. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
2. Recorded name and title of personnel interviewed during the inspection. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
3. Recorded findings not in compliance with statutes and regulations. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
4. Recorded significant findings, if any. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
5. Recorded the collection of all samples, exhibits, photographs, or photocopies to support findings. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
6. Recorded any refusals encountered during the inspection. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)

III. Communication with Establishment Personnel
1. Provided a summary of findings. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
2. Recorded responses, replies, or corrective action commitments. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
IV. General Comments
Enter any general comments or recommendations as a result of this audit.

Name of Auditor _____ Signature of Auditor _____ Date _____

Appendix 4.5: Field Inspection Report Audit Worksheet

State Program: **Reviewed By:**

Performance Period: **Date:**

Cumulative Score (5):

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
III.1																					
III.2																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation worksheets.*																					
Total (4) - *Enter the final sums (subtotal + sums of (3) on this form).*																					

(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.

State Program:											**Reviewed By:**											
Auditor Initials and Date of Audit (1)																				**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																						
Date																						
Performance Factors (2)	**Performance Ratings**																					
I.1																						
I.2																						
I.3																						
I.4																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
III.1																						
III.2																						
Audit Score (2)																						
Subtotal - ***Enter the sum of the totals from all continuation worksheets.***																						
Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***																						

(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.

Appendix 4.6: Sample Collection Audit Form

Sample Collection Audit	
Inspector:	Auditor: Date of Audit:
Establishment Name: Establishment Address:	Type of Sample Collection: ☐ Surveillance ☐ Compliance ☐ Investigational ☐ Regulatory ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:

All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/ (# Acceptable + # Needs Improvement)] x 100*.

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.

I. Sample Collection Observations and Performance

1. Did the inspector follow safety precautions on the animal food label?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector follow the state program's safety protocols for collecting samples?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Did the inspector use the appropriate method, sample collection procedures, and equipment to collect the sample?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Did the inspector seal the sample to initiate chain of custody?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

5. Did the inspector maintain and document sample integrity, security, and chain of custody?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

6. Did the inspector issue a receipt for the sample?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

7. Did the inspector handle, package, and ship samples to prevent compromising the condition of the samples?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

8. Did the inspector deliver or ship samples to the appropriate regulatory testing laboratory within designated timeframes?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

II. General Comments

Enter any general comments or recommendations as a result of this audit.

Name of Auditor _____ Signature of Auditor _____ Date _____

Appendix 4.7: Sample Collection Audit Worksheet

State Program:										**Reviewed By:**												
Performance Period:																			**Date:**			
Cumulative Score (5):																						
Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**	
Initials																						
Date																						
Performance Factors (2)	**Performance Ratings**																					
I.1																						
I.2																						
I.3																						
I.4																						
I.5																						
I.6																						
I.7																						
I.8																						
Audit Score (2)																						
Subtotal - ***Enter the sum of the totals from all continuation worksheets.***																						
Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***																						

(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.

State Program:													**Reviewed By:**								
Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation worksheets.*																					
Total (4) - *Enter the final sums (subtotal + sums of (3) on this form).*																					

(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.

Appendix 4.8: Sample Collection Report Audit Form

Sample Collection Report Audit	
Auditor:	Date of Audit: Date of Sample Collection:
Establishment Name: Establishment Address:	Type of Sample Collection: ☐ Surveillance ☐ Compliance ☐ Investigational ☐ Regulatory ☐ Other:
Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:

All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/ (# Acceptable + # Needs Improvement)] x 100*.

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.

I. Sample Collection Report

1. Identification of sample collector was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Date of the sample collection was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

II. Product Identification

1. Product name was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Lot numbers or any other codes referencing manufacture identification was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

3. Description of product was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

4. Method of collection and any special techniques used to collet sample was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

5. Lot sampled was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

6. Lot size was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

7. Location where sample was collected was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

8. Name and address of responsible party, guarantor, possessor, or distributor was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

9. Sample type (example: surveillance, compliance, investigational, regulatory, or other) was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

10. Analysis requested was recorded, if applicable.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

11. Collection or reproduction of product label, including customer-formula animal food label was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

12. Receiving and distribution information was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

III. General Comments

Enter any general comments or recommendations as a result of this audit.

Name of Auditor | Signature of Auditor | Date

Appendix 4.9: Sample Collection Report Audit Worksheet

State Program:													**Reviewed By:**									
Performance Period:													**Date:**									
Cumulative Score (5):																						
Auditor Initials and Date of Audit (1)																				**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																						
Date																						
Performance Factors (2)	**Performance Ratings**																					
I.1																						
I.2																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
II.11																						
II.12																						
Audit Score (2)																						
Subtotal - *Enter the sum of the totals from all continuation worksheets.*																						
Total (4) - *Enter the final sums (subtotal + sums of (3) on this form).*																						
(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.																						

