

**COOPERATIVE AGREEMENT
AMONG
PENNSYLVANIA DEPARTMENT OF AGRICULTURE
AND
PENNSYLVANIA DEPARTMENT OF HEALTH
AND
PENNAG INDUSTRIES ASSOCIATION POULTRY COUNCIL**

OCTOBER 17, 2017

PURPOSE: To provide reasonable assurance to consumers that Pennsylvania shell eggs (eggs) coming from PEQAP compliant farms are a reduced risk of food-borne disease caused by Salmonella enteritidis (SE).

The parties to this Document are PennAg Industries Association Poultry Council, hereinafter called PennAg, the Pennsylvania Department of Agriculture, hereinafter called PDA, and the Pennsylvania Department of Health, hereinafter called PDH.

WHEREAS, SE associated with eggs has been determined to be a cause of food-borne illness in humans; and

WHEREAS, PennAg, PDA, and PDH wish to assure the safety and quality of eggs; and

WHEREAS, PDH has a duty to protect the people of this Commonwealth and to determine and employ the most efficient and practical means for the prevention and suppression of diseases pursuant to 71 P. S. § 532 (a) and 35 P.S. § 521.1 et seq; and

WHEREAS, PDA has a duty to prevent, suppress, control and eradicate any transmissible diseases of animals and poultry pursuant to 71 P. S. § 442; and

WHEREAS, Sections 501 and 502 of the Administrative Code of 1929 (71 P. S. Sections 181 and 182) require Commonwealth departments and agencies to coordinate their work and activities with other Commonwealth departments and agencies; and

WHEREAS, PennAg represents egg producers who wish to market wholesome and safe eggs;

NOW, THEREFORE, the parties to this Document set forth the following as the terms and conditions of their understanding:

I. Pennsylvania Department of Health

- A. PDH will conduct epidemiological investigations of egg-associated food-borne illness of humans to determine the probable source of the causative agent(s) in accordance with Appendix B attached hereto;
- B. PDH will inform PDA of egg associated food-borne illness and/or food contamination caused by SE and the apparent source of the SE-suspect eggs in accordance with Appendix B attached hereto;
- C. PDH, Bureau of Epidemiology staff will communicate by phone with PDA and PennAg on a regular and ongoing basis regarding ways and means to reduce the risk of egg-associated outbreak of SE disease in humans; and
- D. PDH will participate as a non-voting (ex-officio) member in the PEQAP Oversight Committee.

II. Pennsylvania Department of Agriculture

- A. PDA will facilitate determination of the source of eggs epidemiologically linked with SE illness in humans and/or contamination of food in accordance with Appendix B attached hereto;
- B. PDA will inform flock owners of the testing requirements and the requirement to restrict sale of eggs when determined to be necessary through testing from flocks that have been epidemiologically linked with SE contamination of food products and/or SE illness in humans, according to quality assurance standards set forth by the Pennsylvania Egg Quality Assurance Program (hereinafter PEQAP or Program) and Appendix B attached hereto;
- C. PDA will promote proper handling, refrigeration and cooking of shell eggs by food establishments;
- D. PDA will communicate with PDH and PennAg on a regular and ongoing basis regarding ways and means to manage the risk of egg-associated outbreaks of disease caused by SE in humans;
- E. PDA will provide, subject to resource limitations, oversight, technical advice, and administrative and financial support to PEQAP as outlined in Appendix A;
- F. PDA will monitor PEQAP and labeling of eggs produced by PEQAP participants;

- G. PDA will maintain an electronic record of each PEQAP participant activity, including identification and location of flock owner(s); identification and description of each flock on premises participating in PEQAP; status and outcome of each PEQAP prescribed action; disposition of eggs and birds from PEQAP participating farms if found to be egg SE-positive; sources of birds; and any other information relevant to the SE status of a PEQAP participant. This information shall be provided by the flock owner or his/her designated representative.
- H. PDA representatives will monitor PEQAP activity at intervals determined by PDA. PDA monitoring will be orchestrated by the Bureau of Animal Health and Diagnostic Services, which will establish a schedule and protocol attuned to PEQAP operations;
- I. PDA will conduct PEQAP quality assurance determinations including, but not limited to, independent environmental, rodent, bird or egg sampling for microbiological testing;
- J. PDA will participate in training and program review with PEQAP flock managers;
- K. PDA will provide a report of PEQAP monitoring/oversight results to the PEQAP Oversight Committee; and PEQAP Compliance Committee (in the event of a dispute arbitration) as needed; and
- L. PDA will participate as a non-voting (ex-officio) member in the PEQAP Oversight Committee.

III. PennAg Industries Association Poultry Council

- A. PennAg will promote and orchestrate industry leadership and participation in PEQAP via the PEQAP Oversight Committee;
- B. PennAg Industries will enforce PEQAP standards in accordance with this Cooperative Agreement and operations annex;
- C. PennAg, in concert with Penn State University, the University of Pennsylvania, and PDA, will provide technical and professional counsel to PEQAP, including training and educational services;
- D. PennAg will communicate with PDA and PDH on a regular and ongoing basis regarding ways and means to manage the risk of egg-associated outbreak of SE disease in humans;
- E. PennAg will participate as a voting member in the PEQAP Oversight Committee;

- F. PennAg will participate as a member in the PEQAP Compliance Committee (in the event of a dispute arbitration); and
- G. PennAg will notify egg packing supply companies of issues with dirty supplies. Dirty egg supplies should be documented on the PEQAP inspection forms by PDA inspectors and will result in a warning letter from PennAg to the supplier. A flock owner or manager or packing plant owner or manager may contact PennAg at any time to report dirty egg packing supplies.
- H. PennAg, in cooperation with Penn State, will provide annual training for certification of sample collectors. Refresher courses will be offered as needed. Samplers must be certified by PennAg to submit samples to PADLS. PennAg will provide a current list of certified sample collectors to the PDA PEQAP coordinator for distribution to the PADLS laboratories. The list, including additions and deletions, will be updated on an ongoing basis to ensure it is current and accurate.

