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

The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

OMB Control No. 0910-0760
Expiration Date: 11/30/2024

Deleted: (
Deleted: To be entered after assigned
Deleted:)
Formatted: Not Highlight
Deleted: [
Deleted: enter month day, year
Deleted:]

TABLE OF CONTENTS

Deleted: December 2020

Deleted: December 2020

INTRODUCTION

The Food Safety Modernization Act (FSMA) mandates that the U.S. Food and Drug Administration (FDA) establish an Integrated Food Safety System (IFSS). An IFSS requires partnerships between federal, state, local, and tribal agencies to collaborate and leverage resources to ensure the protection of public health.

The Egg Regulatory Program Standards (ERPS) is a critical component in establishing FDA's IFSS. The ERPS, henceforth also referred to as "program standards," establishes a uniform foundation for regulatory agencies responsible for oversight of eggs and egg products. When fully implemented, the program standards define a set of best practices of a regulatory system. Conformance with the program standards requires a regulatory agency to continuously assess, evaluate, and take necessary corrective actions to address gaps. ERPS conformance will facilitate a system of mutual reliance between the FDA and other regulatory agencies and support continuous improvements in regulatory oversight of eggs and egg products throughout the nation.

The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from egg and egg product-related illness, injury, outbreaks and emergencies. The elements of these standards include: regulatory foundation, staff training, inspections, quality assurance, egg and egg product-related incident response, enforcement, industry outreach, resource management, program assessment and laboratory support.

Each standard is laid out in the following format to ensure uniformity: purpose statement (x.1), requirement summary (x.2), description of program elements (x.3), projected outcomes (x.4), and a list of required documentation (x.5). The program elements describe the best practices of a quality regulatory program. Required elements 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 throughout the program standards. Program elements and corresponding conditions described as "should" are best practices but are optional and not required to fully implement a standard. To fully implement the program standards, the regulatory program must implement all ten standards. "Notes" are used throughout the program standards to provide clarification, alternatives, and guidance that the state program may use to help implement the program standards. "Notes" do not contain requirements and thus will not be subject to an FDA assessment.

The program standards have corresponding self-assessment and supplemental worksheets designed to assist the regulatory program in achieving and sustaining conformance. The state program uses the self-assessment worksheets to determine if the standard's requirements are, or remain, fully met, partially met, or not met. The self-assessments are used to develop an improvement plan for fully implementing the requirements of the program standards.

Deleted: December 2020

FDA will use the program standards as a tool to continuously improve egg inspection contracts and promote the development of a high-quality egg inspection regulatory program, which includes a process for continuous improvement based upon quality management systems. The program standards will assist both FDA and the states in fulfilling their regulatory obligations. Implementation of the program is voluntary. States enrolled in the program standards under a FDA funding vehicle will be expected to develop and implement improvement plans to demonstrate that they are moving toward full implementation and to participate in FDA assessments to determine the level of conformance. States are encouraged to build systems that are sustainable and implement plans that will result in the standards being maintained in conformance.

The goal of the ERPS is to implement a nationally integrated, risk-based, egg safety system focused on protecting public health. The program standards establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of egg inspection programs in the United States. The development and implementation of these program standards will help federal and state programs better direct their regulatory activities toward reducing egg and egg product-related incidents. Consequently, the safety and security of the U.S. food supply will improve as greater focus is placed on prevention.

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.

Deleted: xxxx

Formatted: Not Highlight

Deleted: December 2020

BACKGROUND

In the U.S., federal and state government agencies ensure the safety of eggs and egg products. The FDA is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture (USDA) jurisdiction, are safe, wholesome, and labeled properly. State agencies conduct inspection and regulatory activities that help ensure food produced, processed, or sold within their jurisdictions is safe. Many state agencies also conduct egg inspections under contract with the FDA. These inspections either are performed under the states' laws and authorities or the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or both.

In an effort towards mutual reliance, FDA and the states should maximize their resources, particularly when their jurisdictions are overlapping. One of the foundational principles of an IFSS is the implementation and uniform application of model standards so that federal, state, territorial, tribal and local regulatory agencies conducting inspections under the same set of standards. The ERPS is the newest of several sets of national standards, each with a key role in strengthening the IFSS: Manufactured Food Regulatory Program Standards (MFRPS), Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), and the Animal Feed Regulatory Program Standards (AFRPS). All these standards provide a consistent, underlying foundation that is critical for uniformity across state and federal agencies to ensure the credibility of all programs under an IFSS.

In 2016, FDA awarded cooperative agreements to two state programs with one outcome being to provide recommendations for national egg regulatory program standards. In 2019 a committee comprised of officials from FDA, state agencies, academia, industry and the National Egg Regulatory Officials (NERO) was established to review the recommendations of the awardees. The result of the committee's collaborative work is the development of the first edition of the ERPS, which will strengthen states' egg regulatory programs. These program standards reflect an effort in which FDA has been engaged in partnering, leveraging and empowering agencies to move the vision of a nationally integrated food safety system.

Deleted: December 2020

DEFINITIONS

CONFORMANCE: the fulfillment of a requirement, specifically a state program is using and can demonstrate the use of a particular element, system, or program listed in the ERPS.

CONSUMER COMPLAINT: are complaints made by the public regarding food products, facility, practices, labeling, and any other related activities.

CONTACT HOUR: one contact hour equals 60 minutes. An inspector qualifies for one contact hour of continuing education for each clock hour of participation.

CORRECTION: action to eliminate a detected non-CONFORMANCE.

CORRECTIVE ACTION: action to eliminate the cause of a non-CONFORMANCE and to prevent recurrence.

CURRENT AND FIT-FOR-USE: "current" indicates that documentation is signed and dated in accordance with program policies and 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.

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.

EGG: the shell egg of a domesticated avian species such as chicken, duck, goose, guinea, quail, ratites or turkey. Egg does not include: (a) a balut; or (b) the egg of reptile species, such as alligator.

EGG AND EGG PRODUCT RELATED INCIDENT: contamination or adulteration (threatened or actual) of EGG and EGG PRODUCTs that may occur at any point in the production system (e.g., production, processing, distribution). These incidents may be unintentional or deliberate and may cause EGG and EGG PRODUCT-related illness, injury, outbreaks or emergencies from an unforeseen or sudden occurrence requiring immediate action to protect against substantial risk to animal and/or public health.

EGG HANDLER: any person, excluding the household consumer, who engages in any business in commerce that involves buying or selling any EGGS or processing any EGG PRODUCTS, or otherwise using any EGGS in the preparation of human food.

EGG PRODUCER: any person, firm, or corporation that produces EGGS.

EGG PRODUCTS: all, or a portion of, the contents found inside EGGS separated from the shell and pasteurized in an ESTABLISHMENT, with or without added ingredients, intended for

Deleted: December 2020

human consumption, such as dried, frozen or liquid eggs. Egg Product does not include food which contains EGGS only in a relatively small proportion such as cake mixes.

ENVIRONMENTAL ASSESSMENT (Also referred to as an "Environmental Health Assessment"): an on-site EGG and EGG PRODUCT investigation to assess and rule out the potential that the contaminant of concern was introduced at a particular point in the distribution or production system. This is achieved by identifying contributing factors and environmental antecedents.

EQUIVALENT: state law directly references the relevant federal regulation and/or statutes.

EQUIVALENT IN EFFECT: state law can achieve the same regulatory effect as the federal statutes and/or regulation.

ESTABLISHMENT: a corporate office, factory, outlet, EGG PRODUCER, or other facility manufacturing, processing, packing, holding, transporting, preparing or selling EGGS at wholesale or retail.

EVALUATION: an inspection in which the ability of an inspector is assessed to determine if they are competent to complete independent inspections. The evaluation should assess an inspector's ability to: prepare for an inspection, conduct an inspection, follow procedures identified by the state for the specific type of inspection and communicate during the inspection and on the inspection report.

FDA ASSESSMENT: a systematic, independent, and documented process for obtaining objective evidence and evaluating it to determine the extent to which a requirement is met. The FDA will determine IMPLEMENTATION and CONFORMANCE during each ASSESSMENT.

FIELD INSPECTION AUDIT: an inspection in which a state inspector is accompanied by a QUALIFIED FIELD INSPECTION AUDITOR (either FDA or state) for the purpose of assessing the quality and performance of inspections either contract or state. These inspections may be counted under 2.3.2.3 and 2.3.3.3 Field Training as evaluations, and under 4.3.3 FIELD INSPECTION AUDIT if Appendix 4.3 is used.

IMPLEMENTATION: means a state program has a particular element, system, or program as required in the Program Elements and documentation requirements for the ERPS.

INDUSTRY COMPLAINT: complaints made by industry about inspections or inspectors.

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 to a state inspector during an inspection of a firm and may either be trainer led or trainee led.

Deleted: December 2020

LABORATORY: a lab that conducts measurements and analyses on EGG and associated physical samples, which result in qualitative or quantitative analytical findings that may be used as a basis for regulatory action.

NO AUTHORITY: responsibility for enforcing a specific section of the federal statutes and/or regulations 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: (1) There is no state law EQUIVALENT to the relevant federal law or regulation, or (2) the federal and state laws address the same matter but are inconsistent and do not have the same regulatory effect.

OUTREACH ACTIVITY EVENT: an outreach activity which the state program hosts, co-hosts, or is an invited presenter such as seminars, workshops, conferences, trainings, or meetings that relate to EGG and EGG PRODUCT topics and that support communication and information exchange among the EGG industry stakeholders, academia, other regulators, or consumers.

PREVENTIVE ACTION: action to eliminate the cause of a potential non-CONFORMANCE.

QUALIFIED DATE: the qualified date begins when an inspector has completed all course and field elements and has been signed off to perform independent inspections. This date is used to calculate the start of the continuing education hours.

QUALIFIED FIELD INSPECTION AUDITOR: an individual who is recognized by the regulatory jurisdiction's EGG safety program manager as having field experience and communication skills necessary to audit other inspectors/investigators and who has: successfully completed EGG safety inspection training coursework and field training, been assigned this auditing responsibility, and completed the required audit training per the state program requirements.

Deleted: S

QUALIFIED FIELD INSPECTION TRAINER: an individual who is recognized by the regulatory jurisdiction's EGG safety program manager as having field experience and communication skills necessary to train or supervise other inspectors/investigators and who has: successfully completed EGG safety inspection training coursework and field training, been assigned this training responsibility, and state program includes a definition of "qualified trainer" within their training plan.

REGULATORY FOUNDATION: the law, regulations, rules, ordinances, or other regulatory requirements that govern an EGG facility.

RECALL AUDIT CHECK: are conducted by the state program to verify the firm's recall was successful as defined by the state's recall procedures.

Deleted: S

SAMPLING PROGRAM: a program in which the state collects samples as part of their egg safety program in one or more of the sampling types as defined in the Partnership for Food Protection's (PFP) Food/Feed Testing Laboratories Best Practices Manual (most current

Deleted: December 2020

version). [1] The program can be based on state defined sampling frequency and does not have to be continuous or routine.

SMALL EGG PRODUCER: any EGG PRODUCER with less than 3,000 hens.

START DATE: date an employee is hired or reassigned in or into the state program as the beginning date for training timelines.

STRATEGIC IMPROVEMENT PLAN: a type of improvement plan that includes the following information: (1) the individual element or documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, (3) projected completion dates for each task, (4) personnel responsible, and (5) date completed.

VERIFICATION AUDIT INSPECTION: an inspection in which a qualified FDA or state auditor observes a state qualified auditor performing an audit of a state inspector conducting an inspection.

[1] Reference: PFP Food/Feed Testing Laboratories Best Practices Manual: https://www.pfp-ifss.org/ifss-resources/human-and-animal-food-testing-laboratories-best-practices-manual-december-2018/

Deleted: December 2020

STANDARD No. 1
Regulatory Foundation

1.1 Purpose

This standard describes the elements of the REGULATORY FOUNDATION used by the state program to regulate EGGS.

1.2 Requirement Summary

The state program evaluates the scope of its legal authority and regulatory provisions to ensure the protection of EGGS within its jurisdiction. The state program's evaluation includes a determination of how the state's legal authority and regulatory provisions correspond to the sections of the Federal Food, Drug, and Cosmetic Act (FD&C) and Code of Federal Regulations (CFR) specified in Appendix 1.2.

1.3 Program Elements

1.3.1 Evaluation of Legal Authority

The state program has a written procedure to evaluate the legal authority and regulatory provisions to inspect and investigate, gather evidence, collect and analyze samples and take regulatory actions under state law to ensure the safety and security of EGGS. The written procedure must:

1.3.1.1 Include timeframes for a REGULATORY FOUNDATION evaluation.
1.3.1.2 Describe the REGULATORY FOUNDATION evaluation process, to include whenever significant changes are made to applicable federal and/or state laws and regulations; and
1.3.1.3 Address the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:

1.3.1.3.1 Apply to the regulation of EGGS;
1.3.1.3.2 Delegate authority to the state program;
1.3.1.3.3 Describe the state program's administrative procedures for rulemaking to protect public health; and
1.3.1.3.4 Identifies and lists other state or federal agencies that have authority for any area of the REGULATORY FOUNDATION that the state program lacks.

1.3.2 REGULATORY FOUNDATION Evaluation

1.3.2.1 The state program must complete Appendix 1.2 or equivalent form. The state program conducts an evaluation to determine if they are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT,

Deleted: December 2020

or NO AUTHORITY to sections of the current FD&C Act and CFR Title 21 specified in Appendix 1.2.

1.3.2.2 If the state program has laws and regulations pertinent to the regulation of EGGS, for which there are no federal provisions, these laws and regulations can also be listed in Appendix 1.2 or equivalent form.

Note: In conducting an evaluation, the state program should consult with legal counsel when state law 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.

1.4 Outcome

The state program has conducted an evaluation of the scope of their legal authority and has a REGULATORY FOUNDATION adequate to protect the public health by ensuring the safety and security of EGGS.

1.5 Documentation

The state program maintains the records listed here.

1.5.1 State program's written REGULATORY FOUNDATION evaluation procedure.

1.5.2 The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of EGGS, (2) delegate authority to the state program, (3) describe the state program's administrative procedures for rulemaking to protect public health, (4) identify and list other state or federal agencies that have authority for any area of the REGULATORY FOUNDATION that the state program lacks.

1.5.3 Appendix 1.1 Self-Assessment Worksheet (or equivalent forms)

1.5.4 Appendix 1.2 Regulatory Foundation Worksheet (or equivalent forms)

1.5.5 If applicable, review by legal counsel

Deleted: December 2020

STANDARD No. 2
Training Program

2.1 Purpose

This standard defines the essential elements of a training program for inspectors in a state program to ensure they will have the knowledge, skills, and capabilities to competently inspect ESTABLISHMENTS.

2.2 Requirement Summary

The state program establishes a written training plan that promotes development and demonstrates that all inspectors who will conduct inspections complete coursework, field training, and continuing education to adequately perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The state program uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments. The training plan includes curriculum for basic and advanced inspection training and continuing education. Curriculum consists of coursework and field training.

2.3.1.2 The state program maintains a training history for active inspectors. The training history for all inactive inspectors must be kept for three years or per the state's record retention policy.

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

2.3.1.4 The state program's training record summary and individual training records must include the inspector's START DATE.

2.3.1.5 For inspectors with greater than five years of experience at the date of the initial self-assessment, where their training documentation is not available the state program will:

2.3.1.5.1 Conduct an EVALUATION of the inspector's previous performance and experience to determine if the inspector has completed the required training or whether additional training is needed; and

2.3.1.5.2 Document the results of the EVALUATION.

2.3.2 Basic Inspection Training: The state program requires that each inspector completes inspection training curriculum.

Deleted: December 2020

2.3.2.1 Timeframe: The basic inspection training curriculum shall be successfully completed within 24 months of the inspector's START DATE with the state program.

