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December 21, 2004

United States Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

Re: **DOCKET NOS. 1996P-0418, 1997P-0197, 1998P-0203, AND 2000N-0504. RIN NUMBER 0910-AC14**

The Food and Drug Administration (FDA) *Proposed Rule for Prevention of Salmonella Enteritidis in Shell Eggs During Production* is the first food safety regulation governing a foodborne pathogen at the point of production. Recent public meetings were held in College Park, MD, Chicago, IL, and Los Angeles, CA sponsored by FDA pertaining to the proposed rule. Comments made at these meetings illustrate to government agencies, consumers and egg producers that the success of the plan and public confidence in government officials responsible for developing and implementing production based food safety programs rests upon a sound, defensible science-based approach. Although the proposed rule is in the form of a regulation, it is only through the application of process control principles such as Good Agricultural Practices (GAP) and Hazard Analysis Critical Control Points (HACCP) that progress at the production level can be measured against objective standards and outcome measures.

The California Egg Quality Assurance Program (CEQAP) incorporates such process control principles. The broad support for this program was recognized by the signing of a Partnership Agreement in 1997 by the FDA, the United States Department of Agriculture, (USDA), the California Department of Food and Agriculture (CDFA), the California Department of Health Services (DHS) and representatives from the California Egg Industry. In addition, this partnership was recognized in 1998 for “reinventing government” and received the prestigious Vice Presidential Hammer Award.

The CEQAP is a comprehensive program with third party oversight. The University of California Cooperative Extension provides ongoing training classes, and each industry participant is required to have a trained supervisor who is in charge of implementing the program. Producers must develop a specific flock plan to address chicks, pullets, feed, rodent control, flock health, biosecurity and environmental monitoring for Salmonella enteritidis (SE).

Processors must meet strict requirements for facilities, equipment, biosecurity, cleaning, disinfection and refrigeration. Veterinary Medical Officers from CDFA provide the third party audits of the program. Any participant found out of compliance is given a notice to address any program deficiencies. Failure to comply with mandatory Plan requirements results in loss of certification. As an added incentive, many companies will not purchase eggs from a producer that is not certified.

Human SE has declined in California from 3.60 cases per 100,000 population in 1993 to 1.76 cases per 100,000 population in 2003. The percentage of California outbreak cases due to SE was at a maximum of 21.84 percent in 1996 and was recently at 3.4 percent of outbreak cases in 2003 (CA Department of Health Services). Although it is difficult to directly measure the success of the CEQAP, there have been no reported human SE cases linked to California eggs over the past five years.

Because of the success of the existing CEQAP and other similar state plans, we strongly recommend that FDA consider adopting state programs as an alternative to the proposed regulation. Under such an agreement, FDA would recognize any producer in full compliance with an approved state plan as meeting the requirements of the egg safety regulation. Such an agreement would continue to support the integrity of the many excellent state programs, which are often much more comprehensive in scope than the proposed regulation.

If any regulation goes into effect, we recommend that FDA contract with and provide adequate funds to states to administer production egg safety programs. The CDFA would welcome such a partnership with FDA to administer the California program. CDFA has the expertise and infrastructure in place to provide administration for this program. Such a partnership would provide a seamless transition, since we already provide third party audits of the CEQAP.

We also encourage FDA to review available research and consider alternate strategies to prevent SE contamination of eggs, including vaccination and “competitive exclusion” (CE), which are widely used in Europe and now also being used here in the U.S. Vaccination and CE, as part of a comprehensive plan, may be a very cost-effective mechanism to prevent SE contamination of eggs and may present viable alternatives to egg diversion. Such prevention strategies may prove to be more effective in protecting public health than relying on testing and diverting eggs after the fact.

In addition to prevention strategies at the producer level, CDFA supports a much more comprehensive approach to egg safety. The FSIS SE Risk Assessment states, "*broadly based policy may be more effective than a policy directed solely at one area of the egg production-to-consumption chain."* We recommend mandatory adoption, and adequate funding, to enforce the egg safety requirements in FDA's Model Food Code, to assure proper storage, handling and preparation of eggs in retail facilities. As an example, only pasteurized eggs should be used in an institutional setting where food preparation requires pooling of eggs. Food handlers account for 20 - 30 percent of all SE contaminated food (Guzewich, Bryan). Many current outbreaks continue to be the direct result of improper food handling, an important risk factor that must be more effectively addressed.

Included with this letter is a detailed summary of issues and proposals offered to address scientific, administrative and economic impacts of the proposed rule. CDFA welcomes the opportunity to partner with FDA in a science based, process oriented approach that will assure the continuing availability and safety of eggs produced in California.

Sincerely,

Richard Breitmeyer, DVM, MPVM
State Veterinarian

Attachments

Response to FDA's Proposed Rule:
Prevention of Salmonella enteritidis in Shell Eggs During Production

I. Assumptions and Context for the Proposed Rule

The FSIS SE Risk Assessment

The FSIS SE Risk Assessment *"does not attempt to reflect changes in SE occurrence over time"* (p.68) and is based in large part from regional data collected from Pennsylvania *"it can only be expected to have direct relevance to the Pennsylvania industry"*(p.68). CDFA recommends that FDA continue to collect data that will assist in assessing regional differences over time so as to optimize regional pathogen reduction efforts and develop relevant risk based prevention and control strategies.