State Program:													**Reviewed By:**									
Auditor Initials and Date of Audit (1)																				**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																						
Date																						
Performance Factors (2)	**Performance Ratings**																					
I.1																						
I.2																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
II.11																						
II.12																						
Audit Score (2)																						
Subtotal - *Enter the sum of the totals from all continuation worksheets.*																						
Total (4) - *Enter the final sums (subtotal + sums of (3) on this form).*																						
(6) Use this space to identify and make notes about trends and single performance factors rated as “Needs Improvement” in multiple audits.																						

Appendix 5.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
5.3.1 Animal Food-Related Illnesses or Deaths and Emergencies Procedure		
1. Does the state PROGRAM have a procedure to gather information to identify incidents of ANIMAL FOOD-related illnesses or deaths and EMERGENCIES?		
2. Does the state PROGRAM have a procedure to communicate with the appropriate agencies or departments that investigate ANIMAL FOOD-related illnesses or deaths and EMERGENCIES?		
3. For ANIMAL FOOD-related illnesses or deaths and EMERGENCIES, does the state PROGRAM have a procedure to:		
3.1 Determine the appropriate response?		
3.2 Initiate the response?		
3.3 Complete the response?		
5.3.2 Emergency Event Management		
1. For ANIMAL FOOD-related EMERGENCIES, does the state PROGRAM manage the event using:		
1.1 An Incident Command System? or		
1.2 An official action plan?		

Program Elements	Yes/No	Notes
Does the official action plan include:		
1.2.1 Containment?		
1.2.2 Communication?		
1.2.3 Control?		
1.2.4 Correction and/or Corrective Actions?		
1.2.5 After-action protocols?		
5.3.3 Animal Food-Related Illnesses or Deaths and Emergencies Notification Procedures		
1. Does the state PROGRAM maintain a current list of relevant agencies and emergency contacts that is reviewed and updated at least every 12 months?		
2. Does the state PROGRAM have a procedure to rapidly notify government agencies, departments, and appropriate parties of relevant findings?		
3. Does the state PROGRAM have a procedure to rapidly notify law enforcement agencies when intentional ANIMAL FOOD contamination or ANIMAL FOOD-related terrorism is suspected or threatened?		
4. Does the state PROGRAM have a procedure for:		
4.1 Releasing information to the public?		
4.2 Coordinating media information with other jurisdictions to reduce the impact of ANIMAL FOOD-related illnesses or deaths and EMERGENCIES?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 6.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
6.3.1 Compliance and Enforcement Program		
1. Does the state PROGRAM have a documented compliance and enforcement program that contains ENFORCEMENTSTRATEGIES?		
2. Does the state PROGRAM select an appropriate enforcement tool using the following six factors?		
2.1 Compliance history?		
2.2 Responsiveness?		
2.3 Scope?		
2.4 Nature of the Violation?		
2.5 Impact of the Violation?		
2.6 Resources?		
3. Does the state PROGRAM have a documented description for all factors?		
4. Does the state PROGRAM have documented relative conditions with an assigned numerical weight for all factors?		
5. Does the state PROGRAM have a documented enforcement matrix designed to incorporate the relative conditions of each factor and the application of enforcement tools?		

Program Elements	Yes/No	Notes
6.3.2 Performance Review		
1. Does the state PROGRAM have a procedure for conducting an evaluation of its ENFORCEMENT STRATEGIES at least every 12 months to:		
1.1 Determine if the state PROGRAM'S ENFORCEMENT STRATEGIES were successful in achieving compliance?		
1.2 Identify potential improvements or modifications of the ENFORCEMENT STRATEGIES, if any?		
1.3 Determine if the enforcement priorities remain the same or require modification?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 7.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met**

Program Elements	Yes/No	Notes
7.3.1 Outreach Methods		
Does the state PROGRAM identify the methods that will be used for outreach to inform ANIMAL FOOD industry stakeholders, academia, other regulators, or consumers about ANIMAL FOOD topics?		
7.3.2 Outreach Plan		
Does the state PROGRAM have a documented outreach plan at least every 12 months that supports the state PROGRAM mission? And that includes:		
1. Objectives of an outreach plan?		
2. Target populations?		
3. The types of outreach (including OUTREACH ACTIVITIES or OUTREACH EVENTS)?		
7.3.3 Outreach Events		
Does the state PROGRAM document and evaluate OUTREACH EVENTS using Appendix 7.2, or an equivalent form?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 7.2: Outreach Event Overview and Evaluation

Instructions: Attach documents such as agendas, meeting summaries, and program evaluations to this form.