2.3.2.2 Coursework: The basic inspection training consists of coursework in the subject areas listed in this section.

2.3.2.2.1 Prevailing statutes, regulations, and ordinances
2.3.2.2.2 Public health principles
2.3.2.2.3 Biosecurity protocols and procedures
2.3.2.2.4 Emergency management
2.3.2.2.5 Communications skills
2.3.2.2.6 Basic microbiology
2.3.2.2.7 Basics of HACCP
2.3.2.2.8 Basic sampling technique and preparation
2.3.2.2.9 State program EGG safety inspection manuals and guidance

2.3.2.3 Field Training: The state program has an established basic field training program to complement the coursework curriculum which specifies the following:

2.3.2.3.1 The inspector must complete the field training program prior to performing basic independent inspections;
2.3.2.3.2 Field training checklist of competencies to be mastered and verified in the field by the QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR;
2.3.2.3.3 Written procedures for JOINT FIELD TRAINING INSPECTIONS;
2.3.2.3.4 Number of JOINT FIELD TRAINING INSPECTIONS or FIELD INSPECTION AUDITS that are conducted in ESTABLISHMENTS that are representative of the ESTABLISHMENTS in the state program inventory, as well as the type of work that will be performed by the inspector;
2.3.2.3.5 The qualifications, education, and experience necessary to be identified as a QUALIFIED FIELD INSPECTOR TRAINER and/or QUALIFIED FIELD INSPECTION AUDITOR;
2.3.2.3.6 Appendix 2.3 or an equivalent form must be used to list the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS.

Deleted: December 2020

2.3.3 Advanced Training: The advanced inspection training consists of curriculum in the subject areas listed in this section. Each inspector who will conduct advanced EGG inspections will complete the relevant coursework and field training as described below.

2.3.3.1 Timeframe: The advanced inspection training curriculum shall be successfully completed within the timeframe specified by the state program.

2.3.3.2 Coursework: The advanced inspection training consists of coursework in the subject areas listed in this section.

2.3.3.2.1 EGG Safety Inspections: Complete coursework required to conduct inspections of ESTABLISHMENTS under the oversight of the state program, which may include the EGG safety regulations (21 CFR 115 and 21 CFR 118).

2.3.3.2.2 Traceback investigations

2.3.3.2.3 Foodborne illness investigations

2.3.3.2.4 Other training as developed by the state program

Note: Traceback investigations and foodborne illness investigations advanced training courses are not subject to 2.3.2.2 Field Training requirements.

2.3.3.3 Field Training: The state program has an established advanced field training program to complement the coursework curriculum which specifies the following:

2.3.3.3.1 The inspector must complete the field training program prior to performing advanced independent inspections;

2.3.3.3.2 Participate in two JOINT FIELD TRAINING INSPECTIONS;

2.3.3.3.3 After successful completion of the coursework, participate in one EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR; and

2.3.3.3.4 Within one year after being released to do advanced inspections complete a second EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

Note: Should the course used to satisfy 2.3.2.2.1 include hands-on training at an ESTABLISHMENT, the participation may be counted as one of the two JOINT FIELD TRAINING INSPECTIONS required under 2.3.2.3.1.

Deleted: December 2020

Note: States may add or further subdivide their training by identifying coursework required for inspectors who only inspect EGG distribution/warehouses/retail facilities. The coursework must be clearly defined in the state program training plan.

2.3.4 Continuing Education

The goal of continuing education is to build upon the inspector's knowledge base and enhance their skills and ability to perform inspections. The training plan must include:

2.3.4.1 Each inspector must accumulate 20 CONTACT HOURS of continuing education every 36 months.

2.3.4.2 The 36-month continuing education interval starts at the QUALIFIED DATE, when the training cycle is completed.

2.3.4.3 The state program may establish an alternate timeframe to track continuing education as long as the alternate timeframe and how that timeframe still meets or exceeds the intent of the standard (at least 20 CONTACT HOURS every 36 months) are clearly identified in program procedures.

2.3.4.4 The inspector qualifies for CONTACT HOURS by participation in any of the following activities that are related specifically to EGG inspectional work:

2.3.4.4.1 Attendance at national or regional seminars/technical conferences, such as National Egg Quality School (NEQS) or National Egg Regulatory Officials (NERO);
2.3.4.4.2 Professional symposiums/college courses;
2.3.4.4.3 Training provided by government agencies (e.g., FDA, USDA, state, local);
2.3.4.4.4 In-house training provided by state government agencies;
2.3.4.4.5 Conferences and workshops;
2.3.4.4.6 Distance learning opportunities; or
2.3.4.4.7 Training approved by a QUALIFIED FIELD INSPECTION TRAINER.

2.3.4.5 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of 10 CONTACT HOURS may be accrued from the following EGG-related activities:

2.3.4.5.1 Delivering presentations at professional conferences;
2.3.4.5.2 Providing classroom and/or field training to inspectors, or being a course instructor; or
2.3.4.5.3 Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Deleted: December 2020

2.3.4.6 Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation may include:

2.3.4.6.1 Certificates of completion indicating the course date(s) and number of hours attended or continuous education credits granted;
2.3.4.6.2 Transcripts from a college or university;
2.3.4.6.3 A letter from the administrator of the continuing education program attended;
2.3.4.6.4 A copy of the peer-reviewed article or presentation made at a professional conference; or documentation to verify technical publications related to EGG safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports;
2.3.4.6.5 An agenda and attendance roster; or
2.3.4.6.6 Documentation approved by the QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.5 Coursework Sources: Basic, advanced, and continuing education coursework must be obtained from one of the sources listed here:

2.3.5.1 Training provided by a government agency (including in-house training);
2.3.5.2 Distance learning, for example, satellite downlinks or web-based training;
2.3.5.3 Colleges, schools, research centers, and institutes.

2.4 Outcome

The state program has trained inspectors with the knowledge, skills, and abilities to competently inspect, conduct investigations, gather evidence, collect samples, and take enforcement actions regarding EGG PRODUCERS.

2.5 Documentation

The state program maintains the records listed here.

2.5.1 Written Training Plan
2.5.2 Appendix 2.1 Self-Assessment Worksheet (or equivalent form)
2.5.3 Appendix 2.2 Inspector Training Record (or equivalent form)
2.5.4 Appendix 2.3 Field Training Competencies (or equivalent form)

Deleted: December 2020

2.5.5 Documents verifying successful completion of required courses
2.5.6 Evaluation for experienced inspectors
2.5.7 FIELD TRAINING INSPECTIONS, EVALUATIONS or FIELD INSPECTION AUDITS
2.5.8 Documentation for continuing education credit

Deleted: December 2020

STANDARD No. 3
Inspection Program

3.1 Purpose

This standard describes the elements of an effective EGG safety inspection program.

3.2 Requirement Summary

The state program has written EGG safety inspection and sampling procedures. These procedures provide the foundation for inspecting and sampling at EGG PRODUCERS and EGG HANDLERS to determine compliance with the laws administered by Federal and State jurisdictions.

3.3 Program Elements

3.3.1 Risk-based Inspection Program

The state program has written procedures to:

3.3.1.1 Define an up-to-date inventory of registered EGG PRODUCERS and EGG HANDLERS for which the state has regulatory oversight. The inventory is categorized by the risk associated with the likelihood that an EGG AND EGG PRODUCT RELATED INCIDENT will occur.

3.3.1.2 Determine a firm's level of associated risk and the program's inspectional priorities. The state program must use the risk factors and associated criteria as described in:

3.3.1.2.1 FDA's Multi-Criteria Decision Analysis Methodology Used to Prioritize Inspections of Egg Farms for Monitoring Compliance with the Egg Safety Rule;[2] or

3.3.1.2.2 FD&C Act, Section 421 (a)(1); or

3.3.1.2.3 The state program may choose to develop its own risk-based assessment. If the state program chooses to develop its own risk factor and classification criteria a written rationale must be provided that demonstrates how public health is protected.

3.3.1.3 Prioritize and assign inspection frequencies based on established risk categories.

3.3.2 Inspection Procedure

[2] FDA's Multi-Criteria Decision Analysis Methodology Used to Prioritize Inspections of Egg Farms for Monitoring Compliance with the Egg Safety Rule: https://www.fda.gov/media/81379/download

Deleted: December 2020

The state program has a written procedure for inspecting EGG PRODUCERS and EGG HANDLERS that require the inspectors to:

3.3.2.1 Review the ESTABLISHMENT'S previous inspection report, CONSUMER COMPLAINTS, and current disease status;

3.3.2.2 Have appropriate equipment and forms. Equipment must be verified, operated and maintained as defined by the state program's procedures which may include manufacturer's recommendations;

3.3.2.3 Behave professionally and demonstrate proper biosecurity practices during the inspection similar to those found in:

3.3.2.3.1 Compliance Policy Guidance Manual (CPGM);[3] or

3.3.2.3.2 FDA Investigation Operations Manual (IOM).[4]

3.3.2.4 Follow safety protocols required by the facility and the state program;

3.3.2.5 Make appropriate introductions and explain the purpose and scope of the inspection;

3.3.2.6 Establish jurisdiction;

3.3.2.7 Determine the ESTABLISHMENT registration status;

3.3.2.8 Use suitable interviewing techniques;

3.3.2.9 Assess employee practices critical to the safe and sanitary production, processing and storage of EGGS;

3.3.2.10 Evaluate conditions, practices, components, and/or labeling that could cause the product to be adulterated or misbranded or otherwise in violation of applicable law(s);

3.3.2.11 Recognize significant violative conditions or practices, if present, and record findings consistent with state program procedures;

3.3.2.12 Review and verify that records and procedures for the ESTABLISHMENT'S operation are being kept and properly followed;

3.3.2.13 Collect adequate evidence and documentation to support inspection observations in accordance with state program procedures;

3.3.2.14 Verify correction of deficiencies that were identified during previous inspections;

3.3.2.15 Evaluate the ESTABLISHMENT operations through on-site inspectional observations;

3.3.2.16 Alert the ESTABLISHMENT'S person in charge when an immediate action is necessary to correct a violation;

[3] Reference: FDA Compliance Program Guidance Manual 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule" can be found: https://www.fda.gov/downloads/Food/ComplianceEnforcement/FoodCompliancePrograms/UCM555664.pdf

[4] Reference: FDA's IOM contains several relevant chapters including the following: Chapter 4- Sampling, Chapter 5- Establishment Inspections (includes biosecurity requirements) and Chapter 7- Recall Activities: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual

Deleted: December 2020

3.3.2.17 Explain findings clearly and adequately throughout the inspection;
3.3.2.18 Answer questions and provide information in an appropriate manner; and
3.3.2.19 Write findings accurately, clearly and concisely and provide a copy to the ESTABLISHMENT'S person in charge.

3.3.3 Inspection Report Procedure

The state program has a written inspection report procedure that requires inspectors to:

3.3.3.1 Document significant violative conditions or practices, if present, consistent with state program procedures;
3.3.3.2 Accurately complete the inspection report;
3.3.3.3 Submit the inspection report within designated timeframes consistent with state program procedures;
3.3.3.4 Follow up with corrective, compliance, and enforcement actions as warranted.

3.3.4 Recalls[5]

The state program has a recall system with written recall procedures for:

3.3.4.1 Sharing information about recalls with relevant industry and partner agencies; and
3.3.4.2 Ensuring recalled products are removed promptly from the market; and
3.3.4.3 Performing RECALL AUDIT CHECKS.

3.3.5 Complaints

3.3.5.1 The state program has a written system for handling CONSUMER COMPLAINTS. The system contains procedures for:

3.3.5.1.1 Receiving;
3.3.5.1.2 Tracking;
3.3.5.1.3 Evaluating;
3.3.5.1.4 Responding to;
3.3.5.1.5 Closing; and
3.3.5.1.6 Maintaining records of CONSUMER COMPLAINTS.

3.3.5.2 The state program has a written system for handling INDUSTRY COMPLAINTS. The system contains written procedures for:

[5] Reference: PFP Best Practices for Improving FDA and State Communication During Recalls https://www.pfp-ifss.org/ifss-resources/best-practices-for-improving-fda-and-state-communications-during-recalls-summer-2015/

Deleted: December 2020

3.3.5.2.1 Receiving;
3.3.5.2.2 Evaluating;
3.3.5.2.3 Responding to; and
3.3.5.2.4 Maintaining records of INDUSTRY COMPLAINTS.

3.3.6 SAMPLING PROGRAM

3.3.6.1 State programs that conduct EGG and/or environmental sampling, must have a written sampling plan in place.[6] The state program shall develop, coordinate, and document a written annual sampling plan that includes:

3.3.6.1.1 Sampling priorities;
3.3.6.1.2 Number of samples;
3.3.6.1.3 Type of samples;
3.3.6.1.4 The sample analysis schedule; and
3.3.6.1.5 Availability or coordination of analytical LABORATORY support.

3.3.6.2 For the state programs that conduct environmental or EGG sampling, a SAMPLING PROGRAM must have written sampling procedures that include:

3.3.6.2.1 Methods for Collecting Storing/Transporting and Documenting Samples

3.3.6.2.1.1 Follow the state program's sampling policies, and procedures to assure sample integrity, security, accountability, and chain of custody;
3.3.6.2.1.2 Use appropriate method and equipment to collect the sample;
3.3.6.2.1.3 Seal sample to initiate chain of custody;
3.3.6.2.1.4 Maintain and document sample integrity, security and chain of custody;
3.3.6.2.1.5 Handle, package, and ship sample to ensure sample integrity and prevent compromising condition of sample; and

[6] Reference: FDA's Environmental Sampling and Detection of Salmonella in Poultry Houses: https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm114716.htm

Deleted: December 2020

3.3.6.2.1.6 Deliver or ship sample to the appropriate LABORATORY within acceptable timeframes.

3.3.6.2.2 Instructions for documenting the sample collection must include the following elements when applicable to the states' SAMPLING PROGRAM

Deleted: S

3.3.6.2.2.1 Date of sample collection;
3.3.6.2.2.2 Sample identification which may include: name, firm, house, sample number assigned by the sampler at the time of collection and type (EGG, belt, manure, walkway, etc.);
3.3.6.2.2.3 Method of collection and any special techniques used to collect sample;
3.3.6.2.2.4 Location where sample was collected;
3.3.6.2.2.5 Reason for collection (surveillance, compliance, investigational, regulatory or other);
3.3.6.2.2.6 Analysis requested;
3.3.6.2.2.7 Receiving and distribution information;
3.3.6.2.2.8 Observations recorded at the time of collection; and
3.3.6.2.2.9 Product labels or specific labeling information that is collected or reproduced per state policies.

3.3.6.3 State programs are not required to have a written sampling procedure or sampling plan unless they collect samples. However, these programs must have a statement in lieu of sampling procedures that explains why a SAMPLING PROGRAM is not supported and how the public health is protected because another state or federal agency collects samples and fulfills this need. The statement should include the name of the agency and the type of samples that it collects.

3.4 Outcome

The state program is based on an inspection program that reduces the occurrence of EGG AND EGG PRODUCT RELATED INCIDENTS.

3.5 Documentation

The state program maintains the records listed here.

3.5.1 Appendix 3.1 Self-Assessment Worksheet (or equivalent form)

Deleted: December 2020

3.5.2 An inventory of EGG PRODUCERS and EGG HANDLERS
3.5.3 Written procedures of a risk-based inspection program
3.5.4 Written inspectional report findings
3.5.5 Written inspectional report procedure
3.5.6 Written recall system which includes written recall procedures
3.5.7 Written procedures for CONSUMER COMPLAINTS
3.5.8 Written procedures for INDUSTRY COMPLAINTS
3.5.9 Written sampling plan
3.5.10 Written sampling procedures
3.5.11 Written statement stating how public health is protected in lieu of written sampling plan and sampling procedures

Deleted: December 2020

STANDARD No. 4
Inspection Audit Program

4.1 Purpose

This standard describes auditing procedures necessary for a state program to (1) evaluate the effectiveness and accuracy of the inspection program, inspection records, and sampling records; and (2) identify best practices used to achieve quality inspections and sample collections.