The FSIS SE Risk Assessment states that *"broadly based policy may be more effective than a policy directed solely at one area of the egg production-to-consumption chain"* (p.2). Production, processing, transportation and food preparation and consumption all impact the safety of shell eggs. For this reason it is essential that FDA continue to work with other federal and state agencies to develop a comprehensive and coordinated effort that can continue to further reduce the incidence of SE in humans. A 25% reduction in human illness can be expected by combining mitigations in production, preparation and consumption modules, and not through production alone (p.2).

The NAHMS Layers '99 Study

It is important to note that extrapolation of findings from NAHMS data used in the proposed rule may be limited since farm selection was neither strictly randomized nor census level. Participation from some regions was not proportionate to the size of the population at risk in that region. Data was weighted in order to adjust for response rate by region. Policies developed using this data must take this into account in order to be relevant to real world conditions.

Healthy People 2010 Objective 10-2b

Objective 10-2b. *Salmonella* serotype Enteritidis 1997 Baseline: 44
2010 Target: 22

Target setting method: 50 percent improvement.
Data source: Foodborne Disease Outbreak Surveillance System, CDC, NCID.

In 1997, 12 SE egg-related foodborne disease outbreaks occurred in California and no egg related SE outbreaks have been linked to California eggs between 2000 and 2004. Human SE has declined in California from 3.60 cases per 100,000 population in 1993 to 1.76 cases per 100,000 population in 2003, representing a 51% decrease in human per capita incidence. The percentage of California outbreak cases due to SE was at a maximum of 21.84% in 1996 and was recently at 3.4% of outbreak cases in 2003, representing an 84.4% decline in cases (Dr. Ben Sun, California Department of Health

Services). It is evident that with existing programs and epidemiological trends, the need for further action through regulation is debatable from a cost: benefit perspective. Thus the objectives of Healthy People 2010 have been exceeded in California at the present time. Better allocation of funds can be achieved through risk-based regional prevention and control efforts. The prevalence of SE positive environmental samples from layer ranches declined generally over time from 9.78% (95% CI: 4.85, 18.21) in 1991 to 2.0% (95% CI: 1.17, 3.38) in 2004, indicating a statistically significant change over time. It is likely that the California Egg Quality Assurance Plan (CEQAP) has played a contributing role in declining human illness due to SE in eggs, although it is important to note that many other factors are involved.

At the recent public meeting at Los Angeles, attendees were asked to address specifically how CEQAP would be able to address four key issues in lieu of a regulation.

Four Key Issues California Stakeholders were asked to respond to at the conclusion of the Public Meeting In Los Angeles, November 16, 2004

1. A request for more information on diversion capacity in the region and what alternatives are used presently in lieu of diversion when a positive sample for SE is detected. What do we do when we have a positive environmental sample?

Response: It is the Department's understanding that diversion capacity is limited in California since it is a net importer of eggs. Most eggs meeting grade standards are sold as shell eggs. Egg diversion to breaker plants in California is significantly below the national average (Industry Representative).

The CEQAP requires environmental sampling one time during the life of each flock. Most participants conduct the required sampling at the end of the lay cycle to monitor the effectiveness of their Plan. When a positive environmental swab is detected, the producer private veterinarian initiate an investigation include re-testing the environment on a more intense level and the core components of the quality assurance plan are reviewed, including records. Mitigation efforts such as vaccination using live vaccines, limited cleaning and disinfection and time management methods such as inducing early molt are used. Each situation is handled as unique with its own specific mitigation solutions. More research is needed to evaluate the potential uses of competitive exclusion methods presently used in Europe.

Egg diversion's economic and marketing impacts are best addressed by industry representatives.

2. If FDA were to consider adopting existing egg quality assurance plans such as CEQAP under the proposed rule, would we share data regarding test results with FDA so that they can audit our test results?

Response: Yes, all records would be available for FDA to review.

3. For a State with an existing Quality Assurance Plan such as CEQAP that presently exceeds many of the requirements of the proposed rule, FDA needs to know what additional costs would be incurred to meet the requirements and standards of the proposed rule.

Response: See Section VI. Funding and Section VIII. Economics sections.

4. A request to show specifically how an existing State Quality Assurance Plan, such as CEQAP is different from the proposed rule i.e. describe how a process control-oriented approach differs from the proposed rule.

Response: See Section II. Regulations versus Process Control

Standards and Flexibility

Because the egg industry is diverse regionally, CDFA urges FDA to strike a balance between maintaining standards while allowing for flexibility in methods used to attain those standards.

Measurable Goals and Outcomes

Baseline rates of poultry and human SE are likely not comparable across the U.S., CDFA recommends that FDA establish data collection, assessment and mitigation plans to optimize pathogen reduction efforts and to utilize resources in the most effective and economical way possible.

HACCP and other proven process control principles are used as the basis for meat, dairy and plant product safety. These process control strategies imply tolerance levels and monitoring aimed at measuring progress against those established tolerances. CDFA strongly recommends that if FDA establishes standards and regulations that they support a process control approach to egg safety in order to harmonize food safety standards for consumers in the United States.

II. Regulations Versus Process Control

The Difference In Intent

Regulations are effective in ensuring that minimum standards are met. FDA's proposed rule uses a test and divert strategy where testing is used in order to indicate when diversion is necessary. With process control, emphasis is placed on improving the process itself so that the desired outcome is achieved. In the latter case, testing is done to validate components of the process control plan itself (e.g. employee training, education, record keeping, rodent control, biosecurity, cleaning and disinfection).

Although the proposed rule is in the form of a regulation, it is only through the application of process control principles such as Good Agricultural Practices (GAP) and Hazard Analysis Critical Control Points (HACCP) that progress at the production level

can be measured against such standards and outcome measures. This approach is used by FDA in the Seafood HACCP, Apple Juice HACCP program and by FSIS through the Salmonella Performance Standards. The CEQAP incorporates such process control principles.