IV. General

- A. This Document shall not preclude, expand, or in any way interfere with the exercise of the duty and authority of PDH and PDA to protect human or animal health;
- B. Signature of this Document does not constitute a financial obligation on the part of a signatory. Each signatory party is to use and manage its own funds in carrying out the purpose of this Document;
- C. This Document will become effective upon date of signature and shall continue for the tenure of the program. Further, this Document may be amended at any time by mutual agreement of the parties in writing. It may be terminated by any party upon 30 days written notice to the other parties;
- D. This Document is not intended to and does not create any contractual rights or obligations with respect to the signatory agencies or any other parties; and
- E. Any dispute hereunder between PDH and PDA shall be submitted to the Governor's Office of General Counsel for final resolution.

V. Miscellaneous

A. Definitions

1. For the purpose of this Document, "flock" is defined as all of the poultry in one poultry house.

2. For the purpose of this Document, a “premises” is defined as the property where the poultry house(s) is/are physically located.
 3. For the purpose of this Document, “Adequate Biosecurity” is defined as sufficient flock management procedures in place to ensure that there is no significant potential for SE transmission between premises through exposure to chickens, feed, water, manure, rodents, vehicles, equipment, personnel, or any other fomites/vectors.
 4. For the purpose of this Document, the Q number assigned by PDA identifies the premises and flock.
- B. Whenever this protocol provides that an act is to be done by PDA or PDH, it is to be construed to also permit an authorized designee of that entity to perform that act.
- C. The definition of “epidemiologically implicated” is that a product (or risk factor) was implicated as the cause of an outbreak of human illness by means of finding a significant association between exposure to the product and illness in humans and also through assessment of other relevant factors, which indicate the product to be the cause of the illness. This determination does not require culturing of the causative organism from the product.
- D. If an egg-based foodstuff and/or a fresh whole egg is found to be SE culture positive without epidemiological linkage to a disease outbreak, the fresh whole eggs and/or egg based foodstuff will be treated as if an epidemiological linkage exists until the threat of human disease can be determined. If the trace-back is successful in identifying a possible source flock, eggs from the implicated flock should be appropriately restricted (diverted) and the procedures and protocols established in Sections III-V of Appendix B of this Cooperative Agreement should be followed.
- E. The PEQAP procedures and standards referenced in this Cooperative Agreement are the most current PEQAP procedures and standards in place.

Pennsylvania Department of Agriculture

Name Russell C. Redding
Title Secretary
Signature *Russell Redding*
Date 10/19/2017

**PennAg Industries Association
Poultry Council**

Name CHRISTIAN F. HERR
Title Exc VP
Signature *CHRISTIAN F. HERR*
Date 10/27/2017

Pennsylvania Department of Health

Name Rachel Levine MD
Title Secretary
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Date 5/7/18

PA Department of Health

Alvin Taylor 4/30/18
Chief Counsel Date

PA Department of Agriculture

Richard [unclear] 10/19/17
Chief Counsel Date

Karen Seavitt 5/24/2018
Comptroller Date

N/A
Comptroller Date

Office of General Counsel

C. L. [unclear] 5/15/2018
Deputy General Counsel Date

APPENDIX A

PENNSYLVANIA EGG QUALITY ASSURANCE PROGRAM

I. Statement of Purpose

The Pennsylvania Egg Quality Assurance Program, hereinafter PEQAP or Program, is a voluntary industry program intended to minimize Salmonella enteritidis (SE) contamination of chicken (shell) eggs. Although this program does not guarantee shell eggs to be free of SE contamination, the program does assure commitment of the producer to implementation of those management and monitoring practices most likely to prevent SE contamination. **Basic preventive measures include 1) placement of SE-clean chicks; 2) intensive rodent control; 3) cleaning and disinfection between flocks; 4) environmental monitoring of pullet and layer houses, with continuous testing of eggs from any environmentally SE-positive houses; 5) restriction of SE-positive eggs through diversion to pasteurization, hard cooking, other cooking to sell as a processed egg product, or equivalent; and 6) refrigeration of eggs.** The Pennsylvania Department of Agriculture, hereinafter PDA, provides oversight, administrative support, technical advice, and financial assistance to this program. The Pennsylvania Department of Health, hereinafter PDH, provides oversight and professional advice regarding public health implications. PEQAP participants are assuring the public that they are taking every reasonable precaution to ensure the safety of shell eggs.

II. Program Administration

A. PEQAP Oversight Committee

1. PEQAP is supervised by an Oversight Committee.
2. The PEQAP Oversight Committee consists of representatives of PennAg, PDA, PDH, the Poultry/Egg Industry, Penn State University, and the University of Pennsylvania.
3. Refer to the PEQAP Operations Annex for Oversight Committee voting protocols.
4. PEQAP is administered and coordinated by a Program Director who is the chairperson of the PEQAP Oversight Committee.
5. The PEQAP Oversight Committee shall meet as frequently as needed, but at least twice each year.
6. Procedures, operating protocols, and program standards are established by the PEQAP Oversight Committee.

B. PEQAP Compliance Committee

The Compliance Committee consists of representatives of PennAg, Penn State University, the University of Pennsylvania, and three representatives of the Poultry/Egg Industry as approved by the Oversight Committee. The Compliance Committee shall be involved in dispute arbitration if there is a lack of evidence of violation.