Section I. Overview of Outreach Event

A. Type of outreach event (select all that apply):

_____ Meeting

_____ Extension Event

_____ Task Force/Committee

Workshop

Other

B. Date of outreach event _____

C. Objective of outreach event _____

D. Target population for outreach event _____

Section II. Evaluation of Outreach Event

Program Elements	Yes/No	If no, please explain
A. The purpose and objectives were clearly defined		
B. The context of the outreach event was consistent with the objectives		
C. An evaluation was completed by attendees		
D. State program reviewed and discussed comments from attendees		

Describe what went well, what could be done better, and what more could be done to improve the outreach event.

Completed By:

Name _____ **Date** _____

Appendix 8.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
8.3.1 Workplan		
Does the state PROGRAM have a documented workplan that includes the?		
1. Inspection plan?		
1.1 Number of inspections?		
1.2 Type of inspection?		
1.3 Risk category of establishment or product?		
1.4 Frequency?		
2. Sample plan?		
2.1 Number of samples?		
2.2 Type of samples?		
3. Timeframe that the workplan is applicable?		
8.3.2 Workplan Procedure		
4. Does the state PROGRAM have a procedure for evaluating the workplan that includes?		
4.1 Conducting evaluations of the workplan at least every 12 months?		
4.2 Evaluating alignment with state PROGRAM objectives and resources?		

Program Elements	Yes/No	Notes
5. Does the state PROGRAM have a procedure for identifying and evaluating its resources to accomplish the workplan within the applicable timeframe?		
6. Has the state PROGRAM developed a formula and calculated the number of staff needed to accomplish the state PROGRAM'S ANIMAL FOOD workplan based on staff assignments, responsibilities, and work hours?		
8.3.3 Equipment		
Does the state PROGRAM establish and maintain a list of the equipment required for inspections and sample collections?		
8.3.4 Resource Review		
1. Has the state PROGRAM conducted a baseline evaluation of the resources required to IMPLEMENT the AFRPS? Including the program elements and the documentation requirements in the standards to determine whether the state PROGRAM has:		
1.1 Adequate staff?		
1.2 Equipment?		
1.3 Funding?		
2. Does the state PROGRAM complete subsequent resource evaluations to determine the resources necessary for the state PROGRAM to partially meet, fully meet, or maintain IMPLEMENTATION of the program elements and documentation requirements within three years of the previous evaluation?		
3. Is the evaluation recorded on Appendix 8.2, or an equivalent form?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 8.2: Resources for Implementation of Animal Food Regulatory Program Standards

Instructions: This table provides an overview of a state PROGRAM'S evaluation of the resources needed to IMPLEMENT the Animal Food Regulatory Program Standards. Based on the evaluation, indicate for each standard whether the state PROGRAM has the resources needed for funding, staffing, and equipment by inserting 'Yes' or 'No' in the corresponding block. If 'No', please explain. Resources not related to funding, staffing, and equipment needed for IMPLEMENTATION should be in the "Other Resources Needed" column.

Note: Information technology may be considered as part of the state PROGRAM'S resource needs.

Standard		Funding	Staffing	Equipment	Other resources needed
1	Regulatory Foundation				
2	Training Program				
3	Inspection Program				
4	Audit Program				
5	Animal Food-Related Illness or Death and Emergency Response				
6	Compliance and Enforcement Program				
7	Outreach Program				
8	Program Planning and Resources				
9	Assessment and Improvement				
10	Laboratory Services				
11	Sampling Program				

Appendix 9.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
9.3.1 Self-Assessment Worksheets		
Has the state PROGRAM conducted a baseline evaluation using the self-assessment worksheets from each standard to determine if a standard is fully met, partially met, or not met?		
9.3.2 Strategic Improvement Plan		
Has the state PROGRAM developed a strategic improvement plan to IMPLEMENT the program elements or documentation requirements of each standard? Does the strategic improvement plan include the following, as applicable?		
1. The program element or documentation requirement of the standard that was not met?		
2. Improvements or CORRECTIVE ACTIONS needed to IMPLEMENT the program element or documentation requirement of the standard?		
3. The cause for any DEVIATIONS requiring CORRECTIVE ACTIONS when the state PROGRAM was previously in IMPLEMENTATION with the program element or documentation requirement of a standard?		
4. The PREVENTIVE ACTION taken to prevent future similar DEVIATIONS when the state PROGRAM was previously in IMPLEMENTATION with the program element or documentation requirement of the standard that was corrected?		