Process Control: A Proven Record

CDFA urges FDA to develop and utilize science-based standards and performance measures using a process control approach. Process control is a problem solving process that controls present hazard and reduces future risk. Producers and veterinarians are actively engaged with support from other resource people with responsibility for plan oversight. To prevent or reduce SE, only a comprehensive yet site-specific approach will be adequate to measure progress and achieve program goals.

III. Recognition of Existing Egg Quality Assurance Programs

Recommendation

Because of the success of the existing CEQAP and other similar state plans, we strongly recommend that FDA consider adopting state programs as an alternative to the proposed regulation. Under such an agreement, FDA would recognize any producer in full compliance with an approved state plan as meeting the requirements of the egg safety regulation. Such an agreement would continue to support the integrity of the many excellent state programs, which are often much more comprehensive in scope than the proposed regulation.

For States without existing quality assurance programs or for companies who do not participate in an existing Egg Quality Assurance Plan, they would have the option of joining or developing an effective plan or be governed by FDA's proposed rule.

IV. Testing Protocols

Sampling Unit of Concern

The flock is the sampling unit of concern for environmental testing. FDA proposes to perform environmental manure sampling for each flock at 40-45 weeks of age and 20 weeks after completion of a molt. Blended houses with multiple age groups will create additional challenges for sampling and regulatory action depending on how one defines a "house", especially in regions with varied housing types.

The flock or the house are both stated as the sampling units for egg testing, assuming that a flock is housed alone in its own house. A significant proportion of egg layer premises have more than one flock per house. This will need to be considered in the final rule.

Sample Collectors

The proposed rule does not specify who will be approved to collect samples. Persons collecting samples must be trained in proper handling and sampling techniques using scientifically valid principles including randomization. Some form of certification or approval should be implemented for sample collectors.

Type and Number of Environmental Drag Swabs

Manure drag swabs are currently used by the National Poultry Improvement Plan (NPIP) and all Egg Quality Assurance Plans in the U.S. While other environmental sites may provide additional information, manure drag swabs are most likely to detect SE [1]. CDFA supports FDA's intention to utilize manure drag swabs as an environmental standard using currently analytical methods recognized by the NPIP. Note that under CEQAP, an entire manure row is sampled, and not the 30 feet stated in the proposed rule.

Sixteen manure rows were randomly selected from among the total number of rows in a house except as noted above, or when there were fewer than 16 rows. The probability of detecting at least one positive drag swab was calculated using a binomial distribution model assuming 10% of the drag swab area was contaminated with SE. For an average size egg layer house in California, 16 swabs was calculated to give 81% certainty of detecting SE with a confidence level of 95%, assuming the prevalence of SE on the manure surface in the layer house is 10% (Figure 1).

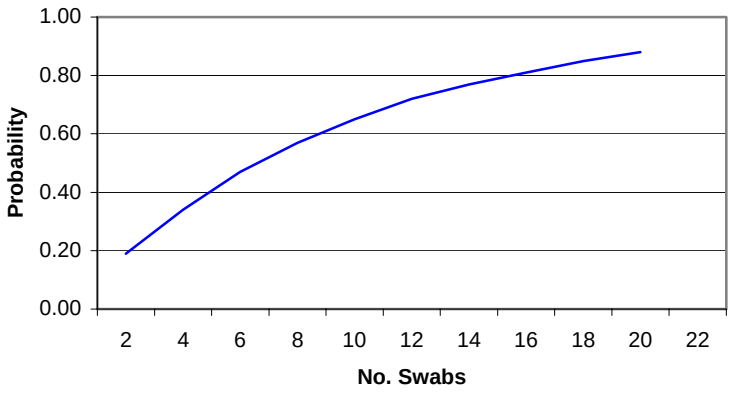

Figure 1. Probability of detecting SE in contaminated layer houses using various numbers of manure drag swabs assuming 10% of the surface area is contaminated

The 16 swabs can be pooled to create four samples and reduce testing cost by 75%. The California SE Validation Study has shown no statistical difference between single swabs and four pooled swabs in their ability to detect Salmonella as a screening test [2,3]. Pooled swab shave been used in SE traceback investigations and have correlated well

each time they were compared with single swabs (California Department of Health Services, California Department of Food and Agriculture data).

Litter or manure sampling. The five principal manure-handling systems found in California layer houses include shallow pit manure banks, manure belts, shallow pit flush, deep pit and the cage-free floor systems. Two drag swabs attached to metal clips, or rings attached to the end of two different poles are used to sample each row or section of manure. Shallow pit manure banks are sampled by dragging two swabs down the length of the row and back, covering the area immediately under the hens contributing to the row of manure. In some types of shallow pit systems the manure under the hens is not accessible and a mechanized scraper removes the manure from the shallow pit to one end of the house. In these instances, the scraper blade is thoroughly sampled. Manure belt systems are preferably sampled while the belts are running by holding drag swabs a proportionate time and distance to equal the length of an "average" row at each belt level comprising a row, or by swabbing the scraper blade at the end of each belt if the belts are not running. Shallow pit flush systems are sampled by applying drag swabs to the vertical edge of the gutter down the length of the gutter and back while care is taken not to walk on a surface yet to be sampled by the collector. Deep pit manure systems are sampled by dragging swabs down and back a bank of manure under each row of hens. Solid or slatted floor cage-free systems are sampled by dividing the total area by 16 and dragging two swabs over each section in four strips in proximity to feeding and watering units, and nest boxes. Care is taken not to walk on a floor surface not yet sampled by the collector. Sixteen manure rows are randomly selected from among the total number of rows in a house except as noted above, or when there are fewer than 16 rows. For an average size egg layer house in California, 16 swabs is calculated to give 81% certainty of detecting SE with a confidence level of 95%, assuming the prevalence of SE on the manure surface in the layer house is 10% [3]. Several representative examples for California poultry houses follow. For a single cage system a manure row is a single shallow row beneath a single layer of cages that ran for 60 m. For a multiple deck cage system a manure row is the accumulated manure from the complex cage system, for a distance of approximately 66 m in length.