4.2 Requirement Summary

The state program has a written process that conducts audits to assess the effectiveness and accuracy of its inspections and sample collections. The auditing procedures have two components: (1) a FIELD INSPECTION AUDIT component, which is an on-site performance evaluation of inspections and, if applicable, sample collections, and (2) a desk audit component, which is a performance review of the written reports of inspections and sample collections.

4.3 Program Elements

4.3.1 Audit Program

The state program has written procedures for:

4.3.1.1 FIELD INSPECTION AUDITS as described in section 4.3.3;
4.3.1.2 Inspection report audits as described in section 4.3.4;
4.3.1.3 Sample report audits as described in section 4.3.5;
4.3.1.4 CORRECTIVE ACTIONS as described in section 4.3.6; and
4.3.1.5 VERIFICATION AUDIT INSPECTIONS of QUALIFIED FIELD INSPECTION AUDITORS.

4.3.2 A review of the performance factor scores and cumulative scores for each type of audit is completed at least every 12 months.

4.3.3 FIELD INSPECTION AUDIT

4.3.3.1 A QUALIFIED FIELD INSPECTION AUDITOR conducts FIELD INSPECTION AUDITS to verify that inspections are consistently performed according to the state's written procedures described in Standard 3.
4.3.3.2 Frequency: A minimum of one FIELD INSPECTION AUDIT of each inspector is conducted every 36 months. Inspections selected for audits should include the highest risk firms that the inspector is trained for including advanced EGG inspections.

Deleted: December 2020

4.3.3.3 If samples are collected during the FIELD INSPECTION AUDIT, the collection of the samples shall also be audited, and the appropriate question(s) answered on Appendix 4.3.

4.3.3.4 Performance is documented on Appendices 4.3 and 4.3a or equivalent forms that meet the program elements in Standard 3, section 3.3.2.

4.3.4 Inspection Report Audit

4.3.4.1 The state program conducts annual reviews of inspection reports to verify that inspectional findings are obtained and reported according to established written procedure. The quality of each inspection report is audited using the performance factors listed in Appendix 4.4 or equivalent form.

4.3.4.2 The state program will review a random selection of inspection reports based on the number of inspections performed in the last 12 months using the table below:

Number of inspections in 12 Months	Minimum Number of Reports Required	Maximum Number of Reports Required
Less than 40 inspections	All	All
40 – 800 inspections	40	40
More than 800 inspections	5% of reports	70

4.3.4.3 Seven percent (7%) of the inspection reports reviewed must be taken from field inspections that were audited.

4.3.4.4 Performance is documented on Appendices 4.4 and 4.4a, or equivalent forms.

4.3.5 Sample Report Audit

4.3.5.1 If samples are collected by the EGG program, the auditing procedures require an annual review of sample reports to verify that sample information is obtained and reported according to the established written procedure described in Standard 3.

4.3.5.2 The state program will review a random selection of sample reports based on the number of samples collected in the last 12 months using the table below:

Deleted: December 2020

Number of samples in 12 Months	Minimum Number of Reports Required	Maximum Number of Reports Required
Less than 40 reports	All	All
40 – 800 reports	40	40
More than 800 reports	5% of reports	70

4.3.5.3 Performance is documented on Appendices 4.5 and 4.5a, or equivalent forms.

4.3.5.4 Sample report audits do not need to be performed unless samples are collected.

4.3.6 CORRECTIVE ACTIONS

The state program shall initiate CORRECTIVE ACTIONS as described in 9.3.5 for the FIELD INSPECTION AUDIT, inspection report audit, and sample report audit, when one or more of the conditions below are met:

4.3.6.1 An individual receives an overall rating of "needs improvement";
4.3.6.2 A single performance factor for the program falls below 80%; or
4.3.6.3 An overall rating for the program falls below 80%.

4.4 Outcome

The state program systematically evaluates and improves its inspection and sample collection systems to ensure that activities and information are adequate, complete, and comply with their procedures and policies.

4.5 Documentation

The state program maintains the records listed here.

4.5.1 Written auditing procedures
4.5.2 Appendix 4.1 Self-Assessment Worksheet (or equivalent form)
4.5.3 Appendix 4.3 Field Inspection Audit Form (or equivalent form)
4.5.4 Appendix 4.3a Performance Rating for Field Inspection Audits (or equivalent form)
4.5.5 Appendix 4.4 Inspection Report Audit Form (or equivalent form)
4.5.6 Appendix 4.4a Performance Rating for Inspection Report Audits (or equivalent form)
4.5.7 Appendix 4.5 Sample Report Audit Form (or equivalent form)
4.5.8 Appendix 4.5a Performance Rating for Sample Report Audits (or equivalent form)

Deleted: December 2020

STANDARD No. 5
Egg-Related Illness, Outbreak and Emergency Response

5.1 Purpose

This standard describes the functions to detect, identify, and respond to alleged EGG AND EGG PRODUCT RELATED INCIDENTS including coordinating roles and responsibilities with other jurisdictions and communicating with appropriate parties.

5.2 Requirement Summary

The state program has written procedures to conduct a response to EGG AND EGG PRODUCT RELATED INCIDENTS. The state program describes surveillance, investigation/ENVIRONMENTAL ASSESSMENT, control measures and post-response activities in collaboration with other agencies and jurisdictions for responding to reports of EGG AND EGG PRODUCT RELATED INCIDENTS, whether unintentional or deliberate, and for generating recommendations for foodborne illness prevention related to EGG and EGG PRODUCTS.

5.3 Program Elements

5.3.1 Coordination of EGG AND EGG PRODUCT RELATED INCIDENTS Response Activities with Other Authorities.

5.3.1.1 Memorandum of understanding with other state agencies. If the responsibility for state EGG AND EGG PRODUCT RELATED INCIDENTS is assigned to another state agency, a memorandum of understanding with this agency is required to fulfill the requirements of this standard.

5.3.1.2 The state program has a written procedure that:

5.3.1.2.1 Identifies and describes the roles, duties, and responsibilities of each program for the requirements in 5.3.2 through 5.3.5;

5.3.1.2.2 Describes agency collaboration as necessary with FDA and other appropriate local, state and federal authorities in multi-jurisdictional EGG AND EGG PRODUCT RELATED INCIDENTS;

5.3.1.2.3 Designates response coordinator(s) to guide program investigation efforts in collaboration with all agencies involved and manage events using a formalized Incident Command System (ICS) structure or an response action plan that includes:

5.3.1.2.3.1 Identifying and executing investigation objectives;

Deleted: December 2020

5.3.1.2.3.2 Managing communications;
5.3.1.2.3.3 Implementing control measures; and
5.3.1.2.3.4 Conducting post-response activities.

5.3.1.2.4 Describes how all government agencies, departments, or appropriate parties are rapidly notified of relevant findings in cases of EGG AND EGG PRODUCT RELATED INCIDENTS; and

5.3.1.2.5 Provides guidance for the immediate notification of law enforcement agencies when intentional EGG AND EGG PRODUCT RELATED INCIDENTS or terrorism are suspected or threatened.

Note: These procedures facilitate sharing of information to identify potential EGG AND EGG PRODUCT RELATED INCIDENTS, and cross-sector events.

5.3.1.3 The state program maintains a list of relevant agencies and emergency contacts that is reviewed and updated according to a frequency defined by the state.

5.3.1.4 The state program maintains records associated with procedures required in Program Elements 5.3.1-5.3.5.

5.3.2 Surveillance

The state program has written procedures to:

5.3.2.1 Uses epidemiological information from appropriate departments or agencies (federal, state, or local) to detect EGG AND EGG PRODUCT RELATED INCIDENTS; and

5.3.2.2 Maintains notifications of EGG AND EGG PRODUCT RELATED INCIDENTS that are reported to the program in a log or database.

5.3.3 Investigation/ENVIRONMENTAL ASSESSMENT

The state program:

5.3.3.1 Has a written procedure with recommended timeframes and criteria to investigate EGG AND EGG PRODUCT RELATED INCIDENTS that include:

5.3.3.1.1 Determining the appropriate response;
5.3.3.1.2 Initiating the response; and
5.3.3.1.3 Completing the response.

5.3.3.2 Has a written procedure to collect environmental data similar to those found in:

Deleted: December 2020

5.3.3.2.1 International Association for Food Protection's (IAFP) "Procedures to Investigate a Foodborne Illnesses"

5.3.3.2.2 Council to Improve Foodborne Outbreak Response's (CIFOR) "Guidelines for Foodborne Disease Outbreak Response" [7]

5.3.3.2.3 FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"[2]

5.3.3.2.4 FDA IOM Chapter 4 "Sampling" and IOM Chapter 5 "Establishment Inspection" Subchapter 5.2.10 "Routine Biosecurity Procedures for Visits to Facilities Housing and Transporting Domestic or Wild Animals"[3]

5.3.3.3 Has a written procedure to coordinate the traceback and traceforward of EGG and EGG PRODUCTS found to contain a hazard or that are implicated in an illness, injury, or outbreak.

5.3.3.4 Has access to LABORATORY support for investigation of reports of EGG AND EGG PRODUCT RELATED INCIDENTS.

Note: Specific requirements for support are contained in Standard 10.

5.3.3.5 Correlates and analyzes ENVIRONMENTAL ASSESSMENT data to identify contributing factors and antecedents that led to EGG AND EGG PRODUCT RELATED INCIDENTS.

5.3.4 Control Measures

The state program:

5.3.4.1 Mitigates and contains EGG AND EGG PRODUCT RELATED INCIDENTS through strategies that include industry education and outreach, enforcement and public awareness activities; and

5.3.4.2 Maintains a written procedure for releasing prevention guidance and information to the public (includes identifying a media person and developing guidelines for coordinating media information with other jurisdictions) to reduce the impact of EGG AND EGG PRODUCT RELATED INCIDENTS.

5.3.5 Post-Response

The state program has written procedures to:

5.3.5.1 Maintain program investigation and ENVIRONMENTAL ASSESSMENT findings and reports;

[7] Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for Foodborne Disease Outbreak Response: https://cifor.us/clearinghouse/cifor-guidelines-for-foodborne-disease-outbreak-response

Deleted: December 2020

5.3.5.2 Distribute final program investigation report(s), including an ENVIRONMENTAL ASSESSMENT, if completed, to relevant agencies responsible for reporting contributing factors and antecedents to CDC; and

5.3.5.3 Distribute recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach.

5.4 Outcome

The state program has written procedures for documenting and investigating EGG AND EGG PRODUCT RELATED INCIDENTS within the program's authority. The program has established communication pathways with government agencies, departments, or appropriate parties to gather and share information to stop, control and prevent EGG AND EGG PRODUCT RELATED INCIDENTS.

5.5 Documentation

The program maintains the records listed here:

5.5.1 Appendix 5.1 Self-Assessment Worksheet (or equivalent form)
5.5.2 Memorandums of Understanding, if applicable
5.5.3 Written procedures for coordination
5.5.4 Emergency contact list
5.5.5 Records associated with procedures required in Program Elements 5.3.1-5.3.5
5.5.6 Written procedures for surveillance
5.5.7 Log(s) or database(s) that tracks notification of EGG AND EGG PRODUCT RELATED INCIDENTS
5.5.8 Written procedures for investigation/ENVIRONMENTAL ASSESSMENT
5.5.9 Written procedures for control measures
5.5.10 Written procedures for post-response
5.5.11 Investigation/ ENVIRONMENTAL ASSESSMENT reports and summaries

Deleted: December 2020

STANDARD No. 6
Compliance and Enforcement Program

6.1 Purpose

This standard describes the elements of an effective enforcement program that includes strategies, procedures, and actions to enforce laws and regulations to achieve compliance.

6.2 Requirement Summary

The state program has a documented enforcement program which describes its compliance strategies and procedures. The program conducts an annual evaluation of the enforcement strategies to identify potential improvements or modifications.

6.3 Program Elements

6.3.1 The state program has a written compliance and enforcement procedure that describes the enforcement strategies, use of enforcement tools and progressive enforcement actions.

Note: Appendix 6.2 provides examples of common enforcement tools and progressive enforcement actions.

6.3.2 The state program has a written procedure for conducting an annual review of its compliance and enforcement procedure to:

6.3.2.1 Determine if the program's enforcement actions were successful in achieving compliance;
6.3.2.2 Identify potential improvements or modifications of the compliance and enforcement procedures, if any;
6.3.2.3 Either review all cases or use a statistical approach to determine a representative number of cases; and
6.3.2.4 Document results of the annual review on Appendix 6.3 or equivalent form.

6.4 Outcome

The state program has an effective enforcement program with documented enforcement strategies that identify a means to appropriately select and apply enforcement tools. An annual review of the enforcement program is conducted to identify potential improvements or modifications.

6.5 Documentation

The state program maintains the records listed here.

6.5.1 Appendix 6.1 Self-Assessment Worksheet (or equivalent form)
6.5.2 Written compliance and enforcement procedure

Deleted: December 2020

6.5.3 Written procedure for conducting an annual review of the compliance and enforcement procedure

6.5.4 Appendix 6.3 Calculation of the Level of Conformance to Compliance Procedures (or equivalent form)

Deleted: December 2020

STANDARD No. 7
Outreach Activities

7.1 Purpose

This standard describes the elements of outreach activities or OUTREACH ACTIVITY EVENTS developed or provided by the state program.

7.2 Requirement Summary

The state program participates in outreach activities or OUTREACH ACTIVITY EVENTS that support communication and information exchange among regulators, industry, academia, SMALL EGG PRODUCERS and consumer representatives. The state program also coordinates or participates in outreach activities or OUTREACH ACTIVITY EVENTS that provide educational information about EGG topics.

7.3 Program Elements

7.3.1 The state program has a written procedure of the methods that will be used for communication with the EGG industry stakeholders (may include SMALL EGG PRODUCERS), academia, other regulators, and consumers. The written procedure includes how the state program will:

Deleted: S

7.3.1.1 Identify the methods for communication with the EGG industry stakeholders, academia, other regulators, and consumers.

7.3.1.2 Interact with industry and consumers by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees.

7.3.1.3 Tailor outreach efforts to a target population which may include dissemination of information using electronic sources and traditional methods such as mailings.

7.3.1.4 Document and evaluate OUTREACH ACTIVITY EVENTS using Appendix 7.2 or equivalent form. Include documents such as agendas and meeting summaries and program evaluations.

7.3.1.5 Implement an outreach and training program that will include SMALL EGG PRODUCERS within the state. It will be inclusive of basic biosecurity and sanitation requirements to reduce the potential of an EGG AND EGG PRODUCT RELATED INCIDENT.

Deleted: S

7.3.2 The state program develops an outreach plan that supports the state program mission and includes:

7.3.2.1 Objectives of the outreach plan;

7.3.2.2 Target population;

7.3.2.3 Types of outreach activities and OUTREACH ACTIVITY EVENTS;

7.3.2.4 Delivery method; and

Deleted: December 2020

7.3.2.5 The templates provided in Appendix 7.3, or equivalent forms, are used to record the outreach plan.

7.4 Outcome

The state program uses outreach activities that will inform and educate varied populations on ways to reduce the occurrence of an EGG AND EGG PRODUCT RELATED INCIDENT.

7.5 Documentation

The state program maintains the records listed here.