Program Elements	Yes/No	Notes
5. Projected completion date for each improvement or CORRECTIVE ACTION?		
6. Personnel responsible?		
7. Date completed?		
9.3.3 Strategic Improvement Plan Review		
Does the state PROGRAM review and update at least every 12 months the following?		
1. The self-assessment worksheets?		
2. The strategic improvement plan?		
9.3.4 Document Control Procedure		
3. Does the state PROGRAM have a procedure for DOCUMENT CONTROL that ensures all guidance and procedures required by the standards are CURRENT AND FIT-FOR-USE?		
4. Does the state PROGRAM maintain a master document list of all documents subject to this procedure to demonstrate they are CURRENT AND FIT-FOR-USE?		
9.3.5 Record Retention		
Does the state PROGRAM retain records required under x.5 of each standard for the three previous years, or per the state PROGRAM'S record retention policy?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 10.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
10.3.1 Laboratory Support		
1. Does the state PROGRAM maintain a list of analytical services the REGULATORY TESTING LABORATORIES provides for the state PROGRAM?		
2. Does the state PROGRAM have a documented formal agreement with the REGULATORY TESTING LABORATORY that conducts routine analytical services unless under the same administrative agency?		
10.3.2 Laboratory Sample Integrity Procedure		
Does the state PROGRAM have procedures developed by the REGULATORY TESTING LABORATORY to maintain the integrity of the samples sent to the REGULATORY TESTING LABORATORY for analytical testing that includes:		
1. Sample receipt?		
2. Preservation?		
3. Storage?		
4. Retention?		
5. Disposal?		
6. Chain of custody?		
7. Report of analysis?		

Program Elements	Yes/No	Notes
8. Methods used to communicate information between the state PROGRAM and REGULATORY TESTING LABORATORY?		
10.3.3 Laboratory Quality Assurance Program		
Does the state PROGRAM utilize REGULATORY TESTING LABORATORIES that:		
1. Are accredited by a recognized accreditation body to ISO/IEC17025:2017 or current version? or		
2. Implement and comply with the AAFCO Quality Assurance/Quality Control guidelines? or		
3. Implement and comply with the ISO/IEC 17025:2017 or current version?		

Assessment Completed By:

Name _____ **Date** _____

Appendix 11.1: Self-Assessment Worksheet

Instructions: The state PROGRAM identifies if they have a specified program element then evaluates if it includes the associated program elements. If the state PROGRAM has the main program element and associated program elements check 'Yes', if not, check 'No'. If "No", please explain why the program element is not met in the Notes column. The Notes column may be used for additional notes.

State Agency _____

Implementation Status **Fully Met** **Partially Met** **Not Met** _____

Program Elements	Yes/No	Notes
11.3.1 Sampling Plan		
Does the state PROGRAM have a documented sampling plan, at least every 12 months, for collecting surveillance, compliance, investigational, regulatory samples, or other samples?		
1. Do the state PROGRAM and REGULATORY TESTING LABORATORY jointly develop and amend the sampling plan, at least every 12 months, for performing routine analytical services to allow for advanced planning and scheduling of work?		
2. Does the sampling plan includes the:		
2.1 Availability or coordination of analytical support?		
2.2 Sampling priorities?		
2.3 SAMPLE ANALYIS SCHEDULE		
Does the SAMPLE ANALYIS SCHEDULE includes the:		
2.3.1 Types of ANIMAL FOOD to be analyzed?		
2.3.2 Number of samples to be collected?		
2.3.3 Estimated timeframe for collection?		
2.3.4 Types of analysis to be performed?		

Program Elements	Yes/No	Notes
11.3.2 Sampling Procedure		
Does the state PROGRAM have procedures for collecting, storing, and transporting samples that includes:		
1. Following safety precautions on ANIMAL FOOD labels?		
2. Following the state PROGRAM'S safety protocols for collecting samples?		
3. Using appropriate method, sampling collection procedures, and equipment to collect the sample?		
4. Sealing the sample to initiate chain of custody?		
5. Maintaining and documenting sample integrity, security, and chain of custody?		
6. Issuing receipt for the sample?		
7. Handling, packaging, and shipping samples to prevent compromising the condition of sample?		
8. Delivering or shipping samples to the appropriate REGULATORY TESTING LABORATORY within designated timeframes?		
11.3.3 Sample Collection Report		
Does the state PROGRAM have a procedure for completing the sample collection report that includes the:		
1. Identification of sample collector?		
2. Date of the sample collection?		
3. Product identification?		
Does the production identification include the:		

Program Elements	Yes/No	Notes
3.1 Name?		
3.2 Lot numbers or any other codes referencing manufacture identification?		
4. Description of product?		
5. Method of collection and any special techniques used to collect sample?		
6. Lot sampled?		
7. Lot size?		
8. Location where sample was collected?		
9. Name and address of responsible party, guarantor, possessor, or distributor?		
10. Sample type (example: surveillance, compliance, investigational, regulatory, or other)?		
11. Analysis requested, if applicable?		
12. Collection or reproduction of product label, including customer-formula label?		
13. Receiving and distribution information?		

Assessment Completed By:

Name _____ **Date** _____