Rational for using Pool versus Single Swabs and PE in combination with DSE versus PE alone for SE Testing of Environmental Samples.

Many producers using a practicing veterinarian and participating in CEQAP, monitor each flock for SE continuously starting from the first week of age (using chick papers) throughout the laying period (using drag swabs) until the flock is marketed or slaughtered. Under the plan, the pooled drag swabs analyzed by PE in combination with DSE are used to validate the core components of the pathogen reduction program for SE by applying process control principles.

The pooling of manure drag-swabs should be considered a cost efficient alternative method to single swabs to reduce the testing costs for the routine monitoring of layer flocks for *Salmonella.* The cost of analyzing single swabs by the PE method only is up to three times that of analyzing pooled swabs by PE followed by DSE (Tables 1 and 2).

The DSE is most effective in detecting SE where the initial primary culture was negative as the result of perhaps injury to the cell or competing coliforms. In a traceback investigation in California layer flocks, single swab sample plates detected 36.7%(11/30) and pooled swab sample plates detected 52.9% (9/17) group D *Salmonella.* There was no difference in confirmed *Salmonella* colonies per maximum of five suspect picks (Chi-Square test for homogeneity, P>0.05) (California Department of Health Services, California Department of Food and Agriculture data). In a recent cross-sectional study of the California layer flocks the researchers found no significant difference in the range of *Salmonella* serotypes isolated using the two methods [2,3]. The single swab method detected three *S. enteritidis* isolates that were not detected by the pooled swab method while the pooled swab method identified one *S. enteritidis* isolate that the single swab method missed. The California Department of Health Services has also acknowledged the similarity between these two methods through a pilot study using parallel testing conducted during a trace back investigation on a known positive ranch. The lack of any apparent difference between these methods must be weighed against the enormous saving in cost (nearly four times as much) when using pooled instead of single swabs. The study concluded that pooled swab method is a good monitoring tool for *S. enteritidis* on a farm basis if done regularly and properly without significant cost to the producer (Appendix A).

CDFA strongly recommends that all group D isolates be sent to the National Veterinary Services Laboratory or approved regional laboratories for identification to rule out false positive reactions to Group D_1 antigen in regional laboratories.

Type and Number of Eggs Tested

FDA proposes that eggs are tested when there is a positive environmental test or during trace back investigations. In Pennsylvania egg testing was found to be predictive for positive eggs when the percentage of positive manure drag swabs was at least 50% [4].

In California, one thousand eighty eggs are randomly selected and then analyzed in 50 pools of 20 eggs; extra eggs are collected, as cracked eggs are not tested.

V. Training

Official Quality Control Supervisor

Training and education are the foundation of CEQAP. The following recommendations pertaining to training are based on 10 years of experience with CEQAP:

1. We recommend to FDA that training for the person responsible for overseeing SE prevention measures be trained in the manner adopted by Egg Quality Assurance Programs using process control principles. The following are administrative requirements of CEQAP:

Administrative

- Develop a farm/premises flock egg quality assurance plan.
- Designate an employee or employees as the official quality control supervisor(s) for in-house operations and for follow-up training.

2. The official quality control supervisor responsible for overseeing SE prevention measures should receive comprehensive training in the following areas (hyperlinks to original material for the CEQAP are included as an example):

Section 1 – *Preparing a Quality Assurance Plan*

Training Session 1 - Preparing a Quality Assurance Plan PDF HTML

Section 2 - *Egg Handling (CEQAP includes egg processing)*

Training Session 2 PDF

Section 3 - *Flock Health Management*

Training Session 3 PDF

Section 4 - *Cleaning, Disinfection and Biosecurity*

Training Session 4 PDF

Section 5 - *Vector Control and Biosecurity*

Training Session 5 PDF

Section 6 - *Environmental Monitoring and Sampling*

Training Session 6 PDF

3. Each Company should designate a person responsible for overseeing the core process control elements of a comprehensive SE reduction program. This person received training from qualified poultry professionals from academia, industry and state agencies.

4. Each State should develop regionally adapted training programs based on industry and marketing structure, with particular consideration for site-specific specific management and housing systems used.

5. Special training provisions must be made for States without a pre-existing EQAP and for small producers that cannot easily get away to attend training. It is recommended that FDA provide qualified poultry professionals and adequate resources from States with a proven existing plan to assist in developing new training pertinent to that State. In some remote areas, it may be necessary to provide a home study curriculum for core components and continuing education credits in order to make training available to all producers and to provide cost effective training across the U.S.

6. Training should include pre-test and post-test (with an appropriate passing score) assessment of the trainees' performance in order to assess competence and quality of training materials.

7. There should be required annual continuing education for all official quality control supervisors by qualified poultry professionals.

8. The official quality control supervisor will develop and review the basic premises quality assurance plan at least once annually or when changing circumstances dictate.

9. That FDA acknowledges the importance of official quality control supervisor by granting an official certificate or qualification upon completion of training and that annual re-certification be contingent upon completion of mandatory continuing education. A passing grade of 90% must be achieved in each module (**Appendix B**).