7.5.1 Written procedure for methods used to communicate with EGG industry stakeholders and consumers
7.5.2 Appendix 7.1 Self-Assessment Worksheet (or equivalent forms)
7.5.3 Appendix 7.2 Outreach Activity Event and Self-Evaluation Worksheet (or equivalent forms)
7.5.4 Appendix 7.3 Outreach Plan or equivalent documentation
7.5.5 Meeting summaries, agendas, or other records documenting OUTREACH ACTIVITY EVENTS with EGG industry, stakeholders, and consumers

Deleted: December 2020

STANDARD No. 8
Program Resources

8.1 Purpose

This standard describes the elements for assessing the resources needed to support an EGG safety regulatory program.

8.2 Requirement Summary

The state program conducts an assessment of resource needs for staffing, equipment, funding and sampling for the EGG safety regulatory program. The state program has procedures for evaluating and validating the workplan.

8.3 Program Elements

8.3.1 The state program has a written workplan. The workplan must include:

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; and
8.3.1.1.4 Frequency.

8.3.1.2 Sample plan as described in Standard 3, section 3.3.6.1 and section 3.3.6.3.

8.3.1.3 Timeframe that the workplan is applicable within a 12-month period.

8.3.2 The state program has a written procedure for evaluating the workplan that includes:

8.3.2.1 Conducting periodic and annual reviews of the workplan; and
8.3.2.2 Reviewing the workplan for alignment with state program objectives and resources.

Deleted: S

Note: FDA and the state program may meet periodically and develop a coordinated workplan.

8.3.3 The state program has a written procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe.

Note: The resource review should include staffing, equipment, and funding needed to support the inspection and sample collection activities identified in the workplan. The resources needed to train and audit field staff, to support LABORATORY services, compliance, education and outreach, and to respond to EGG AND EGG PRODUCT RELATED INCIDENTS should be determined by the state program. The administrative functions needed to support all program areas should be considered when determining program resources.

Deleted: December 2020

8.3.4 To validate the workplan, the state program develops a formula that:

8.3.4.1 Calculates the number of staff needed to accomplish the state programs workplan;
8.3.4.2 Uses numerical values that are based on the state programs data; and
8.3.4.3 Must be used by the state program.

Note: The state program should have adequate staff to inspect the state program's ESTABLISHMENT inventory and to conduct sample collections, based on risk categorization and inspection frequency established by the program in its workplan.

Note: Appendix 8.2 provides example formulas that can be used as a baseline for a state program's workplan. The formulas in Appendix 8.2 do not include methods for estimating staff numbers needed for sample collections, compliance activities, administrative, or other programmatic activities.

8.3.5 A list of the equipment required for inspections and sample collections must be:

8.3.5.1 Established by the state program; and
8.3.5.2 Maintained by the state program.

Note: Appendix 8.3 provides an example list of equipment that may be used for inspections and sample collections.

8.3.6 The state program must conduct a review of the resources required to fully implement the ERPS, including each of the program elements in the individual standards. The review recorded in Appendix 8.4 or equivalent form must determine whether the program has adequate:

8.3.6.1 Staff;
8.3.6.2 Equipment; and
8.3.6.3 Funding.

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

8.3.7 Subsequent resource evaluations must be completed to determine the resources necessary for the state program to achieve and maintain full IMPLEMENTATION and full CONFORMANCE with each Standard.

8.4 Outcome

The state program has a written workplan and assesses and allocates resources needed to support an EGG regulatory program.

8.5 Documentation

The state program maintains the records listed here.

Deleted: December 2020

8.5.1 Appendix 8.1 Self-Assessment Worksheet (or equivalent form)
8.5.2 Written workplan
8.5.3 Written procedure for evaluating the workplan
8.5.4 Written procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe
8.5.5 State Program's Formula for Calculating the Number of Inspectors Required to Conduct Inspections of Egg Facilities
8.5.6 State Program's List of Equipment Used for Inspections and Sample Collections
8.5.7 Appendix 8.4 Resource Summary Report (or equivalent form)

Deleted: December 2020

STANDARD No. 9
Program Assessment

9.1 Purpose

This standard describes the process a state program uses to assess and demonstrate its CONFORMANCE with each of the program standards.

9.2 Requirement Summary

The state program conducts periodic self-assessments of the EGG safety regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the state program by using the program standards. The results of the self-assessments are used to determine areas or functions of the state program that need improvement. The results of the baseline self-assessment are used to develop a STRATEGIC IMPROVEMENT PLAN and establish timeframes for making improvements. Subsequent self-assessments are used to track progress toward achieving and maintain CONFORMANCE with the program standards.

The state program establishes written CORRECTIVE ACTION and PREVENTIVE ACTION (CAPA) procedure(s) for identification and management of non-CONFORMANCE(S) and potential non-CONFORMANCE(S).

9.3 Program Elements

9.3.1 In the first year the state program conducts a baseline self-assessment to determine if the program meets the elements of each standard. The Self-Assessment Worksheets, which are the first appendices for each standard, should be completed to establish the baseline self-assessment. The state program uses the results of its self-assessments to complete Appendix 9.2 or equivalent form.

9.3.2 If the state program fails to meet any of the program elements and documentation requirements of a standard, it develops and maintains a STRATEGIC IMPROVEMENT PLAN that includes the following information:

- 9.3.2.1 The individual element or documentation requirement of the standard that was not met;
- 9.3.2.2 Improvements needed to meet individual element or documentation requirement of the standard that are under development;
- 9.3.2.3 Projected completion dates for each task;
- 9.3.2.4 Personnel responsible; and
- 9.3.2.5 Date completed for each task.

9.3.3 The state program shall review and update the self-assessment appendices and its STRATEGIC IMPROVEMENT PLAN at least annually.

Deleted: S

Deleted: December 2020

9.3.4 The state program participates in FDA ASSESSMENTS to determine IMPLEMENTATION and CONFORMANCE to the standards. The state program addresses FDA ASSESSMENT observations and establishes CORRECTIVE ACTION(S) following the requirements listed in 9.3.5, unless already identified in the STRATEGIC IMPROVEMENT PLAN prior to the start of the FDA ASSESSMENT.

9.3.5 The state program shall establish written CORRECTIVE ACTION and PREVENTIVE ACTION (CAPA) procedure(s) for identification, elimination, and documentation of non-CONFORMANCE(S) and potential non-CONFORMANCE(S).

9.3.5.1 The state program's CAPA procedure(s) shall include:

9.3.5.1.1 Identification of any non-CONFORMANCE(S) or potential non-CONFORMANCE(S);
9.3.5.1.2 The cause(s) of the non-CONFORMANCE(S) or potential non-CONFORMANCE(S);
9.3.5.1.3 The CORRECTION(S) needed to eliminate the non-CONFORMANCE(S);
9.3.5.1.4 CORRECTIVE ACTION(S) or PREVENTIVE ACTION(S) to eliminate the cause of the non-CONFORMANCE(S) or potential non-CONFORMANCE(S);
9.3.5.1.5 The results of CORRECTIVE ACTION(S) or PREVENTIVE ACTION(S) taken; and
9.3.5.1.6 Review of the effectiveness of the CORRECTIVE ACTION(S) or PREVENTIVE ACTION(S).

Deleted: S

9.3.5.2 The state program shall maintain written CAPA records that include the criteria found in 9.3.2.1 – 9.3.2.5 and 9.3.5.1.1 – 9.3.5.1.6.

9.3.6 The state program shall:

9.3.6.1 Have a written DOCUMENT CONTROL procedure that ensures all guidance, procedures, documents, and forms required by the standards are CURRENT AND FIT-FOR-USE.

9.3.6.1.1 All documents subject to this procedure can demonstrate they are CURRENT AND FIT-FOR-USE through maintenance of a master document list or other system that show:

9.3.6.1.1.1 Documents are reviewed for accuracy;

Deleted: December 2020

9.3.6.1.1.2 Documents are approved for release by authorized personnel and signed/dated with an approval or revision date; and

9.3.6.1.1.3 Documents are distributed to and used at the location where the prescribed activity is performed.

9.3.6.2 Retain records or procedures required under each standard for the three previous years, or per the state program's record retention policy, whichever is longer. Records or procedures can be maintained either electronically or in hardcopy.

9.4 Outcome

The state program conforms to the program standards through well-defined and written evaluation activities and a process for continuous improvement.

9.5 Documentation

The state program maintains records listed here:

9.5.1 Appendix 9.1 Self-Assessment Worksheet (or equivalent form)
9.5.2 Appendix 9.2 Self-Assessment Summary Report (or equivalent form)
9.5.3 STRATEGIC IMPROVEMENT PLAN
9.5.4 FDA ASSESSMENT reports
9.5.5 Written CORRECTIVE ACTION and PREVENTIVE ACTION (CAPA) procedure
9.5.6 CAPA records
9.5.7 Written DOCUMENT CONTROL procedure
9.5.8 Record retention policy

Deleted: December 2020

STANDARD No. 10
Laboratory Support

10.1 Purpose

This standard describes the elements of LABORATORY support for an EGG regulatory program.

10.2 Requirement Summary

The state program has access to the LABORATORY services needed to support program functions and documents its LABORATORY capabilities including agreements with external laboratories.

10.3 Program Elements

10.3.1 LABORATORY Support

10.3.1.1 The state program shall have access to a LABORATORY that is capable of analyzing a variety of samples such as: EGG, environmental, or veterinary clinical samples.

10.3.1.2 The state program shall maintain a list of all analytical services the LABORATORY provides for the state program.

10.3.1.3 The state program shall have a contract or written agreement with each LABORATORY and contracted laboratories unless under the same administrative agency. The contract or written agreement can be a memorandum of understanding, e-mail, or any written format but must contain the components below:

10.3.1.3.1 Define the responsibilities of each party;

10.3.1.3.2 Describe the types of testing services to be performed; and

10.3.1.3.3 Describe how exceptions to planned work will be communicated.

10.3.2 ISO Accredited Laboratories

The state program utilizes laboratories that have a current accreditation to the International Organization for Standardization/International Electrotechnical Commission ISO/IEC 17025 (2017 or current version) to analyze EGG or environmental samples.[8] The accreditation body of the LABORATORY must be a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA).

[8] Reference: International Organization for Standardization – ISO/IEC 17025:2017 – General Requirements of Testing and Calibration Laboratories: https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

Deleted: December 2020

10.3.3 Non-ISO Accredited Laboratories

10.3.3.1 If state programs do not use laboratories holding accreditation to ISO/IEC 17025 (2017 or current version), for the analysis of EGG and environmental and/or veterinary clinical samples, then the program must utilize laboratories that have in place a quality system which incorporates the following management and technical requirements of ISO/IEC 17025 (2017 or current version) at a minimum:

10.3.3.1.1 Written quality system which incorporates management and technical requirements of ISO/IEC 17025 (2017 or current version) and associated procedures, that include but are not limited to:

10.3.3.1.1.1 Calibration and maintenance of equipment;
10.3.3.1.1.2 Analyses are performed using validated and verified test procedures;[9]
10.3.3.1.1.3 Documentation of sample traceability;
10.3.3.1.1.4 Documentation of analytical results and analysts performing work;
10.3.3.1.1.5 Analysts that are trained and authorized to perform technical procedures;
10.3.3.1.1.6 Periodic audits; and
10.3.3.1.1.7 Chain of Custody/Records.

10.3.3.1.2 A written procedure that defines the activities necessary when non-conforming work occurs. The procedure must describe how quality control data are assessed to assure that test results from non-conforming work are not released. The procedure must describe how cause analysis and problem resolution are recorded.

10.3.3.1.3 A DOCUMENT CONTROL procedure that assures documents issued to personnel are current, suitable, and reviewed and approved by authorized personnel prior to release. The procedure must also assure that obsolete documents are removed from use.

10.3.3.1.4 A written record keeping process that assures that records of original observations and data collection are maintained

[9] Reference: Bacteriological Analytical Manual (BAM) Chapter 5: Salmonella: https://www.fda.gov/food/laboratory-methods-food/bam-chapter-5-salmonella

Deleted: December 2020

and sufficient to establish traceability of test results, to sample handling and storage, to sample analysis including data collection, to equipment calibration and maintenance, and to the review of test results prior to release.

10.3.3.1.5 A written process to assure that reference materials and reference cultures are fit for purpose, are not outdated, and are traceable to a lot number or other unique indicator.

10.3.3.1.6 A written process to assure that the LABORATORY participates in relevant and available proficiency testing activities.

10.3.3.1.7 A written process for reporting regulatory data results.[1]

10.4 Outcome

The state program has access to LABORATORY services described in this standard.

10.5 Documentation

The state program maintains records listed here.

10.5.1 Appendix 10.1 Self-assessment worksheet (or equivalent form)

10.5.2 Contracts or written agreements with participating laboratories

10.5.3 List of services provided by laboratories

10.5.4 ISO Accredited LABORATORY: ISO/IEC 17025 (2017 or current version) Certificate and Scope of Accreditation.

10.5.5 Non-ISO Accredited Laboratories Documents:

10.5.5.1 Written Quality System

10.5.5.2 Written procedure for non-conforming work

10.5.5.3 DOCUMENT CONTROL Procedure

10.5.5.4 Record Keeping Process

10.5.5.5 Process for Ensuring Quality of Reference Materials and Cultures

10.5.5.6 Process for LABORATORY Proficiency Testing Activities

10.5.5.7 Process for Reporting Data Results

Deleted: December 2020

Appendix 1.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
1.3.1 Evaluation of Legal Authority		
1. Does the state program have a written procedure to evaluate the legal authority and regulatory provisions to inspect and investigate, gather evidence, collect and analyze samples and take regulatory actions under state law to ensure the safety and security of EGGS?		
Does the written procedure include:		
1. Timeframes for a REGULATORY FOUNDATION evaluation?		
2. REGULATORY FOUNDATION evaluation process, to include whenever significant changes are made to applicable Federal and/or state laws and regulations?		
3. Address the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:		
a. Apply to the regulation of EGGS?		
b. Delegate authority to the state program?		
c. Describe the state program's administrative procedures for rulemaking to protect public health?		
d. Identifies and lists other state or federal agencies that have authority for any area of the REGULATORY FOUNDATION that the state program lacks?		
1.3.2 Regulatory Foundation Evaluation		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
1. The state program must complete Appendix 1.2 or equivalent form. The state program conducts an evaluation to determine if they are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to sections of the current Federal Food, Drug, and Cosmetic Act (FD&C Act) and Code of Federal Regulations (CFR) Title 21 specified in Appendix 1.2.		
2. If the state program has laws and regulations pertinent to the regulation of EGGS, for which there are no Federal provisions, these laws and regulations can also be listed in Appendix 1.2 or equivalent form.		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 1.2 – Regulatory Foundation Worksheet

Instructions: *Determine if state laws and regulations are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to federal statutes and regulations. Select "NO AUTHORITY" if regulatory responsibility for a statue or regulation falls under the jurisdiction of another agency.*

For those statutes 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 shall be used in part to detail differences between state and federal laws and regulations. This self-assessment relates only to human food, animal food and public health. Any commodities within the statutes and regulations outside this scope do not need to be included on the self-assessment.

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_____

Federal Food, Drug & Cosmetic Act

FD&C Act	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
201	Definitions (f), (k), (m), (r)	Choose an item.			
301	Prohibited acts (a), (b), (c), (d), (e), (f), and (k)	Choose an item.			
303*	Penalties	Choose an item.			
304**	Seizure	Choose an item.			
401	Definitions and standards for food	Choose an item.			

Deleted: December 2020

FD&C Act	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
402	Adulterated food	Choose an item.			
403	Misbranded food (a)-(s)	Choose an item.			
404	Emergency permit control	Choose an item.			
406	Tolerances for poisonous ingredients in food	Choose an item.			
701	Regulations and hearings	Choose an item.			
703***	Records of interstate shipments	Choose an item.			
704	Inspection	Choose an item.			

*Penalties may vary from Federal statute.
**Although the state program may not have authority for seizure, the state program could have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, withdrawal from distribution, and embargoes.
*** This section covers records in interstate commerce. State laws should include intrastate records.