III. Participation

- A. Any poultry producer and egg packing facility in Pennsylvania may participate in PEQAP. Participation of flocks located outside of Pennsylvania will be at the discretion of the Oversight Committee and PDA. Flocks located outside of Pennsylvania will be required to pay for all PEQAP testing per the current PADLS fee schedule for out-of-state participating flocks.
- B. Participation in PEQAP is voluntary and a participant may withdraw at any time.
- C. All egg packing plant owners must apply for logo use through PennAg before using the logo and must be on file as a PEQAP participant with the PDA Bureau of Food Safety and Laboratory Services by January 30th of each year after initial enrollment.
- D. Flock owners wishing to participate in PEQAP must pass a flock house inspection by the PDA inspector before being accepted into the program and before utilizing the PEQAP logo. An environmental test (LY6) is required when a flock joins PEQAP (birds must be in the house for at least 14 days before sample collection).
- E. PEQAP participants withdrawing a flock (identified by Q number) from the program due to non-compliance will be required to pay non-PEQAP in-state testing fees for testing of the next flock for one year when returning to the program. An environmental test (LY6) is required when returning to the program. If the premise has been off the program for more than two years, any flock will be treated as a new flock joining the program and must meet the program requirements before utilizing the logo.
- F. Although every effort will be made to reach out and encourage compliance with PEQAP standards through education and progressive enforcement efforts, ultimately failure to comply may result in termination from PEQAP. PennAg is responsible for removing participants from the program if necessary.

- G. Flock, egg, and premises testing information shall be the property of the flock owner and shall be treated confidentially.
- H. No evidence of SE contamination of the participant flock, premises, or eggs produced thereon shall be withheld from PDA, PDH, PennAg, and the PEQAP Compliance Committee.
- I. Although the poultry house is the basic unit for program operations, if a premises includes multiple layer houses, all houses must be enrolled in the Program.
- J. Participation in the program offers no warranty by PEQAP, expressed or implied, that eggs produced under this program are free of SE.
- K. Representatives of PEQAP and/or PDA may conduct independent spot-checking of compliance with program protocols.
- L. Nothing in these conditions shall be or become the basis for a claim for damages of any nature whatsoever against PEQAP, PennAg, PDA, or PDH, their employees or agents.
- M. Participants understand that their participation in PEQAP does not relieve them of responsibility to comply with applicable statutes and regulations of PDA and PDH relative to food-borne diseases.

IV. Program Requirements for Participants

A. PULLETS

1. Chicks shall be obtained from (NPIP or equivalent) *S. enteritidis*-monitored negative breeder flocks.
2. It is recommended that chick delivery containers are swabbed (every 10th container liner) and submitted to a laboratory for SE culture (PS1).
3. Manure in pullet grower facilities shall be cultured when the pullets are 14-16 weeks of age (PS2). A culture shall consist of two samples taken from the manure beneath each row of cages.
4. Pullet houses with SE-positive chick samples (PS1) or manure samples (PS2) must be cleaned and disinfected before new chicks are placed. Manure must be removed before placement of new chicks (refer to the Operations Annex). Following cleaning and disinfection, the house must pass inspection by the PDA inspector. If manure is not removed and/or the house fails inspection, the new flock shall be considered to be SE-

positive and the bird owner shall pay non-PEQAP in-state testing fees for environmental testing.

B. LAYERS

1. Pullets shall be obtained from SE-monitored negative breeder flocks. All pullets placed in layer houses shall have a negative environmental (PS2) test at time of placement (tested at 14-16 weeks of age). If the PS2 is not done and the status is unknown, or if the test is SE-positive, the destination house will be considered SE-positive and the manure in the destination house must be cultured 7-14 days after placement of the pullets (LY5). This includes pullets originating from other states. If the LY5 is SE-positive, the flock owner shall pay non-PEQAP in-state testing fees for the egg testing of the four sets of eggs submitted bi-weekly. If all four sets of eggs are negative, the flock is considered to be back in compliance (unless an inspection is failed) and the owner will be charged the PA PEQAP participant fee for the quarterly testing for the life of the flock per the current PADLS fee schedule. If any of the egg sets tests SE-positive, the owner must pay non-PEQAP in-state testing fees for the rest of the egg testing for the life of the flock. If the LY5 is negative, the flock owner will be charged the PA PEQAP participant fee for testing to maintain participation in the program.
2. Manure in layer facilities shall be cultured at 29-31 weeks of age (LY1) and again at 40-45 weeks of age (LY2). A culture of the manure will consist of two samples taken from the manure beneath each row of cages.
3. When adequate manure drag samples cannot be obtained safely due to conditions in the pit, PDA may consider egg belt testing (and possibly other samples) as a replacement.
4. Houses with SE-positive environmental samples must be thoroughly cleaned and disinfected between flocks according to program standards (refer to the Operations Annex). Manure must be removed before placement of new pullets. Following cleaning and disinfection (C & D), the house must pass a C & D inspection by the PDA inspector. If manure is not removed and/or the house fails inspection, the new flock shall be out of compliance and shall be considered to be SE-positive and the owner shall pay non-PEQAP in-state testing fees for all testing for the life of that flock.
5. Houses/facilities participating in PEQAP will be inspected by a PDA inspector at least once per year. A standardized inspection form will be utilized to evaluate the house. There are 10 scored items on the inspection form: A house must obtain a satisfactory score for the one critical item (temperature of egg cooler must be 45 degrees F or lower) and 7/9 of the

non-critical items (approximately 80%) on the inspection form for the flock to be considered to be in compliance. The cooler temperature may be recorded from a properly maintained logbook or from a thermometer in the cooler, at the inspector's discretion. If the cooler temperature is not in compliance, the participant will have 10 business days to call for and pass a re-inspection.