10. That FDA audit training records from each State to assure equivalence in the degree of training required but that it allow for flexibility in the designing the specific program elements.

State Agency Representatives

1. That all State agency representatives overseeing SE prevention measures be required to receive the same training required of the official quality control supervisor.

2. That all State agency representatives receive training necessary to conduct uniformly administered audits of egg production facilities.

3. That all State and Federal agency representatives receive standardized training on conducting trace back investigations through a formal cooperative agreement among agencies.

Laboratory Personnel

1. That all laboratory personnel conducting Salmonella testing receive standardized training through a formal cooperative agreement among agencies.

Sample Collectors

1. Who will be approved to collect samples is yet to be resolved by FDA. Persons collecting samples must be trained and used standardized protocols in proper handling and sampling techniques using scientifically valid principles, including randomization. Module 6 of the CEQAP training program includes such necessary training elements.

2. In order for the regulatory program to be credible, chain of custody issues must also be addressed and implemented.

VI. Funding

FDA has allocated $8 million annually to administer the proposed regulatory program across the U.S. CDFA estimates that it presently uses One Person Year (PY) to administer the core duties of maintaining databases and auditing its producers. Current audits are focused on record keeping and require biosecurity measures that prevent more than two-three site visits per week when other operational demands permit. Audits can normally be completed statewide every year however, recent emergencies have required diverting personnel from CEQAP, which is currently a voluntary program.

Administrative Costs for CEQAP

We estimate that it will take two positions and $175,000 to $200,000 to administer the program in California. If CDFA veterinarians collect samples, this estimate could increase to include another field position. This estimate does not include laboratory costs (discussed under Economic Issues)

Estimates of Laboratory Costs for Testing (includes, media, reagents and technician time)

When estimating the cost of SE testing one should bear in mind the prevalence of the total Salmonella load in the layer environment and the prevalence of SE in the particular region. Other factors to consider are the method of sampling (pool versus single) and the analytical method used (primary enrichment versus primary enrichment combined with delayed secondary enrichment method). The different cost estimates and rationales for using one or the other method is discussed below. The California Animal Health and Food Safety Laboratory provided these estimates.

Scenarios for Cost Estimates for Environmental Drag Swabs

Primary Culture with Selective Enrichment for Salmonella

1. No *Salmonella* detected – No suspect isolates screened
   Total cost = $8.95
2. No *Salmonella* detected – Suspect colony Rule-Out (5 colonies)
   Total cost = $20.85.
3. *Salmonella* sp. detected – NOT Group D1 (5 isolates)
   Total cost = $41.55
4. *Salmonella* sp. – Group D1 (1 isolate submitted for serotyping)
   Total cost = $58.60

Primary culture with Selective Enrichment followed by Delayed Secondary Enrichment Method

1. No *Salmonella* detected – No suspect isolates screened
   Total cost = 23.15 + 8.95= $32.10
2. No *Salmonella* detected – Suspect colony Rule-Out (5 colonies)
   Total cost 23.25 + 20.85=$ 44.1
3. *Salmonella* sp. detected – NOT Group D1 (5 isolates)
   Total cost = 23.15+ 41.55= $64.70
4. *Salmonella* sp. – Group D1 (1 isolate submitted for serotyping)
   Total cost = $58.60Total cost 23.15+ 58.60= $81.75

FDA's proposed rule states that 32 individual drag swabs will be tested per house for SE at 40-45 weeks of age during the first cycle and 20 weeks after the end of molt during the second cycle and thereafter 20 weeks later after each molt.

Assuming a prevalence rate of 10% SE isolation and rule out of 90% non group D Salmonella, 32 swabs per house, for a minimum of 3 tests for the life of the flock comparisons are made using 32 individual swabs cultured by primary enrichment culture method only, versus 8 pools of 4 swabs each cultured by PE followed by DSE are shown below in Table 1 and 2.

Table 1. Scenarios for cost estimates, $

Prevalence 10% SE; 90% non group D salmonella: PE culture, single swabs (n=32)

Scenario Type Primary culture only	**Unit Price**	**For 32 swabs cost/house**	**3 Testing 1 house**	**3 Testing 5 houses**	**3 Testing 7 Houses**
1. No salmonella detected, No suspect isolates screened	$8.95	$8.95 x 32 = 286.40	$859.2	$4296	$6014.40
2. No salmonella detected, suspect colony rule-out (5 colonies)	$20.85	$20.85 x 32 = 667.20	$2001.6	$10,008	$14,011.20
3. Salmonella sp. Detected – NOT group D1 (5 isolates)	$41.55	90x32x$41.55 = 196.60	$3589.8	$17,949	$25,126.60
4. Salmonella sp. Group D1 (1 isolate submitted for serotyping)	$58.60	32 x .1 x $58.60 = $87.50 32 x .9 x $41.55 = $1196.60 = $1384.0	$4152.0	$20,760	$29,064

Table 2. Scenarios for cost estimates, $					
Prevalence 10% SE; 90% non group D salmonella : PE & DSE Using 4 pool swabs (n=8)					
Scenario Types	**Unit Price**	**For 8 pools (32 swabs)**	**3 Testing 1 house**	**3 Testing 5 houses**	**3 Testing 7 Houses**
1. No salmonella detected, No suspect isolates screened	$32.10	$256.80	$770.40	$3852	$5390
2. No salmonella detected, suspect colony rule-out (5 colonies)	$44.10	$352.80	$1058.40	$5292	$7406
3. Salmonella sp. Detected – NOT group D1 (5 isolates)	$64.70	$465.84	$1397.52	$6987	$9779
4. Salmonella sp. Group D1 (1 isolate submitted for serotyping)	$81.75	$531.24	$1593.70	$7968.50	$11,155.90

Cost Estimates for Testing 1000 Eggs (includes labor, media and reagents):

1000 eggs, 50 pools, 20 eggs/pool= $1013.88, assuming all pools are negative.