Deleted: S

Deleted: S

Title 21 Code of Federal Regulations: Food and Drugs

CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
1	General enforcement regulations (§ 1.20-1.24) and (Subpart O § 1.900-1.934)	Choose an item.			

Deleted: December 2020

CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
7	Enforcement policy (ONLY § 7.1-7.13 and § 7.40-7.59)	Choose an item.			
101	Food labeling (EXCEPT § 101.108)	Choose an item.			
105	Foods for special dietary use	Choose an item.			
109	Unavoidable contaminants in food for human consumption and food- packaging materials	Choose an item.			
110[10]	Current good manufacturing practice in manufacturing, packing, or holding human food	Choose an item.			
115	Shell eggs	Choose an item.			

[10] Part 110 was modernized and codified in Part 117 by the current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventative Controls for Human Food Rule (21 CFR Part 117).

Deleted: December 2020

CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
117	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	Choose an item.			
118	Production, Storage, And Transportation of Shell Eggs	Choose an item.			

State law and regulations:

State laws and regulations used by the program to address regulatory responsibilities outside of FDA jurisdiction are listed below.

Assessment Completed By:

Name_____ **Date**_____

Deleted: December 2020

Appendix 2.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
2.3.1 Training Plan and Training Records		
Does the state program:		
1. Use a written training plan that ensures all inspectors receive training required to adequately perform their work assignments?		
a. Training plan includes curriculum for basic and advanced inspection training and continuing education?		
b. Training plan curriculum consists of coursework and field training?		
2. Maintain a training history for active inspectors?		
3. Keep the training history for all inactive inspectors for three years or per the state's record retention policy?		
4. Maintains records documenting the training completed by all inspectors using Appendix 2.2 or an equivalent form?		
5. Training record summary and individual training records include the inspector's START DATE?		
6. For inspectors with greater than five years of experience at the date of the initial self-assessment, where their training documentation is not available, does the state program:		
a. Conduct an EVALUATION of the inspector's previous performance and experience to determine if the inspector has completed the required training or whether additional training is needed?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
b. Document the results of the EVALUATION?		
2.3.2 Basic Inspection Training		
Does the state program training plan require:		
1. Basic inspection training curriculum to be successfully completed within 24 months of the inspector's START DATE with the state program?		
2. Coursework in the subject areas:		
a. Prevailing statutes, regulations, and ordinances?		
b. Public health principles?		
c. Biosecurity protocols and procedures?		
d. Emergency Management?		
e. Communications skills?		
f. Basic Microbiology?		
g. Basics of HACCP?		
h. Basic sampling technique and preparation?		
i. State program EGG safety inspection manuals and guidance?		
3. An established basic field training program to complement the coursework curriculum that includes:		
a. The inspector must complete the basic field training program prior to performing independent inspections?		
b. Field training checklist of competencies to be mastered and verified in the field by the QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR?		
c. Written procedures for JOINT FIELD TRAINING INSPECTIONS?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
d. Number of JOINT FIELD TRAINING INSPECTIONS or FIELD INSPECTION AUDITS that are conducted in ESTABLISHMENTS that are representative of the ESTABLISHMENTS in the state program inventory, as well as the type of work that will be performed by the inspector?		
e. The qualifications, education, and experience necessary to be identified as a QUALIFIED FIELD INSPECTOR TRAINER and/or QUALIFIED FIELD INSPECTION AUDITOR?		
f. Using Appendix 2.3 or an equivalent form to list the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS?		
2.3.3 Advanced Training		
Does the state program training plan require:		
1. Each inspector who will conduct advanced EGG inspections will complete the relevant coursework and field training?		
2. That advanced inspection training curriculum shall be successfully completed within the timeframe specified by the state program?		
3. The advanced inspection training consists of coursework in the subject areas listed in this section.		
a. EGG Safety Inspections: Complete coursework required to conduct inspections of ESTABLISHMENTS under the oversight of the state program, which may include the Egg Safety Rule regulations (21 CFR 115 and 21 CFR 118)?		
b. Traceback Investigations?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
c. Foodborne Illness Investigations?		
d. Other training as developed by the state program?		
4. An established advanced field training program to complement the coursework curriculum that includes:		
a. Requiring the inspector to complete the field training program prior to performing advanced independent inspections?		
b. Participating in two JOINT FIELD TRAINING INSPECTIONS?		
c. After successful completion of the course participate in one EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections?		
d. Within one year after being released to do advanced inspections complete a second EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR?		
2.3.4 Continuing Education		
Does the state program training plan include:		
1. Each inspector must accumulate 20 CONTACT HOURS of continuing education every 36 months?		
2. The 36 month continuing education interval starts at the QUALIFIED DATE, when the training cycle is completed?		
3. An alternate timeframe to track continuing education as long as the alternate timeframe and how that timeframe still meets or exceeds the intent of the standard (at least 20		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
CONTACT HOURS every 36 months) are clearly identified in program procedures?		
4. The inspector qualifies for CONTACT HOURS by participation in any of the activities listed in 2.3.4.4.1 – 2.3.4.4.7 that are related specifically to EGG inspectional work?		
5. A maximum of 10 CONTACT HOURS may be accrued from the activities listed in 2.3.4.5.1 – 2.3.4.5.3?		
6. Documentation must accompany each activity submitted for continuing education credit?		
2.3.5 Coursework Sources		
1. Is basic, advanced, and continuing education coursework obtained from one of the sources listed in 2.3.5.1 – 2.3.5.3?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 2.2 – Inspector Training Record

State Agency: _____

Name of Inspector _____ **START DATE** _____

Note: 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".

Coursework Curriculum Areas

Subject Areas	Date Completed	Coursework Name and Location of Training	Documentation Verifying Completion (Yes/No)
Basic			
Prevailing statutes, regulations, and ordinances			
Public health principles			
Biosecurity protocols and procedures			
Emergency management			
Communication skills			
Basic microbiology			
Basics of HACCP			
Basic sampling technique and preparation			
State program EGG safety inspection manuals and guidance			

Deleted: December 2020

Subject Areas	Date Completed	Coursework Name and Location of Training	Documentation Verifying Completion (Yes/No)
Advanced			
EGG safety inspections			
Traceback investigations			
Foodborne illness investigations			
Other training as developed by the state program			

Deleted: December 2020

Appendix 2.2 – Inspector Training Record (continued)

Name of Inspector _____ QUALIFIED DATE _____

JOINT FIELD TRAINING INSPECTION

Minimum Number of JOINT FIELD TRAINING INSPECTIONS Required:_____

ESTABLISHMENT Name and Location	Date Completed	Documentation Available for Review (Yes/No)

EVALUATIONS

ESTABLISHMENT Name and Location	Date Completed	EVALUATION Acceptable (Yes/No)	Documentation Available for Review (Yes/No)

FIELD INSPECTION AUDITS

Minimum Number of FIELD INSPECTION AUDITS Required:_____

ESTABLISHMENT Name and Location	Date Completed	Acceptable (Yes/No)	Documentation Available for Review (Yes/No)

Deleted: December 2020

Appendix 2.2 – Inspector Training Record (continued)

Name of Inspector _____ QUALIFIED DATE _____

CONTINUING EDUCATION

A total of 20 CONTACT HOURS required every 36 months. Total CONTACT HOURS is the sum of both charts below.

Activities in Program Element 2.3.4.4 *Maximum of 20 CONTACT HOURS*

Type of Activity *(Provide Title and Brief Description)*	**Date Completed**	**Documentation Available for Review (Yes/No)**	**CONTACT HOURS Earned**
		Subtotal	
		Total CONTACT HOURS Earned	

Presenting, Training, or Publishing (Program Element 2.3.4.5) *Maximum of 10 CONTACT HOURS*

Type of Activity *(Provide Title and Brief Description)*	**Date Completed**	**Documentation Available for Review (Yes/No)**	**CONTACT HOURS Earned**
		Subtotal	

Deleted: December 2020

Appendix 2.3 – Field Training Competencies

State Agency: _____

Name of Inspector: _____ **START DATE:** _____

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

Competency	Description

Deleted: December 2020

Appendix 3.1 – Self Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
3.3.1 Risk-based inspection program		
Does the state program have written procedures to:		
1. Define an up-to-date inventory of registered EGG PRODUCERS and EGG HANDLERS for which the state has regulatory oversight?		
2. Categorize the inventory by the risk associated with the likelihood that an EGG AND EGG PRODUCT RELATED INCIDENT will occur?		
3. Determine a firm's level of associated risk and the program's inspectional priorities?		
4. Use the risk factors and associated criteria as described in 3.3.1.2.1 – 3.3.1.2.3?		
5. Prioritize and assign inspection frequencies based on established risk categories?		
3.3.2 Inspection Procedure		
Does the state program have written procedures for inspecting EGG PRODUCERS and EGG HANDLERS that require the inspectors to:		
1. Review the ESTABLISHMENT'S previous inspection report, CONSUMER COMPLAINTS, and current disease status?		
2. Have appropriate equipment and forms?		
3. Use equipment that has been verified, operated and maintained as defined by the state program's procedures which may include manufacturer's recommendations?		

Deleted: S

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
4. Behave professionally and demonstrate proper biosecurity practices during the inspection similar to those listed in 3.3.2.3.1 – 3.3.2.3.2?		
5. Follow safety protocols required by the facility and the state program?		
6. Make appropriate introductions and explain the purpose and scope of the inspection?		
7. Establish jurisdiction?		
8. Determine the ESTABLISHMENT registration status?		
9. Use suitable interviewing techniques?		
10. Assess employee practices critical to the safe and sanitary production, processing and storage of EGGS?		
11. Evaluate conditions, practices, components, and/or labeling that could cause the product to be adulterated or misbranded or otherwise in violation of applicable law(s)?		
12. Recognize significant violative conditions or practices, if present, and record findings consistent with state program procedures?		
13. Review and verify that records and procedures for the ESTABLISHMENT'S operation are being kept and properly followed?		
14. Collect adequate evidence and documentation to support inspection observations in accordance with state program procedures?		
15. Verify correction of deficiencies that were identified during previous inspections?		
16. Evaluate the ESTABLISHMENT operations through on-site inspectional observations?		
17. Alert the ESTABLISHMENT'S person in charge when an immediate action is necessary to correct a violation?		

Deleted: S

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
18. Explain findings clearly and adequately throughout the inspection?		
19. Answer questions and provide information in an appropriate manner?		
20. Write findings accurately, clearly and concisely and provide a copy to the ESTABLISHMENT'S person in charge?		
3.3.3 Inspection Report Procedure		
Does the state program have a written inspection report procedure that requires inspectors to:		
1. Document significant violative conditions or practices, if present, consistent with state program procedures?		
2. Accurately complete the inspection report?		
3. Submit the inspection report within designated timeframes consistent with state program procedures?		
4. Follow up with corrective, compliance, and enforcement actions as warranted?		
3.3.4 Recalls		
Does the state program have a recall system with written recall procedures for:		
1. Sharing information about recalls with relevant industry and partner agencies?		
2. Ensuring recalled products are removed promptly from the market?		
3. Performing RECALL AUDIT CHECKS?		
3.3.5 Complaints		
Does the state program have a written system for handling CONSUMER COMPLAINTS that contains procedures for:		
1. Receiving?		
2. Tracking?		
3. Evaluating?		

Deleted: S

Deleted: S

Deleted: S

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
4. Responding to?		
5. Closing?		
6. Maintaining records of CONSUMER COMPLAINTS?		
Does the state program have a written system for handling INDUSTRY COMPLAINTS that contains procedures for:		
1. Receiving?		
2. Evaluating?		
3. Responding to?		
4. Maintaining records of INDUSTRY COMPLAINTS?		
3.3.6 Sampling Program		
1. Does the state program that conducts EGG and/or environmental sampling have a written annual sampling plan?		
2. For state programs that conduct sampling, does the written sampling plan include:		
a. Sampling priorities?		
b. The sample analysis schedule?		
c. Availability or coordination of analytical LABORATORY support?		
3. Does the state program that conducts environmental or EGG sampling have written sampling procedures that include:		
a. Methods for collecting storing/Transporting and documenting samples that include:		
i) Following the state program's sampling policies and procedures to assure sample integrity, security, accountability, and chain of custody?		
ii) Using appropriate method and equipment to collect the sample?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
iii) Sealing sample to initiate chain of custody?		
iv) Maintaining and documenting sample integrity, security and chain of custody?		
v) Handling, packaging, and shipping sample to ensure sample integrity and prevent compromising condition of sample?		
vi) Delivering or shipping sample to the appropriate LABORATORY within acceptable timeframes?		
b. Instructions for documenting the sample collection including the following elements when applicable to the states' SAMPLING PROGRAM:		
i) Date of sample collection?		
ii) Sample identification which may include: name, firm, house, sample number assigned by the sampler at the time of collection and type (EGG, belt, manure, walkway, etc.)?		
iii) Method of collection and any special techniques used to collect sample?		
iv) Location where sample was collected?		
v) Sample type/reason for collection (surveillance, compliance, investigational, regulatory or other)?		
vi) Analysis requested?		
vii) Receiving and distribution information?		
viii) Observations recorded at the time of collection?		
ix) Product labels or specific labeling information that is collected or reproduced per state policies?		
4. If the state program does not collect samples:		
a. Is there a statement in lieu of sampling procedures that explains why a		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
SAMPLING PROGRAM is not supported and how the public health is protected because another state or federal agency collects samples and fulfills this need?		
b. Does the statement include the name of the agency and the type of samples that it collects?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 4.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
4.3.1 Audit Program		
Does the state program have written procedures for:		
1. FIELD INSPECTION AUDITS as described in section 4.3.3?		
2. Inspection report audits as described in section 4.3.4?		
3. Sample report audits as described in section 4.3.5?		
4. CORRECTIVE ACTIONS as described in section 4.3.6?		
5. VERIFICATION AUDIT INSPECTIONS of QUALIFIED FIELD INSPECITON AUDITORS?		
4.3.2 Does the state program review the scores for completed audits at least every 12 months?		
4.3.3 Field Inspection Audit		
Does the state program have written procedures for conducting FIELD INSPECTION AUDITS that include:		
1. A QUALIFIED FIELD INSPECTION AUDITOR conducts FIELD INSPECTION AUDITS?		
2. A minimum of one FIELD INSPECTION AUDIT of each inspector is conducted every 36 months?		
3. Selecting inspections for audits that include the highest risk firms the inspector is trained for such as advanced EGG inspections?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
4. If samples are collected during the FIELD INSPECTION AUDIT, the collection of the samples shall also be audited, and the appropriate question(s) answered on Appendix 4.3?		
5. Performance is documented on Appendices 4.3 and 4.3a or equivalent forms that meet the program elements in Standard 3, section 3.3.2?		
4.3.4 Inspection Report Audits		
Does the state program have written procedures for inspection report audits that include:		
1. The state program conducts annual reviews of inspection reports to verify that inspectional findings are obtained and reported according to established written procedure?		
2. The state program will review a random selection of inspection reports based on the number of inspections performed in the last 12 months using the table in 4.3.4.2?		
3. Seven percent (7%) of the inspection reports reviewed must be taken from field inspections that were audited?		
4. The quality of each inspection report is audited using the performance factors listed in Appendix 4.4, or equivalent?		
5. An overall inspection report rating is calculated using Appendix 4.4a, or equivalent?		
4.3.5 Sample Report Audit		
1. Does the state program collect samples?		
If samples were collected, does the state program have written procedures for conducting sample report audits that include:		
1. An annual review of sample reports?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
2. Reviewing a random selection of sample reports based on the number of samples collected in the last 12 months using the table in 4.3.4.1?		
3. The quality of each sample report is audited using the performance factors listed in Appendix 4.5, or equivalent form?		
4. The overall sample report rating is calculated using Appendix 4.5a, or equivalent form?		
4.3.6 CORRECTIVE ACTIONS		
Does the state program initiate CORRECTIVE ACTIONS when:		
1. An individual receives an overall rating of "needs improvement"?		
2. A single performance factor for the program falls below 80%?		
3. An overall rating for the program falls below 80%?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 4.2 – Instructions for Performance Ratings of Audit Findings

The three performance rating of audit findings summary appendices (4.3a, 4.4a and 4.5a) allow the state program to recognize trends and identify specific areas in their audit program that may need improvement.