6. For flocks in compliance based on the most recent house inspection by a PDA inspector, regular environmental and egg testing will be available to the participant at the PA in-state PEQAP participant fee, unless/until three SE-positive egg pools are reported (refer to Section IV, Eggs).
7. If a flock owner or flock manager questions inspection results, an appeal may be directed to the PEQAP Compliance Committee.
8. PDA inspectors will notify the service person for the flock of the annual inspection. The service person will **not** notify the flock manager of the pending inspection. If the service person cannot schedule the inspection within a reasonable period of time (at the PDA inspector's discretion), the flock owner is responsible for providing a representative to accompany the PDA inspector.
9. PDA reserves the right to collect environmental and egg samples for testing with at least 24 hours notice to the flock manager, unless the flock is implicated in an egg-associated outbreak of human SE, in which case PDA may collect samples without prior notice. If the test results from those samples are SE-positive and the flock is out of compliance, the flock owner must pay non-PEQAP in-state testing fees for subsequent testing.
10. Companies selling eggs produced from out-of-state flocks shall ensure that applications for program enrollment, proof of testing, third-party inspection forms, and other documents for PEQAP compliance are submitted to the PEQAP coordinator as required for all PEQAP flocks. Flocks for which forms are not on hand by the required deadline will be out of compliance.
11. PEQAP flocks determined to be infected by culture of SE from internal organs shall be subject to the same egg testing requirements as an environmentally SE-positive flock. All laboratories shall report all SE-positive specimens to the PDA PEQAP coordinator as soon as those results are available.
12. Regular environmental testing will remain available to the participant at the PA PEQAP participant fee. If an SE- positive environmental test is reported on samples taken from a non-compliant flock, the owner of that

flock is responsible for paying non-PEQAP in-state testing fees for all subsequent testing.

C. EGGS

- 1) Houses and flocks implicated as a possible source of eggs causing egg-associated human SE or SE contamination of food shall be subject to testing and, if applicable, egg restriction (diversion), based on the PEQAP protocol (refers to Appendix B, exhibit 1, section III).
- 2) Houses with negative environmental samples may be required to test eggs if implicated in an outbreak of egg-associated human SE or SE contamination of food.
- 3) Houses with SE-positive environmental samples must begin egg testing. Egg testing consists of testing 1,000 nest run eggs or a combination of all available blood spot eggs plus additional nest run eggs to total 1,000 eggs, four times, at two-week intervals. These eggs will be cultured in pools of 20.
- 4) Results of egg testing must be received by the PEQAP coordinator within 10 business days of the laboratory notification of the flock manager or participant of a SE- positive environmental test.
- 5) Egg testing may replace environmental testing in flocks which are not involved in a trace-back.
- 6) If all of the four egg tests (refer to #3 above) are negative for SE, 1,000 eggs (nest run and blood spot) must be sampled each quarter for the life of the flock, with no restriction (diversion) of eggs.
- 7) If any egg pool is positive for SE, all eggs produced on or after the time that the flock owner is notified of the positive results by the PEQAP coordinator or by the testing laboratory must be restricted through diversion for pasteurization, hard cooking, other cooking to sell as a processed egg product, or equivalent. The diversion form must be received by the PDA PEQAP coordinator on the date diversion begins.
- 8) Following return to the table egg market after release from egg restriction (diversion) (refer to #7 above), 1,000 eggs (nest run and blood spot) must be sampled each quarter for the life of the flock. If any subsequent egg tests are positive, the eggs will again be under restriction (diversion).
- 9) If three egg tests are positive for SE (do not need to be consecutive submissions), eggs from that flock must be restricted (diverted) for the life

of the flock and the flock owner will be responsible for the cost of any additional testing (non-PEQAP in-state testing fees).

- 10) As additional experience is gained, environmental and egg testing requirements may be modified.

D. MOLTED FLOCKS

- 1) Manure from molted flocks shall be tested at four – six weeks after the end of the molting process (LY3). If manure is SE-positive, eggs shall be tested as described for a laying flock (refer to Section IV B. and C.).
- 2) The rodent control and monitoring program established by the PEQAP Oversight Committee must be maintained at all times (refer to the Operations Annex).

E. BIOSECURITY

All participants must maintain biosecurity standards established by the PEQAP Oversight Committee (refer to the Operations Annex).

F. REFRIGERATION

Eggs stored at layer farms shall be refrigerated according to temperature requirements established by the Egg Refrigeration Law and the PEQAP Oversight Committee (refer to the Operations Annex).

G. EGG PACKAGING

1. All eggs packed with the PEQAP logo must be packed at a packing facility participating in good standing with the program and must be produced from PEQAP flocks in good standing. Egg processing and plant sanitation program requirements are established by the PEQAP Oversight Committee (refer to the Operations Annex).
2. All on-site egg packing plants (in-line and nest run) must pass general sanitation inspections by the PDA PEQAP inspectors at the time of the PEQAP flock inspections, even if the logo is not being used in these plants. The PDA Bureau of Food Safety and Laboratory Services is responsible for at least quarterly inspections of packing plants.
3. All egg packing plants on PEQAP must comply with all applicable PDA and PEQAP standards for packing and labeling of eggs.
4. A current flock identification code list must be provided to PennAg upon registration for the use of the logo, and must be updated throughout the

year within three business days as changes are made to flock identification codes. PennAg will share the flock identification code list with the PEQAP coordinator and the Bureau Food Safety and Laboratory Services.

H. ORGANIC FLOCKS

Organic flocks will be treated as any other participating flock and must abide by the program Standards (refer to the Operations Annex).

I. OUT OF STATE FLOCKS

Out of state flocks supplying eggs for packing under the PEQAP logo must meet or exceed all PEQAP requirements.