In a previous study [5] where the overall prevalence of group D *Salmonella* was 2.28 per 10,000, egg testing and egg diversion for pasteurization for a duration of 19 months and resulted in a net loss of $3,027,505 (2004 dollar value) to the producer. Cost estimates were for a company with 176,000 birds.

CDFA recommends that FDA establish a scientific committee to address laboratory methods and costs before implementing the proposed rule.

VII. Regulatory Oversight and Cooperative Agreements

Notification

FDA does not state if, when or how positive results are to be reported when there is a positive sample of any kind. Communication protocols must be developed to coordinate this regulatory function.

Laboratory Accreditation

CDFA strongly recommends that all laboratories conducting tests related to the proposed rule be accredited by FDA in order to meet basic standards for training, analytical methods and reagents including laboratories currently recognized by NPIP.

Chain of Custody

If the proposed regulation is enacted, it will be important to protect the integrity of all samples collected in order to maintain chain of custody, from a regulatory point of view. CDFA proposes that environmental samples should be collected by trained and certified practicing veterinarians or producers at the specified intervals while annual audits and egg sampling be handled by agency representatives, as is presently done by CEQAP.

Formal Cooperative Agreements

FDA has indicated its intention to enter into formal cooperative with State agencies. Because of the success of the existing CEQAP and other similar state plans, we strongly recommend that FDA consider adopting state programs as an alternative to the proposed regulation. Under such an agreement, FDA would recognize any producer in full compliance with an approved state plan as meeting the requirements of the egg safety regulation. Such an agreement would continue to support the integrity of the many excellent state programs, which are often much more comprehensive in scope than the proposed regulation.

VIII. Economic Issues

FDA's proposed rule acknowledges that under certain circumstances, some egg producers will be negatively impacted by the test and diversion and costs may exceed benefits of the regulation. It is possible that some producers will not be able to resolve their problem with SE by any other means than through attrition. The cost of eradicating SE from one ranch in California included $2.4 million spent by the producer but not including an additional $116,582 in laboratory costs [7] (**Appendix C**).

IX. Long-Term Implications of the Proposed Rule

Promote Alternatives to Diversion

Under the proposed rule, a positive egg tests results in diversion of eggs. Scientific advances are being made in Europe, which show promise and should be explored in the U.S. CDFA urges FDA to support research to find alternatives to egg diversion through a combination of vaccination, competitive exclusion and management strategies that will protect public health as well as the egg supply.

Impeding Progress Made Through Existing Egg Quality Assurance Programs

The first rule of medicine is *"Do No Harm"*. Both the Pennsylvania and California plans have been in existence for over 10 years and have been successful in reducing the risk of finding SE in eggs. It is obvious that there is a general downward trend. The core elements of these programs are tested by time and exceed those presented in the proposed rule: the main issue being its lack of comprehensiveness and flexibility to meet local needs and demands. Should these programs be replaced and should the

human incidence of SE increase, we will have failed in protecting public health and the supply of fresh shell eggs.

Impact on Future Trace Back Investigations

There will be implications of the proposed rule for future trace back investigations. CDFA strongly urges FDA to work with State epidemiologists and poultry professionals to develop rigorous, uniform, unbiased, science-based standards for conducting trace back investigations and to work cooperatively with state officials and poultry professionals in prescribing specific corrective action at the production level. Every outbreak investigation needs to be fully completed, documented and treated as a learning opportunity that will prevent future outbreaks. Response strategies must also be developed to address false-positive non-motile Salmonella Group D_1 isolations other than SE. Furthermore, CDFA encourages FDA to consider indemnifying producers when it is necessary to depopulate affected flocks, as practiced in Canada.

Comprehensiveness of the Federal Plan to Reduce SE in Eggs

No other regulation by FSIS is yet proposed to address processing, or by FDA to address retail establishments. Without a comprehensive farm to fork plan the proposed rule will not solve the problem of its own accord. The FSIS SE Risk Assessment states that quote, "*broadly based policy may be more effective than a policy directed solely at one area of the egg production-to-consumption chain."* For this reason it is essential that FDA continue to work with other federal and state agencies to develop a comprehensive and coordinated effort that can effectively reduce the incidence of SE in humans.

To that end, CDFA strongly urges FDA to make the Model Food Code provisions governing eggs to be mandated and enforced nationally by law.