Deleted: S

These summary appendices are used to calculate an overall rating during the performance period and identify areas for improvement. The state program shall initiate CORRECTIVE ACTIONS as described in 9.3.5 when one or more of the conditions below are met: (a) an individual receives an overall rating of "needs improvement"; (b) a single performance factor for the program falls below 80%; or (c) an overall rating for the program falls below 80%.

Deleted: S

INSTRUCTIONS:

(1) For each audit, record the firm identification number, inspection date, auditor's initials and date of audit.

(3) For each audit (vertical column), record the rating for each performance factor (A = acceptable; NI = needs improvement). Record the individual audit score on the row indicated.

(4) Count the number of "A" and "NI" for each performance factor (horizontal) and record the total number of "A" and "NI" ratings. Calculate the performance factor score using the formula below:

A_t = horizontal total of acceptable ratings.
NI_t = horizontal total of needs improvement ratings.
Performance Factor Score = $[A_t/(A_t + Ni_t)] \times 100$

(5) Sum the Total Number of "A" and "NI" ratings for all audits.

$\sum A_t$ = vertical sum of acceptable ratings.
$\sum NI_t$ = vertical sum of needs improvement ratings.

NOTE: $\sum$ *is the statistical symbol for the sum of all numbers.*

(6) Calculate the cumulative score for all audits. Record the cumulative score in the space provided at the top of the worksheet.

Cumulative Score = $[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

(7) Identify and make notes about trends and single performance factors rated as "NI" in multiple audits.

Deleted: December 2020

Appendix 4.3 – Field Inspection Audit Form

EGG REGULATORY PROGRAM STANDARDS FIELD INSPECTION AUDIT FORM	
Auditor	State inspector
Firm	License #
FDA FEI # (if applicable)	
Firm address	
Inspection dates	Type of inspection
Time in Time out	Overall rating ☐ Acceptable ☐ Needs Improvement

NOTE: Every item marked "Needs Improvements" must be accompanied by an explanation of why the item was identified as needing improvement.

Overall Rating: If three or less items are marked "Needs Improvement," the overall rating is "Acceptable." If four or more items are marked "Needs Improvement," the overall rating is "Needs Improvement." The overall rating must be marked in the space provided in the header on the first page.

Each performance factor needs to be evaluated and rated as "Acceptable" or "Needs Improvement" by the state program auditor except for sections:

*IV. Sample Collection***.** If samples are not collected during this FIELD INSPECTION AUDIT leave the scoring for these three questions blank.

I. Pre - Inspection Assessment

1. Did the inspector review the state's ESTABLISHMENT file for the previous inspection reports and possible complaints, or access other available resources in preparation for the inspections?

   ☐ Acceptable ☐ Needs Improvement

   Comments *(required for Needs Improvement)*

Deleted: December 2020

2. Did the inspector use appropriate equipment and forms to conduct the inspection?

☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

II. Inspection Observations

1. Was FDA/state jurisdiction established?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

2. Did the inspector determine if the firm is registered as an EGG PRODUCER within the FDA and/or state if applicable?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. Did the inspector assess the employee practices critical to the safe and sanitary production and storage of EGGS?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

4. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

5. Did the inspector recognize significant violative conditions or practices if present and record findings consistent with state and/or FDA procedures?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

Deleted: December 2020

6. Did the inspector distinguish between significant versus insignificant observations, and isolated incidents versus trends?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

7. Did the inspector review and evaluate the appropriate records and procedures for this ESTABLISHMENT's operations and effectively apply the information obtained from the review?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

8. Did the inspector collect adequate evidence and documentation in accordance with state procedures given the nature of the inspectional findings?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

9. Did the inspector verify correction of deficiencies identified during the previous inspection?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

10. Did the inspector act in a professional manner and demonstrate proper sanitary and biosecurity practices during the inspection?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

III. Oral and Written Communication

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope or the inspection?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

Deleted: December 2020

2. Did the inspector use suitable interviewing techniques?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. Did the inspector explain findings clearly and adequately throughout the inspections?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

4. Did the inspector alert the firm's appropriate management when immediate CORRECTIVE ACTION was necessary?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

5. Did the inspector answer questions and provide information in an appropriate manner?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

6. Did the inspector write their findings accurately, clearly and concisely on the state form/document or Form FDA 483 left with the firm?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

IV. Sample Collection

Note to Auditor: These three questions are only answered if samples are collected as part of the FIELD INSPECTION AUDIT. These three questions should be left blank if no samples were collected.

1. Did the inspector follow the state's program sampling policies and procedures to assure sample integrity, security, accountability, and chain of custody?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

Deleted: December 2020

2. Did the inspector use the appropriate method and equipment to collect the sample? ☐ Acceptable ☐ Needs Improvement Comments *(required for Needs Improvement)*
3. Did the inspector seal the sample and initiate chain of custody to maintain and document sample integrity and security? ☐ Acceptable ☐ Needs Improvement Comments *(required for Needs Improvement)*
Additional Comments

SIGNATURE OF AUDITOR	DATE

Deleted: December 2020

Appendix 4.3a – Performance Rating for the Field Inspection Audits

State Program:_____ **Performance Period:**_____
Reviewed by:_____ **Cumulative Score:**_____
Date Reviewed:_____

Notes: A = acceptable, NI = needs improvement

Firm ID #																
Inspection Date																
Auditor's Initials																
Date of Audit																

Performance Factors	**Performance ratings**																**A_t**	**Ni_t**	**Performance Factor Score**
I.1																			
I.2																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
II.7																			
II.8																			
II.9																			
II.10																			
III.1																			
III.2																			
III.3																			
III.4																			
III.5																			
III.6																			

Deleted: December 2020

IV.1																			
IV.2																			
IV.3																			
Audit Score																			

Subtotal		
Total – Enter the final sums (subtotal + all continuation sheets)		

USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Deleted: December 2020

Appendix 4.3b – Guidance for Completing the Field Inspection Audit Form

This document provides guidance on assigning ratings during an audit for each of the performance factors listed on Appendix 4.3 Field Inspection Audit Form. For each performance factor examples of actions and observations that would likely result in a "needs improvement" rating are provided.

I. PREINSPECTION ASSESSMENT

1. Did the inspector review the state's ESTABLISHMENT file for the previous inspection reports and possible complaints or access other available resources in preparation for the inspection?

Deleted: S

References:

- State program's ESTABLISHMENT files and/or FDA ESTABLISHMENT files
- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- FDA IOM, Subchapter 5.2 "Inspection Procedures"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector does not review the previous inspection report.
b. The inspector does not review the firm's response letter that promised CORRECTIVE ACTIONS after the last inspection.
c. The inspector does not follow-up on a CONSUMER COMPLAINT.

2. Did the inspector use appropriate equipment and forms to conduct the inspection?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- FDA IOM, Subchapter 5.2 "Inspection Procedures"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector does not present appropriate credentials and written Notice of Inspection (when required) to the owner, operator, or agent in charge.
b. The inspector does not don appropriate disposable personal protective equipment.
c. The inspector does not have a flashlight to examine conditions within low lit poultry houses.

Deleted: December 2020

II. INSPECTION OBSERVATIONS AND PERFORMANCE

1. Was FDA/state jurisdiction established?

References:

- IOM, Subchapter 5.1 "Inspection Information"
- State program's standard operating procedures
- FD&C Act
- State law (if applicable)

Examples of a "needs improvement" rating:

a. The inspector does not confirm whether the EGG PRODUCER is producing EGGS for the table EGG market.
b. The inspector does not inquire about the interstate movement of EGGS.

2. Did the inspector determine if the firm is registered as an EGG PRODUCER with the FDA (and/or state if applicable)?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- State program's standard operating procedures
- 21 CFR Part 118.11
- State law (if applicable)

Examples of a "needs improvement" rating:

a. The inspector does not confirm whether the firm is registered as an EGG PRODUCER with the FDA (and the state if applicable).

3. Did the inspector assess employee practices critical to the safe and sanitary production and storage of EGGS?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- State program's standard operating procedures
- 21 CFR Part 118
- Food Drug & Cosmetic Act, Section 402(a)(4)
- State law (if applicable)

Examples of a "needs improvement" rating:

a. The inspector does not evaluate biosecurity measures of employees working within a poultry house.

Deleted: December 2020

b. The inspector does not assess sanitation practices conducted by employees working within the on-site packing facility that is not actively enrolled in the USDA/AMS voluntary EGG grading program.
c. The EGG PRODUCER holds EGGS for the table market within a refrigerated trailer beginning 36 hours after the time of lay. The inspector does not check the ambient temperature of the trailer where EGGS are stored.

4. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- State program's standard operating procedures
- 21 CFR Part 118
- State law (if applicable)

Examples of a "needs improvement" rating:

a. The inspector does not recognize the gross amount of rodent activity seen within the poultry house.
b. Although the EGG PRODUCER monitors for flies within the poultry house, the inspector does not recognize the use of parasitic wasps as a biological control method that is not an acceptable control method to lower the fly population.
c. The inspector does not perform his/her own flock age calculation to determine compliance when evaluating whether environmental testing for Salmonella Enteritidis (SE) was performed by the EGG PRODUCER when the flock was between 40 to 45 weeks of age.

5. Did the inspector recognize significant violative conditions or practices if present and record findings consistent with state and/or FDA procedures?

Deleted: S

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- State program's standard operating procedures
- 21 CFR Part 118
- State law (if applicable)

Examples of a "needs improvement" rating:

a. The inspector is aware the EGG PRODUCER did not disinfect the cleaned poultry house after an environmental test was positive for SE. The EGG PRODUCER had previously repopulated the poultry house and is selling the EGGS to the table EGG market. The

Deleted: December 2020

inspector did not recognize the poultry house was not cleaned and disinfected properly prior to housing a new flock which makes the environment within the poultry house positive for SE.

b. The inspector discovers the EGG PROUDCER does not have an SE prevention plan as required by the Egg Safety Rule based upon operations. The EGG PRODUCER has operated in this manner for at least five years. The inspector does not record this finding as a violation.

6. Did the inspector distinguish between significant versus insignificant observations and isolated incidents versus trends?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- State program's standard operating procedures
- 21 CFR Part 118
- State law (if applicable)

Examples of a "needs improvement" rating:

a. The inspector notes a minor record keeping deficiency pertaining to one out of 600 refrigeration records showing the time of the refrigeration check was not documented.

b. During the inspection of a poultry house, the inspector focuses on a mortality pile stored against the back wall without evidence showing it was attracting rodents and/or flies. The inspector objects to this daily practice without properly considering that mortality checks occur daily, and piles are picked up daily by a third-party trucking company.

c. The inspector notices the EGG PRODUCER uses an environmental sampling drag swab pre-moistened with skim milk and does not recognize the significance of this finding as the sampling methodology does not comply with the Egg Safety Rule.

7. Did the inspector review and evaluate the appropriate records and procedures for this ESTABLISHMENT's operation and effectively apply the information obtained from this review?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- State's Standard Operating Procedures
- 21 CFR Part 118
- State law (if applicable)

Examples of a "needs improvement" rating:

Deleted: December 2020

a. The inspector does not review the SE prevention plan, which is required based upon the EGG PRODUCER's applicability to the Egg Safety Rule.
b. The inspector does not review refrigeration records when inspecting an EGG PRODUCER that sends 100% of EGGS to a treatment plant.
c. The inspector reviews the SE prevention plan which indicates 12 mechanical traps are located around the inside perimeter of the poultry house. However, the inspector does not verify there are 12 mechanical traps around the inside perimeter when he/she inspects the poultry house.

8. Did the inspector collect adequate evidence and documentation in accordance with state procedures given the nature of the inspectional findings?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 5.3 "Evidence Development"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector does not capture photographic evidence showing pest control deficiencies within the poultry house.
b. The inspector does not collect a copy of the SE prevention plan as evidence to substantiate deficiencies.

9. Did the inspector verify correction of deficiencies identified during the previous inspections?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 5.2 "Inspection Procedures"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. Although improper refrigeration of EGGS was identified during the previous inspection, the inspector does not determine if the deficiency was corrected.
b. During the previous inspection, the inspector documented a gross rodent infestation inside a poultry house. During the current inspection, the manager tells the inspector that the rodent problem was properly dealt with. The inspector reviews pest control records but does not visually verify the current environment within the poultry house to ascertain whether corrective action was achieved.

Deleted: December 2020

10. Did the inspector act in a professional manner and demonstrate proper sanitary and biosecurity practices during the inspection?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 5.2 "Inspection Procedures"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector has combative behavior during the inspection.
b. The inspector does not follow FDA and/or state biosecurity procedures.
c. The inspector does not follow the EGG PRODUCER's biosecurity procedures while inspecting between poultry houses.

III. ORAL AND WRITTEN COMMUNICATION

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 5.1 "Inspection Information"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector does not explain why he/she is at the firm.
b. The inspector enters through the back door and begins examining a storage area without notifying anyone at the firm.

2. Did the inspector use suitable interviewing techniques?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 5.2 "Inspection Procedures"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector's requests for information are vague; consequently, the firm provides documents that are unrelated to the inspection.

Deleted: December 2020

b. The EGG PRODUCER is unable to respond to a request for information, because the inspector spoke in unfamiliar and confusing jargon.
c. When the EGG PRODUCER's responses are evasive, the inspector does not ask follow-up questions to obtain the necessary information. Consequently, the answers to the questions are incomplete.

3. Did the inspector explain findings clearly and adequately throughout the inspection?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 5.2 "Inspection Procedures"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector does not discuss a significant observation at the close-out meeting.
b. The inspector is vague during his/her discussion with the EGG PRODUCER at the end of the inspection. Therefore, the EGG PRODUCER is unaware of the significance of the observations and that corrective actions are needed.

4. Did the inspector alert the firm's appropriate management when an immediate corrective action was necessary?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 5.2 "Inspection Procedures"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector does not notify the EGG PRODUCER the poultry house environment is still considered SE positive when becoming aware the poultry house was not cleaned and disinfected after an SE positive environment test in accordance to the Egg Safety Rule.
b. The inspector didn't notify the EGG PRODUCER when he/she saw a swarm of flies above a pile of cracked EGGS dropped from an EGG belt.
c. The inspector does not discuss with the EGG PRODUCER a significant deficiency observed in the poultry house before leaving the firm that day.

5. Did the inspector answer questions and provide information in an appropriate manner?

References:

Deleted: December 2020

- FDA CPGM 7303.836 “Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule”
- IOM, Subchapter 5.2 “Inspection Procedures”
- State program’s standard operating procedures

Examples of a “needs improvement” rating:

a. The inspector fabricates an answer to a policy question that could lead the firm to take an inappropriate corrective action.
b. The inspector dictates an inappropriate corrective action for a deficiency.

6. Did the inspector write their findings accurately, clearly and concisely on the state form/document or FDA 483 left with the firm?

References:

- FDA CPGM 7303.836 “Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule”
- IOM, Subchapter 5.2 “Inspection Procedures”
- State program’s standard operating procedures

Examples of a “needs improvement” rating:

a. The list of findings shows that the “firm did not follow SE prevention measures” with no further explanation.
b. The inspector fails to write on the list of findings that he/she observed gross rodent infestation in one of the houses.