V. Participant Responsibility (Refer to the Operations Annex for protocols)

Participants agree that they or their representatives shall:

- A. Cooperate with the PEQAP Oversight Committee, PDA and PDH in carrying out the prescribed monitoring and prevention procedures, including compliance with on-farm rodent control and sanitation management practices as established by the PEQAP Oversight Committee.
- B. Participate in training sessions on sample collection and SE-prevention procedures.
- C. Conduct sample collection in accordance with program protocols covering testing of chicks, pullets, eggs, and environmental samples. Only trained and certified collectors may collect and submit samples for PEQAP testing.
- D. Transport samples to a designated laboratory.
- E. Estimate the rodent population by rodent indexing at least once each month and maintain a standard rodent log provided by PDA for each flock in the program. Execute an appropriate rodent control program as needed.
- F. Restrict eggs, through diversion to pasteurization, hard cooking, and other cooking to sell as a processed egg product, or equivalent in accordance with the requirements of this agreement if eggs are positive for SE. The participant must maintain records of diversion for at least six months.
- G. Clean and disinfect environmentally positive (SE) layer or pullet houses between flock placements according to standards set by the PEQAP Oversight Committee.

- H. Contact the PEQAP inspector to schedule a C&D inspection of positive houses that have been wet-washed or dry-cleaned. Failure to schedule an inspection, or failure to pass inspection, will result in the house being out of compliance, and the new flock will be considered to be positive. All testing will be at the flock owner's expense for the life of that flock (non-PEQAP in-state testing fees).
 - I. Maintain adequate biosecurity and practice good poultry management according to standards set by the PEQAP Oversight Committee.
- VI. Violation of program standards

Consequences for violations of PEQAP standards will be enforced by PennAg Industries. Consequences for violations include the following:

- A. Violations of logo use and/or packing plant standards
 - 1. The PEQAP logo may only be utilized by owners of packing plants who have applied for the privilege through PennAg and whose packing plant meets all program standards.
 - 2. Packing of eggs in containers with the PEQAP logo by a packing plant which is not currently in good standing with PEQAP is a mislabeling violation.
 - 3. Packing of eggs which are not produced from flocks currently in good standing with PEQAP in containers with the PEQAP logo is a mislabeling violation.
 - 4. Failure to meet packing plant standards on PDA (Bureau of Food Safety and Laboratory Services and/or Bureau of Animal Health and Diagnostic Services) inspections is a violation of program standards. The seriousness of the violation will be determined at the discretion of the Bureau of Food Safety and Laboratory Services.
 - 5. Consequences of violations, as they pertain to the PEQAP and this agreement, (the time period for violations will be a rolling three-year period – any violation which has been on record for three years will be dropped):
 - a. First violation: PennAg will send a letter to the plant owner stating that the violation has been documented and that future violations will result in a more severe consequence.
 - b. Second violation: Penn Ag will impose a 30 day suspension from use of the PEQAP logo at that site. Suspension start

date and requirements for reinstatement will be outlined in a letter, and start date will be approximately two weeks from date on the letter. At the discretion of PennAg, if the plant meets the requirements for reinstatement within the two weeks before suspension begins, the plant may avoid suspension for this violation. However, if another violation occurs, the plant will be suspended for at least 30 days.

- c. Third violation: PennAg will impose a six month suspension from use of the logo. All packing sites under that ownership at the time of the violation are included in the suspension. Suspension start date and requirements for reinstatement will be outlined in a letter, and start date will be approximately two weeks from date on the letter.
- d. Fourth violation: PennAg will impose a 12 month suspension from use of the logo. All packing sites under that ownership at the time of the violation are included in the suspension. Suspension start date and requirements for reinstatement will be outlined in a letter, and start date will be approximately two weeks from date on the letter.
- e. Additional violations: Penn Ag will increase the length of suspension an additional six months for each additional violation. All packing sites under that ownership at the time of the violation are included in the suspension. Suspension start date and requirements for reinstatement will be outlined in a letter, and start date will be approximately two weeks from date on the letter.
- f. All mislabeled egg violations: If mislabeled eggs are identified, in addition to PennAg actions outlined in this Section VI: 5 a-e), the Bureau of Food Safety and Laboratory Services will recommend a voluntary recall of mislabeled distributed eggs and will alert impacted stakeholders. The Bureau of Food Safety and Laboratory Services may initiate legal action if mislabeled eggs are not removed from commerce.

B. Violations of sample collection and testing protocols

- 1. Any layer flock environmental sample which is received at the laboratory more than 10 business days past the due date will be considered to be a missed test and an LY6 will be required immediately at non-PEQAP in-state testing cost or the flock will be suspended by PennAg until testing requirements have been met.

2. Any eggs for testing which are not received within 10 business days of the laboratory notification of the participant of a SE- positive environmental test will be considered to be a missed test and the flock will be suspended by PennAg until all required negative egg testing (4 biweekly sets of 1,000 eggs) for that flock has been completed.
3. If samples which are not collected by a certified sample collector are submitted for testing, the participant has five business days to submit new samples collected by a certified sample collector, or PennAg will suspend that flock from PEQAP until samples for that test have been collected by a certified sample collector and submitted for testing. The flock owner will pay non-PEQAP in-state testing fees for testing of those samples.

C. Violations of egg diversion requirements

If eggs from an SE egg- positive flock are not diverted in accordance with PEQAP standards, PennAg will suspend that flock from PEQAP for the life of that flock and will notify PDA. Eggs from an SE egg-positive PEQAP flock shall not be sold as table eggs.