X. Specific Responses to FDA's Request for Input on the Following Topics

FDA is soliciting comments on the Following Issues:

a. 5 LOG REDUCTION

This is beyond the scope of the production module but appears to be the only method currently being used officially by FDA (e.g. Apple Juice). Post pasteurization contamination should also be addressed as part of the farm to fork continuum.

b. MAKING THE MODEL FOOD CODE MANDATORY

Yes, for the reasons given above.

c. WHETHER PULLETS NEED TO COME FROM AN SE MONITORED FACILITY

FDA should allow for flexibility in this area. This option reduced the risk of introducing SE onto the layer far. The actual need to monitor will depend on the risk of introducing SE and the management system used.

d. REFRIGERATION OF EGGS AFTER THEY LEAVE THE FARM

e. 36 HOUR THRESHOLD FOR REFRIGERATION OF EGGS

Dr. Ralph Ernst a Poultry Scientist and a specialist in egg research from the University of California, Davis has stated "*The details of the regulation about required refrigeration of eggs at the farm before processing specify a temperature of 45^{o}F. That storage temperature would present a problem for safe and sanitary washing of these eggs when they are transported to a shell egg processing plant. USDA, AMS recommends an egg washing temperature of 110^{o}F. Lower temperatures are allowed (as low as 90^{o}F) but the control of bacteria in the wash water and successful egg cleaning are improved with 110^{o}F to 115^{o}F wash water. Research has shown that thermal checks increase when there is more than a 50^{o}F difference between egg temperature and wash water temperature. If eggs were refrigerated on the farm at 45^{o}F the egg wash water temperature could not exceed 95^{o}F. While this is technically possible, it is clear that any regulations requiring farm refrigeration before processing, should be coordinated with egg washing regulations."*

f. TESTING MANURE VERSUS TESTING EGG MACHINERY

For routine use the manure drag swab is the most sensitive and practical sample to collect from California layer houses [1]. A certain amount of flexibility could be exercised in this regard.

g. ALTERNATIVE SAMPLING METHODS

Egg roll-outs, egg belts, fan blades, rodents, walkways, flies and air sampling have been used but are not as sensitive as manure drag swabs [1]. The most important sampling principle to maintain is to collect a representative sample from each kind of house. It is important that manure rows are selected randomly since not all rows from all houses can be sampled.

h. THE NEED TO SAMPLE EGGS EVERY 2 WEEKS

Various Salmonellae have been shown to cycle through houses every 2-3 weeks [5]. The use of a 2-week sampling interval is empirical and is related to trace back methods developed in the late 1980's. There does not appear to be a more reliable alternative at this time. Reducing the testing interval to 1 week apart would greatly increase the speed with which eggs from a negative flock can enter the shell egg market and reduce losses considerably. Downtime represents the major economic cost for producers when any disease strikes.

i. WHETHER TO REQUIRE A WRITTEN SE PREVENTION PLAN

CDFA supports a comprehensive approach to SE prevention including individualized premises plans and record keeping. CEQAP already requires a written plan that must be reviewed annually. Management and marketing changes necessitate this regular review.

j. RECORD-KEEPING REQUIREMENTS FOR EGG SAMPLING, EGG TESTING AND EGG DIVERSION

These records alone are not comprehensive enough to reduce risk for an SE prevention plan. Records allow veterinarians, producers and agencies to monitor the core components of a pathogen reduction program. They also demonstrate due diligence on the part of the producer.

k. WHETHER FDA SHOULD REQUIRE ALL PRODUCERS TO REGISTER UNDER THE PROGRAM TO CREATE A NATIONAL DATABASE

To create a "level playing field" across the U.S., registering all producers is necessary. It may be possible for FDA to cooperate with USDA/APHIS, which is presently developing a premises identification program for all animal premises in the U.S.

l. NEW APPROACHES TO ENFORCEMENT AMONG FEDERAL, STATE AND LOCAL AUTHORITIES

When necessary, enforcement action should be coordinated between all relevant federal and state public health and animal health agencies. Every outbreak investigation needs to be fully completed, documented and treated as a learning opportunity that will prevent future outbreaks.

m. USE OF ALTERNATIVE DIETS IN MOLTING PROGRAMS

Dr. Peter Holt, USDA has studies alternative molt diets and shown them to beneficial in an experimental setting. These methods have yet to be tested under field conditions in conjunction with vaccines and competitive exclusion. This issue will bring additional cost implications for the producer so additional research is needed in this area.

n. USE OF COMPETITIVE EXCLUSION TREATMENTS DURING MOLT

European researchers are successfully using competitive exclusion as an adjunct to management and vaccination. This area holds much potential for the future. CDFA strongly encourages experimental and field based studies to fully explore the potential benefits of competitive exclusion as an alternative to egg diversion.

o. ALTERNATIVE TIMING OF ENVIRONMENTAL TESTING DURING OR FOLLOWING MOLT

The 20-week post-molt test proposed by FDA coincides with end of lay testing commonly used by CEQAP participants and is useful since it provides information prior to depopulation and cleaning and disinfection. This is the best time to aggressively increase intervention measures to prevent carry-over of SE into the next flock.

p. PROHIBITING INDUCED MOLTING FOR BIRDS IN POSITIVE HOUSES

No evidence exists that molting is directly associated with a positive layer environment. Bird age is a confounding factor. Molted birds can be vaccinated for SE during molt to further reduce the risk of producing SE positive eggs post-molt.

q. WET VERSUS DRY CLEANING METHODS BETWEEN FLOCKS

Two issues are of importance, namely practicality and science. In colder climates, wet cleaning is difficult between flocks due to mechanical and human safety concerns. Studies with swine in Denmark have shown that wet cleaning is more highly associated (OR 4.8) with sub-clinical infection of swine with Salmonella [6]. Flexibility will allow producers to use what works best for each location since other important variables may influence results (e.g. concrete floors versus dirt floors).

r. USE OF EGG YOLK ANTIBODY TESTING AS AN ALTERNATIVE TO ENVIRONMENTAL TESTING

Egg yolk antibody testing has been used affectively in Denmark but has met with mixed results thus far in the U.S. mainly related to technical challenges, as witnessed in the NAHMS study. The concept of using egg yolk antibodies to assess exposure of the national flock is a useful one and should not extended beyond that use. CDFA encourages FDA to establish a technical working group that can consider this tool in the context of traditional bacteriological and emerging molecular testing methods.