IV. SAMPLE COLLECTION

Note: These three questions are only answered if samples are collected as part of the FIELD INSPECTION AUDIT. Leave blank if no samples were collected.

1. Did the inspector follow the state program’s sampling policies and procedures to assure sample integrity, security, accountability, and chain of custody?

References:

- FDA CPGM 7303.836 “Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule”
- IOM, Subchapter 4.3 “Sampling: Collection Technique”
- State program’s standard operating procedures

Examples of a “needs improvement” rating:

a. The inspector collected an environmental sample within a poultry house, however didn’t drive the sample to the laboratory until two days after collection.

Deleted: December 2020

b. The inspector collected environmental samples from three poultry houses. After collecting each sample, the inspector left the unsealed samples outside his/her vehicle and without proper refrigeration.

2. Did the inspector use the appropriate method and equipment to collect the sample?

References:

- FDA CPGM 7303.836 "Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule"
- IOM, Subchapter 4.3 "Sampling: Collection Technique"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector did not collect the environmental sample by drag swabbing the manure even though the manure was suitable for collection purposes.
b. The inspector did not aseptically moisten the sterile gauze pad with canned evaporated milk prior to use.
c. The inspector pooled sub samples.

3. Did the inspector seal the sample and initiate chain of custody to maintain and document sample integrity and security?

References:

- FDA CPGM 7303.836 - Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule
- IOM, Subchapter 4.5 "Sampling: Preparation, Handling, Shipping"
- State program's standard operating procedures

Examples of a "needs improvement" rating:

a. The inspector did not officially seal the environmental sample after collection as required by policy.
b. The inspector did not create chain of custody documentation as required by policy.

Deleted: December 2020

Appendix 4.4 – Inspection Report Audit Form

EGG SAFETY REGULATORY PROGRAM STANDARDS INSPECTION REPORT AUDIT FORM	
Auditor: State inspector:	Date of audit: Date of inspection:
License #:	FDA FEI # (if applicable):
Firm Name: Firm address:	Type of Inspection: ☐ FDA Targeted Inspection ☐ FDA Comprehensive Inspection ☐ State Inspection ☐ Other:
Total number: 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. If the audit score is below eighty percent, the audit rating must be marked as "Needs Improvement."

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

I. Inspection Report Observations and Performance

1. The inspector submitted the report within designated timeframes.
   ☐ Acceptable ☐ Needs Improvement
   Comments *(required for Needs Improvement)*

2. All required fields on inspection report or related forms are completed.
   ☐ Acceptable ☐ Needs Improvement
   Comments *(required for Needs Improvement)*

Deleted: December 2020

3. Written observations were clear and concise.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

4. The inspector followed all current and applicable report writing and documentation procedures.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

5. The violations identified by the inspector are based on state and/or federal regulations.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

6. The inspector reviewed past inspection findings and acts on repeated or unresolved violations.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

7. The inspector correctly recorded significant findings (if any).
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

8. The inspector recorded the collection of all samples, exhibits, photographs, or photocopies to support findings.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

9. The inspector obtains and documents on-site CORRECTIVE ACTION at the time of inspection as appropriate to the type of violation.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

Deleted: December 2020

10. The inspector followed through and documented compliance activities per state policy.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

General Comments

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

Deleted: December 2020

Appendix 4.4a – Performance Rating for Inspection Report Audits

State Program:_____ **Performance Period:**_____
Reviewed by:_____ **Cumulative Score:**_____
Date Reviewed:_____

Notes: A = acceptable, NI = needs improvement

Firm ID #																
Inspection Date																
Auditor's Initials																
Date of Audit																

Performance Factors	**Performance ratings**																**A_t**	**Ni_t**	**Performance Factor Score**
I.1																			
I.2																			
I.3																			
I.4																			
I.5																			
I.6																			
I.7																			
I.8																			
I.9																			
I.10																			
Audit Score																			
																Subtotal		
																Total – Enter the final sums (subtotal + all continuation sheets)		

USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Deleted: December 2020

Appendix 4.5 – Sample Report Audit Form

EGG SAFETY REGULATORY PROGRAM STANDARDS SAMPLE REPORT AUDIT FORM	
Auditor:	Date of audit:
License #:	FDA FEI (if applicable) #:
Firm name: Firm address:	Date of sample collection: Sample ID #:
Total number: 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.

Sample report audits do not need to be performed unless samples are collected.

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 Report Observations and Performance

1. Method of collection and equipment was appropriate.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

2. Recorded sample seal application per state procedure.
   ☐ Acceptable ☐ Needs improvement
   Comments *(required for Needs Improvement)*

Deleted: December 2020

3. Maintain and document sample integrity, security and chain of custody. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
4. Sample was handled, packaged, and shipped to prevent compromising the condition or integrity of the sample, as evidenced by acceptance and testing by the receiving laboratory. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
5. Sample was delivered or shipped to an appropriate laboratory within acceptable timeframes. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
II. Sample Report
1. Date of sample collection was recorded. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
2. Sample identification which may include: name, firm, house, sample number assigned by the sampler at the time of collection, and sample type (i.e., EGG, belt, manure, walkway, etc.) was recorded. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
3. Method of collection and any special techniques used to collect sample was recorded. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
4. Location where sample was collected was recorded. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*

Deleted: December 2020

5. Reason for collection was recorded (surveillance, compliance, investigational, regulatory, or other). ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
6. Analysis requested was recorded. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
7. Receiving and distribution information was recorded. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
8. Observations regarding the sample were recorded, if any. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
9. Product labels and/or labeling information was collected per state policies. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
General Comments
Enter any general comments or recommendations as a result of this audit.

Deleted: December 2020

Appendix 4.5a – Performance Rating for Sample Report Audits

State Program:_____ **Performance Period:**_____
Reviewed by:_____ **Cumulative Score:**_____
Date Reviewed:_____

Notes: A = acceptable, NI = needs improvement Sample report audits do not need to be performed unless samples are collected.

Firm ID #																
Inspection Date																
Auditor's Initials																
Date of Audit																

Performance Factors	**Performance ratings**																**A_t**	**Ni_t**	**Performance Factor Score**
I.1																			
I.2																			
I.3																			
I.4																			
I.5																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
II.7																			
II.8																			
II.9																			
Audit Score																			
																Subtotal			
																Total – Enter the final sums (subtotal + all continuation sheets)			

Deleted: December 2020

USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Deleted: December 2020

Appendix 5.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
5.3.1 Coordination of EGG AND EGG PRODUCT RELATED INCIDENTS Response Activities with Other Authorities		
Does the state program have:		
1. A memorandum of understanding with other state agencies?		
2. A written procedure that:		
a. Identifies and describes the roles, duties, and responsibilities of each program for the requirements in 5.3.2-5.3.5?		
b. Describes agency collaboration as necessary with FDA and other appropriate local, state and federal authorities in multi-jurisdictional EGG AND EGG PRODUCT RELATED INCIDENTS?		
c. Designates response coordinator(s) to guide program investigation efforts in collaboration with all agencies involved and manage events using a formalized Incident Command System (ICS) structure or an official action plan that includes:		
i) Outlining containment?		
ii) Communication?		
iii) Control?		
iv) CORRECTION?		
v) After action protocol?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
d. Describes how all government agencies, departments, or appropriate parties are rapidly notified of relevant findings in cases of EGG AND EGG PRODUCT RELATED INCIDENTS?		
e. Provides guidance for the immediate notification of law enforcement agencies when intentional EGG AND EGG PRODUCT RELATED INCIDENTS or terrorism is suspected or threatened?		
3. A list of relevant agencies and emergency contacts that is reviewed and updated according to a frequency defined by the state?		
5.3.2 Surveillance		
Does the state program:		
1. Use epidemiological information from appropriate departments or agencies (federal, state, or local) to detect incidents of EGG AND EGG PRODUCT RELATED INCIDENTS?		
2. Maintain notifications of EGG AND EGG PRODUCT RELATED INCIDENTS that are reported to the program in a log or database?		
5.3.3 Investigation/ ENVIRONMENTAL ASSESSMENT		
Does the state program:		
1. Have a written procedure with recommended timeframes and criteria to investigate EGG AND EGG PRODUCT RELATED INCIDENTS that include:		
a. Determining the appropriate response?		
b. Initiating the response?		
c. Completing the response?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
2. Have a written procedure to collect environmental data similar to those found in the documents listed in 5.3.3.2.1 - 5.3.3.2.4?		
3. Have a written procedure to coordinate the traceback and traceforward of EGG and EGG PRODUCTS found to contain a hazard or that are implicated in an illness, injury, outbreak?		
4. Have access to LABORATORY support for investigation of reports of EGG AND EGG PRODUCT RELATED INCIDENTS?		
5. Correlate and analyze ENVIRONMENTAL ASSESSMENT data to identify contributing factors and antecedents that led to EGG AND EGG PRODUCT RELATED INCIDENTS?		
5.3.4 Control Measures		
Does the state program:		
1. Mitigate and contain EGG AND EGG PRODUCT RELATED INCIDENTS and EMERGENCIES through strategies that include industry education and outreach, enforcement and public awareness activities?		
2. Maintain a written procedure for releasing prevention guidance and information to the public (includes identifying a media person and developing guidelines for coordinating media information with other jurisdictions) to reduce the impact of EGG AND EGG PRODUCT RELATED INCIDENTS?		
5.3.5 Post-Response		
Does the state program have written procedures to:		
1. Maintain program investigation and ENVIRONMENTAL ASSESSMENT findings and reports?		
2. Distribute final program investigation report(s), including an ENVIRONMENTAL ASSESSMENT if completed, to relevant		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
agencies responsible for reporting contributing factors and antecedents to CDC?		
3. Distribute recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 6.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
6.3.1 Does the state program have a written compliance and enforcement procedure that describes the enforcement strategies, use of enforcement tools and progressive enforcement actions?		
6.3.2 Does the state program have a written procedure for conducting an annual review of its compliance and enforcement procedures to:		
1. Determine if the state program's enforcement actions were successful in achieving compliance?		
2. Identify potential improvements or modifications of the compliance and enforcement procedures, if any?		
3. Review all cases, otherwise, a statistical approach should be used?		
4. Document the results of the annual review on Appendix 6.3, or equivalent form?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 6.2 – Examples of Enforcement Tools and Progressive Enforcement Actions

Below is a list of common enforcement tools that may be used by state programs. An explanation of each tool has been provided. An example of how to apply these tools in a progressive enforcement action is included below this list.

Advisory or informational letter – can be used as a form for both compliance assistance and education and would usually apply to non-repetitive violations of no risk to health, safety, or the environment. Administrative violations involving product registration and payment of fees are examples.

Warning letters with or without a required response – usually used to clearly outline the violation and require CORRECTIVE ACTION(s). The letter might or might not request a written response upon CORRECTION. This tool would be appropriate for violations that have or could present risk to health, safety, or the environment. Further, it could be appropriate for repetitive administrative violations.

Informal hearings or meetings – used to provide an opportunity to bring together parties to discuss and understand the nature of a violation. It may lead to an agreed order or consent decree. Use of this tool would be appropriate for many violations including those that may be chronic; threats to health, safety or the environment; civil penalties, license denials, revocation, or other serious administrative actions. This tool may be used in conjunction with others to facilitate compliance.

Civil penalty – monetary penalty assessed for a violation. Civil penalty fines are based on a numeric point matrix determined by the severity of the violation and the repeat nature of the offense. A notice shall be given and an opportunity for an administrative (formal) hearing must be provided. This tool should be used in addition to other tools to prevent chronic violations or to address illegal acts when other tools are not available. Where appropriate, an informational letter, warning letter, informal hearing or meeting, or administrative hearing should precede the use of civil penalties.

Denial, suspension, or revocation of an EGG HANDLER registration certificates – the program may refuse to issue, or may deny, suspend or revoke a registration certificate based on the severity of the violation(s), including creating a hazard to human health or the environment or in the distribution of the marketing of EGGS intended for human consumption, repetitive failure to comply with statutes and/or regulations, and/or unregistered persons marketing EGGS.

Administrative hearing – opportunity for an administrative (formal) hearing is provided to the regulated ESTABLISHMENT prior to the issuance of a civil penalty, license denial, or license revocation. An administrative hearing may result in a consent decree with the regulated ESTABLISHMENT. This tool should be used in chronic violations or when threats to health or safety exist.

EGGS held off-sale and seized – EGGS that are held off sale and/or seized are determined to be a public nuisance by an enforcement officer. If the violator refuses or fails within a reasonable time specified by the enforcement officer to commence to bring the EGGS and their containers

Deleted: December 2020

in compliance with these regulations, the EGGS and their containers may be seized by an enforcement officer.

Injunction – may be used to restrain a firm from any or all violations. The tool would be used in case of a serious threat of immediate or irreparable harm. Use may also be appropriate to restrain a firm from operation in wanton violation of a chronic nature involving administrative aspects of the law.

Criminal prosecution – may be pursued against a firm or person that impedes, obstructs, hinders, or otherwise prevents or attempts to prevent enforcement of EGG safety regulation. This tool can be used for any violation, but other tools may be appropriate.

Example of Progressive Enforcement Actions:

1. Each violation falls into one of four levels: compliant, low, moderate, and high; with the compliant level having no penalties associated with it and the high level having the most serious penalties enforced. As the violation levels increase from compliant to high, there may be a higher human health risk associated with it.

2. Each violation is discussed with the firm, and an enforcement tool(s) selected and enforced. Choose the appropriate enforcement tool(s) for the violation level based on relevant factor(s) (i.e. history of violator, high economic benefit gained by non-compliance, non-cooperation of the violator, and/or high risk to human health).

3. The more factors determined to be relevant, the higher possible penalty of enforcement tool(s) should be selected and enforced for each violation.

4. The enforcement tools are listed for each violation level ranging from the lowest possible penalty to highest possible penalty.

Deleted: December 2020

Appendix 6.3 – Calculation of the Level of Conformance to Compliance Procedures

State Agency_____

Rating for CONFORMANCE to compliance procedures:

Firm identification number	Enforcement action recommended	Compliance procedures followed (A/NI)	Use this space to explain improvements needed to follow compliance procedures

Subtotal	**Enter the sum of the totals from all continuation sheets**	**A_t =**	**NI_t =**	
Total	**Enter the final sums --subtotal + sums on this form**	**A_t =**	**NI_t =**	

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 6.3a – Instructions for Review of Compliance and Enforcement Procedure

Appendix 6.3 is used to record the enforcement actions recommended in the past 12 months and to calculate the state program's rating for conformance to compliance procedures. Supporting documents should be referenced and maintained by the state program. Please indicate if an action was taken because voluntary compliance was not achieved. Document if changes are need to the compliance and enforcement procedure.

All cases must be reviewed; otherwise, a statistical approach is used to determine a representative number of cases. Use continuation sheets as necessary.

INSTRUCTIONS: (1) Record the firm's identification number and the recommended enforcement action.

(2) For each type of enforcement action, record the level of conformance to compliance procedures.

A = acceptable; NI = needs improvement

(3) Record the A_t and NI_t.

A_t = vertical sum of acceptable ratings.

NI_t = vertical sum of needs improvement ratings.

(4) Calculate the overall rating for the state program's conformance to compliance procedures. Record the rating in the box located at the top of Appendix 6.3.

Formula: Performance factor rating = $[A_t / (A_t + NI_t)] \times 100$

Deleted: December 2020

Appendix 7.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
7.3.1 Does the state program have a written procedure of the methods that will be used for communication with the EGG industry stakeholders (may include SMALL EGG PRODUCERS), academia, other regulators, and consumers?		
Does the written procedure include how the state program will:		
1. Identify the methods for communication with the EGG industry stakeholders, academia, other regulators, and consumers?		
2. Interact with industry and consumers by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees?		
3. Tailor outreach efforts to a target population which may include dissemination of information using electronic sources and traditional methods such as mailings?		
4. Document and evaluate OUTREACH ACTIVITY EVENTS using Appendix 7.2 or equivalent form?		
5. Maintain documents such as agendas and meeting summaries and program evaluations?		
6. Implement an outreach and training program that will include SMALL EGG PRODUCERS within the state and be inclusive of basic biosecurity and sanitation requirements to reduce the potential of an EGG AND EGG PRODUCT RELATED INCIDENT?		