D. Violations of inspection

1. If a participating house passes a PDA inspection, but one or more non-critical items on the form were marked unsatisfactory, planned corrective actions will be documented in the comment section on the inspection form by the inspector and will be reviewed with the participating flock manager at the next normal inspection. A copy of the inspection form will be left with the flock manager.
2. If any of the non-critical items marked unsatisfactory are items which were marked unsatisfactory on the most recent previous inspection, the inspection will be failed, and the participant must schedule a reinspection with the inspector to have the house reinspected within 14 business days (contingent upon inspector's availability). Planned corrective actions must be documented on the inspection form (in the comment section) and must be signed by the flock manager and the inspector. If any of the same items are failed on reinspection, the flock will be suspended by PennAg for 180 days.
3. If a participating house fails an inspection (<80% of noncritical items passed), the participant must schedule a reinspection with the inspector to have the house reinspected within 14 days of the failed inspection (contingent upon the inspector's availability). The

planned corrective actions must be included on the inspection form (in comment section) and must be signed by the participant and the inspector. If any of the same items are failed on reinspection, the flock will be suspended by PennAg for 180 days.

4. If the cooler temperature (critical item) is above 45 degrees Fahrenheit at inspection, the participant will have 10 business days to pass a reinspection. If the cooler temperature is above 45 degrees Fahrenheit on reinspection, the flock will be suspended from the program for 180 days by PennAg.
5. At any reinspection, the inspector will focus on the inspection of failed items only, but if there are obvious failures of other items on general observation, the inspector will mark those items unsatisfactory on the inspection form.
6. At the end of the 180-day suspension period, a regular inspection may be scheduled.

E. Refusal to allow PDA to collect samples or perform inspections

Refusal to allow PDA to collect samples or perform inspections will result in the flock being suspended by PennAg for 180 days.

APPENDIX B

Egg-Associated Salmonella enteritidis (SE) Outbreaks in Humans

I. Statement of Purpose

The purpose of Appendix B is to establish procedures by which the Pennsylvania Department of Health (PDH) and the Pennsylvania Department of Agriculture (PDA) can jointly assure that eggs from PEQAP flocks and premises epidemiologically linked with egg-associated SE outbreaks in humans, are reasonably safe for human consumption. Specific standards for assuring reasonable safety shall be those standards established by the Pennsylvania Egg Quality Assurance Program (PEQAP or Program) and agreed to by PDH and PDA.

II. Procedure

- A. PDH will conduct epidemiologic investigations of egg-associated SE involving Pennsylvania residents or foods produced, processed or shipped from or within the Commonwealth, in accordance with Exhibit 1, “Protocol for Investigation and Control of Salmonella enteritidis (SE) Outbreaks in Humans”.
- B. PDH will inform PDA of epidemiologic data indicating that eggs produced and/or marketed in Pennsylvania are implicated in an egg-associated SE contamination of food or outbreak of SE illness in humans, and will provide PDA with information, documents, and records necessary to initiate determination of the egg source, as set forth in paragraph II.G. of this Appendix B.
- C. PDA will inform owners of PEQAP flocks implicated in egg-associated contamination of food or egg-associated outbreaks of SE illness in humans of the requirement to conduct appropriate testing, and, when applicable, to restrict marketing and use of their eggs and birds in accordance with PEQAP standards (refer to Appendix B, Exhibit 1).
- D. PDA shall monitor implicated PEQAP flocks to ensure that PEQAP protocols stated in this appendix are followed.
- E. PDA shall inform PDH and other interested governmental agencies of the compliance response of PEQAP participants in regard to SE-suspect eggs.
- F. PDH and PDA, as permitted under applicable statutes and regulations, will collaborate to bring to bear appropriate compliance measures on recalcitrant owners of PEQAP flocks, premises, and/or eggs implicated in egg-associated SE contamination of food or outbreaks of SE illness in humans.

- G. The following forms will be used as needed to implement Appendix B:
1. Information Needed by all Parties about a Human Outbreak of Food-Borne Salmonella Prior to Initiation of Flock Testing of Commercial Layer Houses (Exhibit 2);
 2. Department of Health Request for Egg Trace;
 3. Egg Restriction (diversion) Advisory; and
 4. Release of Flock from Restriction (diversion).
- H. PDH and PDA may revise any of the above forms to better carry out the purpose of this Document.

APPENDIX B
(Exhibit 1)
PROTOCOL FOR INVESTIGATION AND CONTROL
OF
SALMONELLA ENTERITIDIS (SE) OUTBREAKS IN HUMANS
INVOLVING FLOCKS PARTICIPATING IN PEQAP

- I. Investigation and Assessment of Epidemiologic Outbreak Data
 - A. PDH is responsible for epidemiologic investigations of SE involving Pennsylvania residents or foods produced, processed, or shipped from or within the Commonwealth. PDH will review all pertinent data collection from the state and local government agencies as needed.
 - B. If PDH determines that eggs are epidemiologically implicated in an SE outbreak, the procedures outlined in Sections II-IV shall be followed.
- II. Egg Trace-Back
 - A. If review of epidemiological data associated with a suspected SE outbreak suggests that eggs from a PEQAP flock are implicated as a possible source of SE in an outbreak, PDH will do the following:
 - 1. Request that PDA immediately initiate an egg trace-back to identify the source PEQAP flock or premises of such eggs.
 - 2. Ensure that the necessary pages of the form (for trace-back of eggs to the point of origin production - Exhibit 2) are completed and submitted to PDA.
 - B. At the request of PDH, PDA shall conduct the egg trace-back. PDA shall apprise PDH of the name and location of all premises to which the eggs are traced. Information provided verbally shall be later confirmed in writing.
- III. Actions To Be Taken When a PEQAP Flock or Premises is suspected as a Possible Source of Implicated Eggs
 - A. PDH will send an action memorandum to PDA requesting appropriate testing, and restrictions, if applicable, per the provisions of this Document by email, with hard copy to follow by mail. The action memorandum shall also request that PDA immediately inform the flock owner of the public health implications of SE-contaminated eggs.
 - B. PDA will ensure that the appropriate environmental samples and/or the appropriate number of eggs are collected for culture from all implicated flocks according to the Pennsylvania Egg Quality Assurance Program (PEQAP) testing protocols (see below).

1. Environmental testing for flocks implicated in a trace-back consists of two (2) manure drags from the manure beneath each row of cages for each implicated flock; egg belt swabs; and any other testing necessary to adhere to trace-back testing guidelines. Samples shall be taken and submitted for testing by a PDA inspector. Samples shall be representative of the building or premises and flocks where the suspect birds are located except when epidemiology indicates a specific flock, in which case only the environment (and eggs if applicable) from the suspect flock are sampled. When adequate manure drag samples cannot be obtained safely due to conditions in the pit, PDA may consider drag samples taken from the walkways between cage rows, or from other specified areas as determined by PDA, as replacements.
 2. The flock owner may elect to test eggs concurrently with environmental testing. (Egg testing is not mandatory unless an SE-positive environmental test is reported). Egg testing does not replace environmental testing in flocks implicated in a trace-back.
- C. Egg testing for PEQAP flocks implicated in a trace-back consists of culture of 1,000 eggs from each implicated flock, four times, at two-week intervals, for a total of 4,000 eggs.
 - D. If an implicated flock is in molt at the time that environmental or egg testing is required, environmental testing will be conducted at that time. If egg testing is necessary, egg testing will begin as soon as the flock goes back into egg production.
 - E. If an egg trace-back implicates multiple flocks on a single premises, all flocks must follow guidelines outlined in sections III B & C, unless implicated eggs can be traced to specific houses or flocks on premises (at discretion of PDA).
 - F. PDA will be responsible for monitoring of implicated PEQAP flocks to maintain adherence to the testing and restriction guidelines stated in this Appendix. PDA will also be responsible for monitoring rodent control and cleaning and disinfection (C&D) through post-C&D inspection of positive houses.
 - G. If an out-of-state outbreak is traced to Pennsylvania-origin PEQAP eggs, PDA may be asked by PDH to perform egg trace-backs, following all protocols established in this document.

- IV. Actions To Be Taken Based on Test Results for PEQAP Flocks Implicated in a Trace-back
- A. In the event of an SE- positive environmental sample in a PEQAP flock implicated in a trace-back, immediate egg diversion and egg testing are required (refer to section III for egg testing protocols and section V for release from egg diversion information).
 - B. If PEQAP records show that an implicated flock had a negative environmental sample soon after the date of the outbreak, the flock may be permitted to forgo testing and diversion requirements.
 - C. If PEQAP records show that an implicated flock had a positive environmental sample soon after the date of the outbreak, immediate egg testing and diversion shall be required.
 - D. All houses associated with SE-positive PEQAP flocks implicated in an SE outbreak must be cleaned and disinfected after the flock is removed and pass a post-cleaning and disinfection inspection by the PDA inspector before placement of the next flock. (Refer to the Operations Annex for PEQAP standards for cleaning and disinfection). If the houses fail to pass the C&D inspection, the new flock will be considered positive and egg testing will be required at the flock owner's expense (non-PEQAP in-state testing fees).
 - E. PDA will monitor compliance of the restricted premises and will apprise PDH of any compliance failures. If information on lack of compliance is provided verbally, the communication shall be confirmed in writing specifying the details of noncompliance, and the names and telephone numbers of persons with firsthand knowledge of the noncompliance.
 - F. If PDA advises PDH that a lack of compliance exists, PDA may request the assistance of PDH to seek a court order to compel the participant to exclude its fresh eggs from the fresh egg market. PDH will assist PDA, as needed, to prepare and present the case to seek appropriate relief.
- V. Release of Egg Restrictions (diversion) for PEQAP Flocks Implicated in a Trace-back
- A. Options include:
 - 1. The flock can be depopulated immediately, followed by appropriate rodent control and cleaning and disinfection; or
 - 2. The participant can proceed with egg testing of the flock (1,000 eggs, four times, at two-week intervals);

- If all of those 4,000 eggs from the implicated flock are SE-negative, PDA will immediately release eggs from restriction (diversion).
 - However, 1,000 eggs will be cultured each quarter for the life of that flock. Egg restriction (diversion) is reinstated if a subsequent egg test is SE-positive.
 - If three egg tests are positive for SE (3,000 eggs, do not need to be consecutive submissions), eggs from that flock must be diverted for the life of the flock and the flock owner will be responsible for any additional testing costs (non-PEQAP in-state testing fees).
- B. All houses associated with SE-positive PEQAP flocks must be cleaned and disinfected according to PEQAP standards after the flock is removed following PEQAP standards. All houses associated with SE-positive PEQAP flocks must pass a post-C&D inspection by a PDA inspector before placement of the next flock. (Refer to the Operations Annex for PEQAP standards for cleaning and disinfection.)

(PLEASE ATTACH EXTRA PAGE WITH A DESCRIPTIVE SUMMARY OF PRESENT CONCLUSION AND TENTATIVE DIRECTION OF FURTHER WORK-UP FOR THIS OUTBREAK.)