Deleted: December 2020

7.3.2 Does the state program develop an outreach plan that supports the state program mission and includes:		
1. Objectives of the outreach plan?		
2. Target population?		
3. Types of outreach activities and OUTREACH ACTIVITY EVENTS?		
4. Delivery method?		
5. The templates provided in Appendix 7.3, or equivalent forms, are used to record the outreach plan?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 7.2 – Outreach Activity Event and Self-Evaluation Worksheet

This worksheet is completed by the state program to document OUTREACH ACTIVITY EVENTS. Attach verifying documents such as agendas and meeting summaries and program evaluations to this form.

Section I. Overview of OUTREACH ACTIVITY EVENT

a. Type of OUTREACH ACTIVITY EVENT (check one):

☐ Seminar ☐ Workshop ☐ Training course

☐ Other: _____

b. Subject or name of OUTREACH ACTIVITY EVENT: _____

c. Date of OUTREACH ACTIVITY EVENT:_____

d. Host organization:_____

Section II. Self-Evaluation of OUTREACH ACTIVITY EVENT

Program Elements	Yes/No	If no, please explain.
a. The purpose and objectives were clearly defined		
b. The content of the OUTREACH ACTIVITY EVENT was consistent with the objectives		
c. The activity was tailored to a target population Identify target population:		
d. An evaluation was completed by attendees		

Section III. Critique of OUTREACH ACTIVITY EVENT

Discuss what went well, what could be done better, and what more could be done to improve the OUTREACH ACTIVITY EVENT. Address comments from attendees, if available.

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 7.3 – Outreach Plan

When developing the Outreach Plan the state program may choose to use one of the following templates or another equivalent form. The content, design, and frequency of update should be determined by the state program.

A. Outreach Plan in Chart Format

Effective Date(s)_____

Objective	Target Population	Type of Outreach Activity	Delivery Method

Completed By:

Name_____**Date**_____

B. Outreach Plan in Paragraph Format

Effective Date(s)_____

Outreach Objective(s):

List and provide details of outreach activities and OUTREACH ACTIVITY EVENTS that will be used to help support each objective, including the target population and the method of delivery.

Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 8.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
8.3.1 Does the state program have a written workplan?		
Does the written workplan include:		
1. Inspection plan		
a. Number of inspections?		
b. Type of inspection?		
c. Risk category of ESTABLISHMENT?		
d. Frequency?		
2. Sample plan as described in Standard 3, section 3.3.6.1?		
3. Timeframe that the workplan is applicable within a 12-month period?		
8.3.2 Does the state program have a written procedure for evaluating the workplan?		
Does the written procedure include:		
1. Conducting periodic and annual reviews of the workplan?		
2. Reviewing the workplan for alignment with state program objectives and resources?		
8.3.3 Does the state program have a written procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe?		
8.3.4 Does the state program develop a formula to validate the workplan that:		
1. Calculates the number of staff needed to accomplish the state programs workplan?		

Deleted: S

Deleted: S

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
2. Uses numerical values that are based on the state programs data?		
3. Must be used by the state program?		
8.3.5 Is a list of the equipment required for inspections and sample collections must be:		
1. Established by the state program?		
2. Maintained by the state program?		
8.3.6 The state program must:		
1. Conduct a review of the resources required to fully implement the ERPS, including each of the program elements in the individual Standards?		
2. Is the review recorded on Appendix 8.4 or equivalent form?		
3. Did the resource review determine if the state program has adequate:		
a. Staff?		
b. Equipment?		
c. Funding?		
8.3.7 Are subsequent resource evaluations completed to determine the resources necessary for the state program to achieve and maintain full IMPLEMENTATION and full CONFORMANCE with each Standard?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 8.2 – Example Formula for Calculating the Number of Inspectors Required to Conduct Inspections of Egg Establishments

This appendix is an example of how to calculate the number of inspectors required to conduct inspections of EGG ESTABLISHMENTS. A state program may use this example to develop a formula that is suitable for the state program's needs and based on data that can be verified. This formula is not applicable to staff needs for other state program areas including sample collection, response, laboratory services, or administration.

Calculating the Number of Inspectors:

1. The following data must be collected. Records must be maintained to verify the data used in the calculations.

   - Risk categorization of EGG ESTABLISHMENTS (example categorization: high risk, medium risk, and low risk)
   - Number of EGG ESTABLISHMENTS in each risk category
   - Percent of ESTABLISHMENTS to be inspected each year in each risk category (in percent)
   - Percent of ESTABLISHMENTS to be re-inspected each year in each risk category (in percent)
   - Average inspection time, including travel time, of EGG ESTABLISHMENTS in each risk category (in hours)
   - ***Note**: The following formulas do not account for sample collections. For state programs that utilize inspectors to collect samples, the state programs should consider adding additional time to the average inspection time, if appropriate, to account for sample collection.*

2. Calculate the available annual inspection time, in hours, per inspector (AIT).

   The state program should determine the average number of hours an inspector has available to conduct inspections each year after accounting for annual leave, sick leave, holidays, training, and other state program activities.

3. Calculate the number of hours required to inspect EGG ESTABLISHMENTS in each risk category.

   The following examples utilize three risk categories: high risk, medium risk, and low risk.

Deleted: December 2020

- For High Risk EGG ESTABLISHMENTS:

[(#HR x %HRF) + (#HR x %HRRF)] x HRaIT = hHRI per year

Key	Description
#HR	Number of High Risk ESTABLISHMENTS
%HRF	Percent of High Risk ESTABLISHMENTS to be Inspected per Year (%)
%HRRF	Percent of High Risk ESTABLISHMENTS to be Re-Inspected per Year (%)
HRaIT	High Risk ESTABLISHMENTS Average Inspection Time (h)
hHRI per year	Total Hours of High Risk Inspections per Year

- For Medium Risk EGG ESTABLISHMENTS:

[(#MR x %MRF) + (#MR x %MRRF)] x MRaIT = hMRI per year

Key	Description
#MR	Number of Medium Risk ESTABLISHMENTS
%MRF	Percent of Medium Risk ESTABLISHMENTS to be Inspected per Year (%)
%MRRF	Percent of Medium Risk ESTABLISHMENTS to be Re-Inspected per Year (%)
MRaIT	Medium Risk ESTABLISHMENTS Average Inspection Time (h)
hMRI per year	Total Hours of Medium Risk Inspections per Year (h)

- For Low Risk EGG ESTABLISHMENTS:

[(#LR x %LRF) + (#LR x %LRRF)] x LRaIT = hLRI per year

Key	Description
#LR	Number of Low Risk ESTABLISHMENT
%LRF	Percent of Low Risk ESTABLISHMENT to be Inspected per Year (%)
%LRRF	Percent of Low Risk ESTABLISHMENT to be Re-Inspected per Year (%)
LRaIT	Low Risk ESTABLISHMENT Average Inspection Time (h)
hLRI per year	Total Hours of Low Risk Inspections per year (h)

4. Using the data calculated in 2 and 3, calculate the number of inspectors required to ensure coverage of state program's ESTABLISHMENT inventory.

   (hHRI per year + hMRI per year + hLRI per year) / AIT = **Number of Inspectors Needed**

Deleted: December 2020

Appendix 8.3 – Example List of Equipment Used for Inspections and Sample Collections

Standard 8 requires a state program to develop a list of equipment needed to conduct inspections and sample collections when applicable. The list provided below is an example equipment list for inspections and sample collections. The state program may use the chart below to record whether the equipment is assigned, available to inspectors, or not available.

Equipment	Assigned	Available	Not Available
Alcohol swabs and wipes			
Lysol or other approved spray sanitizers			
Hand sanitizer			
Disinfectant approved for car tires and undercarriage			
Measuring tape			
Camera			
Cell phone			
Clipboard			
Computer and printer			
Credentials			
Eye protection			
Flashlight (head lamp) and holder			
Hearing protection			
Official seals			
Paper, pen, masking tape, and marker			
Protective clothing (Tyvek suit, gloves, and shoe covers)			
Garbage and Ziplock bags			
Regulations, policies, and designated reference material			
Required forms			
Disposable respirators/masks			
Hairnet			
Shipping containers (OPTIONAL)			
Thermometer			
Egg candler			
Scales			

Deleted: December 2020

Air cell gauge			
Vehicle			
OPTIONAL EQUIPMENT FOR SAMPLES			
Sampling equipment (sterile containers, bags, or swabs, evaporated milk, labels, marker, sterilized & nitrile gloves)			
Bus tub			
Knife and scissors			
Can opener			
Coolant (ice and freezer packs)			
Paper towels			
Garbage and Ziplock bags			
Sterile gauze packages			
Ice chest			
Whirl Paks			

Deleted: December 2020

Appendix 8.4 – Resource Summary Report

This table provides an overview of a state program's evaluation of the resources needed to implement the Egg Regulatory Program Standards. Based on the review, 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 should be in the "Other Resources Needed" column. The administrative functions needed to support all program areas should be considered when determining program resources.

State Agency_____

No.	Standard	Funding	Staffing	Equipment	Other Resources Needed
1	Regulatory Foundation				
2	Training Program				
3	Inspection Program				
4	Inspection Audit Program				
5	Egg-Related Illness, Outbreak, and Emergency Response				
6	Compliance and Enforcement				
7	Outreach Activities				
8	Program Resources				
9	Program Assessment				
10	Laboratory Support				

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 9.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
9.3.1 Does the state program conduct a baseline self-assessment:		
1. Within the first year?		
2. Using the self-assessment worksheets associated with each standard?		
3. Using the results of its self-assessments to complete Appendix 9.2?		
9.3.2 If the state program fails to meet any of the program elements or documentation requirements, did the state program develop a STRATEGIC IMPROVEMENT PLAN?		
Does the STRATEGIC IMPROVEMENT PLAN include:		
1. The individual element or documentation requirement that was not met?		
2. Improvements needed to meet individual element or documentation requirement of the standard that are under development?		
3. Projected completion dates for each task?		
4. Personnel responsible?		
5. Date completed for each task?		
9.3.3 Does the state program review and update the self-assessment appendices and STRATEGIC IMPROVEMENT PLAN at least annually?		
9.3.4 Does the state program:		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
1. Participate in FDA ASSESSMENTS to determine IMPLEMENTATION and CONFORMANCE to the standards?		
2. Address FDA ASSESSMENT observations and establish CORRECTIVE ACTIONS?		
9.3.5 Does the state program have written CORRECTIVE ACTION and PREVENTIVE ACTION (CAPA) procedure(s)?		
1. Do the CAPA procedure(s) include:		
a. Identification of any non-CONFORMANCE(S) or potential non-CONFORMANCE(S)?		
b. The cause(s) of the non-CONFORMANCE(S) or potential non-CONFORMANCE(S)?		
c. The CORRECTION(S) needed to eliminate the non-CONFORMANCE(S)?		
d. CORRECTIVE ACTION(S) or PREVENTIVE ACTION(S) to eliminate the cause of the non-CONFORMANCE(S) or potential non-CONFORMANCE(S)?		
e. The results of CORRECTIVE ACTION(S) or PREVENTIVE ACTION(S) taken?		
f. Review of the effectiveness of the CORRECTIVE ACTION(S) or PREVENTIVE ACTION(S)?		
2. Does the state program maintain written CAPA records that include the criteria found in 9.3.2.1 – 9.3.2.5 and 9.3.5.1.1 – 9.3.5.1.6?		
9.3.6 Does the state program:		
1. Have a written DOCUMENT CONTROL procedure?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
a. Is the state program able to demonstrate that all documents are CURRENT AND FIT-FOR-USE though maintaining a master document list or other system?		
b. Does the master document list or other system show:		
i) Documents are reviewed for accuracy?		
ii) Documents are approved for release by authorized personnel and signed/dated with an approval or revision date?		
iii) Documents are distributed to and used at the location where the prescribed activity is performed?		
2. Retain records or procedures required under each standard for the three previous years, or per the state program's record retention policy, whichever is longer?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020

Appendix 9.2 – Self-Assessment Summary Report

State agency: _____

Report completed by: _____
(NAME) **(DATE)**

Standard	**Self-Assessment**	**IMPLEMENTATION**	**Explain improvements needed to fully IMPLEMENT standards** *(required for incomplete self-assessment and partial IMPLEMENTATION)*
1. Regulatory Foundation	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
2. Training Program	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
3. Inspection Program	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
4. Inspection Audit Program	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
5. Egg-Related Illness, Outbreak & Emergency Response	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
6. Compliance and Enforcement	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	

Deleted: December 2020

Standard	Self-Assessment	IMPLEMENTATION	**Explain improvements needed to fully IMPLEMENT standards** *(required for incomplete self-assessment and partial IMPLEMENTATION)*
7. Outreach Activities	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
8. Program Resources	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
9. Program Assessment	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
10. Laboratory Support	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	

Deleted: December 2020

Appendix 10.1 – Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluate if it includes the associated components. If the state program has the main component and associated components indicate "Yes", if not, indicate "No".

State Agency_____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
10.3.1 Laboratory Support		
Does the state program:		
1. Have access to a LABORATORY that is capable of analyzing a variety of samples such as: EGG, environmental, or veterinary clinical samples?		
2. Maintain a list of all analytical services the LABORATORY provides for the state program?		
3. Have a contract or written agreement with each LABORATORY and contracted laboratories unless under the same administrative agency?		
4. Maintain contracts or written agreements with each LABORATORY that:		
a. Define the responsibilities of each party?		
b. Describe the types of testing services to be performed?		
c. Describe how exceptions to planned work will be communicated?		
10.3.2 ISO Accredited Laboratories		
1. Does the state program utilize laboratories that have a current accreditation to the International Organization for Standardization/International Electrotechnical Commission ISO/IEC 17025 (2017 or current version) to analyze EGG or environmental samples?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
2. Is the accreditation body of the LABORATORY a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA)?		
10.3.3 Non-ISO Accredited Laboratories		
If the state program is not using laboratories holding accreditation to ISO/IEC 17025 (2017 or current version), is the program utilizing laboratories that have:		
1. A written quality system which incorporates management and technical requirements of ISO/IEC 17025 (2017 or current version) and associated procedures?		
Does the written quality system include:		
a. Calibration and maintenance of equipment?		
b. Analyses are performed using validated and verified test procedures?		
c. Documentation of sample traceability?		
d. Documentation of analytical results and analysts performing work?		
e. Analysts that are trained and authorized to perform technical procedures?		
f. Periodic audits?		
g. Chain of Custody/Records?		
2. A written procedure that defines the activities necessary when non-conforming work occurs?		
Does the written procedure describe:		
a. How quality control data are assessed to assure that test results from non-conforming work are not released?		

Deleted: December 2020

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
b. How cause analysis and problem resolution are recorded?		
3. A DOCUMENT CONTROL procedure that assures documents issued to personnel are current, suitable, and reviewed and approved by authorized personnel prior to release and assures that obsolete documents are removed from use?		
4. A written record keeping process that assures that records of original observations and data collection are maintained and sufficient to establish traceability of test results, to sample handling and storage, to sample analysis including data collection, to equipment calibration and maintenance, and to the review of test results prior to release?		
5. A written process to assure that reference materials and reference cultures are fit for purpose, are not outdated, and are traceable to a lot number or other unique indicator?		
6. A written process to assure that the LABORATORY participates in relevant and available proficiency testing activities?		
7. A written process for reporting regulatory data results?		

Assessment Completed By:

Name_____**Date**_____

Deleted: December 2020