9. ATTACH EGG-TRACE FORM TO DELINEATE THE TRACEBACK TO THE PROCESSOR(S)/PRODUCER(S) BEING ASKED TO TEST:

Salmonella Outbreak Information

ID # _____

Location of Outbreak _____
(City, State)

Date of Outbreak _____

I. SHELL EGG TRACING INFORMATION FROM OUTBREAK LOCATION

A. Date(s) that eggs used in the incriminated food vehicle were received at the outbreak location was:

| | | |
|-------|--------|------|
| Month | Day(s) | Year |
|-------|--------|------|

1. Is this date an:

_____ a. Estimated date (s)
or

_____ b. Actual date verified by record-check
by investigator.

CIRCLE CORRECT LETTERS IN B & C

B. Were the implicated eggs:

- a. Fresh shell eggs
- b. Pasteurized eggs

C. Type and packing method of outbreak eggs:

1. Size –

- a. Large
- b. Medium
- c. Small
- d. Jumbo

2. Color –

- a. White
- b. Brown

3. Pack Type –

- a. 12 egg cartons packed in cases

ID # _____

- b. loose packed in cases
- c. other (specify) _____

4. Grade –

- a. AA
- b. A
- c. B

5. Brand, if applicable _____

D. Were cartons or cases in which the eggs used in the implicated food vehicle came to the outbreak scene still available at time of investigation?

Yes _____ No _____

E. Lot designation and packer MDA registration # on outbreak egg cases or cartons. Please record exact form of code numbers and letters (specify if date stamped says “expiration date”.) Record as not available if “D” above was “No”. _____

F. Usual size of egg order and frequency of delivery to outbreak location (examples: 6 cases, 2 times per week; or 40 cases once per month, etc.)

G. Was the egg order and/or delivery of the outbreak eggs different from their usual egg? supply procedures? _____ Yes _____ No (If yes, explain on additional page)

H. Date, packer, packer MDA registration #, etc. from all cases or cartons and invoices at the outbreak location at the time of the investigation:

| # of Cases | Name & Add of Packer | Name & Add of Distrib | Reg. # of Packer | Lot designation | Expir Date | Lots in Delivery |
|------------|----------------------|-----------------------|------------------|-----------------|------------|------------------|
|------------|----------------------|-----------------------|------------------|-----------------|------------|------------------|

ID# _____

I. Outbreak eggs were received directly from: (Name and address of distributor, broker, dealer, or processing plant that delivers the eggs to the outbreak location) _____

J. Is this the only source of eggs for the outbreak location? _____ Yes _____ No

K. The delivery in "I" was verified by:

Investigator's Name _____

Agency: _____

Location: _____

The method of obtaining information was determined by:

- ___ 1. Receipt and/or invoice check by investigator
- ___ 2. Accepting location manager's information, unverified.

Date above information obtained: _____

II: EGG INFORMATION FROM SOURCES OUTSIDE OUTBREAK LOCATION

A. The final egg provider to the outbreak location was listed in "I" above. If there were other "middlemen" that handled the paperwork, (i.e. brokers or dealers), storage, and/or transport/distribution (i.e. dealers, warehouses, etc.) please define these by listing each in their order of occurrence going back from the outbreak towards the farm origin. Please provide their name and address and give the name and organization of the investigator that interviewed each of these "middlemen."

IF THIS TRACE "DIVIDES" TO INVOLVE MORE THAN ONE SOURCE BROKER, DEALER, OR PROCESSOR, PLEASE COMPLETE THIS SECTION FOR EACH "DIVISION" AND ATTACH TO REPORT.

| | <u>Name</u> | - <u>Address</u> | <u>Investigator</u> | - <u>Agency</u> |
|--|-------------|------------------|---------------------|-----------------|
| <u>Final Egg Provider to Outbreak-</u> | _____ | _____ | _____ | _____ |
| _____ - | _____ | _____ | _____ | _____ |
| _____ - | _____ | _____ | _____ | _____ |
| _____ - | _____ | _____ | _____ | _____ |
| _____ - | _____ | _____ | _____ | _____ |
| _____ - | _____ | _____ | _____ | _____ |

Egg Processing Plant (if Pasteurized) - _____

Egg Packer (plant that packed the eggs) - _____

Farm Origin - _____
- _____
- _____
- _____
- _____

In order to facilitate prompt investigation and testing of implicated flocks as soon as possible, please complete and send Parts I and II above to the State Department of Agriculture of state(s) where farms of origin above are located.

III. PREPARATION OF EGGS OR EGG-CONTAINING PRODUCTS

If a potential vehicle contained eggs or egg products, complete the following:

A. Egg information:

- a. Fresh shell Eggs (complete pages 1 and 2)
- b. Pasteurized: Brand: _____
Date of Receipt: _____/_____/_____
Lot # or other identifying info:

B. Method of preparation and storage (include times and temperatures; use of additional pages if necessary):

C. What food storage or preparation errors were identified?

| | Yes | No | Unknown |
|---|-------|-------|---------|
| D. Were eggs eaten raw or uncooked? | _____ | _____ | _____ |
| Were eggs pre-cracked? | _____ | _____ | _____ |
| Were eggs pooled? (i.e. broken together in one container?) | _____ | _____ | _____ |
| If so, how long were they held prior to cooking? | _____ | | |
| Were eggs separated? | _____ | _____ | _____ |
| If yes, with what and how? | _____ | | |

E. How many eggs are used in each recipe batch? _____

F. At what temperature were the eggs stored in the kitchen? _____

G. How long were the eggs stored after they were initially received? _____

H. If pasteurized eggs were used in the same kitchen, what were they used for? _____

I. Was there potential for cross-contamination with a kitchen instrument used to prepare eggs? _____ No _____ Yes; if yes, describe circumstances and utensils involved:

J. Source of eggs: (complete pages 1 and 2 of this form)

K. Did the food handler who prepared the implicated food eat the implicated item?
_____ No _____ Yes: explain _____

Did the food handler who prepared the implicated food have symptoms of Gastroenteritis? _____ No _____ Yes: List them: _____

Date onset of symptoms: _____ Date symptoms resolved: _____

Was the food handler who prepared the implicated food tested for Salmonella?

_____ No _____ Yes: if yes, give date: _____

Result: _____

Investigator: _____ Date: _____