s. ALTERNATIVES FOR PRODUCERS IN HAWAII (NO BREAKER PLANTS)

It is evident that areas lacking egg breaker capacity, including California will be at a competitive disadvantage and contribute to an uneven playing field. CDFA encourages FDA to consider indemnifying producers when it is necessary to depopulate affected flocks, as practiced in Canada.

t. WHETHER TO REQUIRE REFRIGERATION OF EGGS DESTINED FOR FOOD MANUFACTURING

Current industry practices have not contributed to an increase in risk to humans.

u. WHETHER TO MAKE THE MODEL FOOD CODE MANDATORY FOR ALL STATES TO ADOPT AS LAW

Yes. It is imperative that the retail food industry be part of a collective effort to reduce human illness. Over 50% of all known food borne illnesses are of viral origin, so the cross-benefits to protecting human health would expected to be synergistic.

v. WHETHER TO REQUIRE INSTITUTIONS TO SERVE ONLY PASTEURIZED EGGS TO HIGHLY SUSCEPTIBLE POPULATIONS
   i. USE OF GRADE A EGGS ONLY
   ii. USE OF RAW EGGS TRANSPORTED ONLY UNDER REFRIGERATION
   iii. USING ONLY PASTEURIZED EGG PRODUCTS
   iv. REQUIRING COOKING RAW EGGS AND EGG PRODUCTS THOROUGHLY
   v. SUBSTITUTING EGGS PREPARED USING 5-LOG REDUCTION METHOD

CDFA recommends that pasteurized egg products be used for highly susceptible populations to reduce risk from shell eggs to the lowest level possible. More importantly, it is imperative that nursing homes and other institutions follow the Model Food Code to prevent post-pasteurization contamination of pasteurized eggs in order to prevent propagated outbreaks in these confined settings.

w. HOW MANY FARMS PACK THEIR OWN EGGS

Over 50% of registered egg producers in California pack there own eggs but this figure is declining over time as smaller producers ship their eggs off-line to larger processors (Don Bell, Emeritus, UC Riverside Poultry Extension).

x. 36 HOUR REFRIGERATION REQUIREMENT – THERMAL CHECKS

Please see previous comments from Dr. Ralph Ernst.

y. THE WAY TO SAMPLE LARGE VERSUS SMALL FARMS

For environmental tests the number of samples taken should be the same for all farms since sampling is done on a unit surface area basis as explained previously in this report [3]. Since there is no statistical advantage in sampling 1000 compared to 480 eggs, it would be reasonable to sample small flocks using a smaller number of eggs so that the economic burden of taking eggs out of the egg market is reduced while fulfilling FDA's egg testing requirements.

z. THE COST OF TRAINING FOOD SERVICE INDUSTRY EMPLOYEES

Food handlers account for 20 - 30 % of all SE contaminated food (Guzewich, Bryan). In one California egg trace back, it was discovered that an itinerant cook, his wife and young child had tested positive for Salmonella 2 months before the outbreak occurred and the investigating health department was unable to contact

him. Yes, food service managers and food handlers all require basic training in proper hygiene and food preparation methods. The *Serve Safe Food Training Program* is a nationally accredited training program that should be made mandatory for all food service employees. The California Department of Health Services can be consulted to obtain training costs associated with the program.

aa. ESTIMATED PROGRAM MANAGEMENT COSTS

See discussion under Section VI. Funding.

bb. ACTUAL BURDEN OF RECORD-KEEPING

For producers participating in CEQAP, this burden has remained at a manageable level and has not been a cause for leaving the voluntary program. For States without an egg quality assurance plan, there will be an adjustment period that can be ameliorated through adequate training and support. For CDFA, the demand for increased record keeping will be related to added time necessary to sample if necessary, document testing, store data, analyze results and audit reports with FDA.

cc. WHAT OTHER INFORMATION SHOULD BE COLLECTED?

FDA should establish a working group comprised of federal and state officials that will develop a systematic approach that will help set goals and objectives of the program based on internal workings of the plan and as well as externally related to broader SE public health goals in accordance with *Healthy People 2010* objectives. Regional approaches to program assessment should be developed in order to adjust the program based on regional results.

1. Internal - All records pertaining to the flock plan, rodent control, cleaning and disinfection, test dates, test results, records related to diversion, other corrective action taken, training records, audit reports
2. External – Public health SE statistics, SE trends in eggs and other foods, molecular epidemiological data, FoodNet and State trends

dd. WAYS TO IMPROVE THE QUALITY AND ACCURACY OF DATA THAT WILL BE COLLECTED

The purpose of collecting data is to assess the efficacy of the program regionally over time.

1. Develop a working group that will develop and monitor progress of data collection, data quality and data analysis components
2. Develop standardized electronic data collection forms, protocols and other tools
3. Develop a coordinated, secure data storage system with internal quality checks
4. Develop an accessible user-friendly data retrieval system

5. Develop a flexible query system that will allow for flexible analyses
6. Develop and generate regular reports to all stakeholders on general and regional trends

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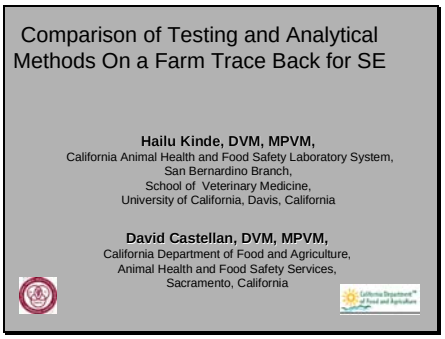
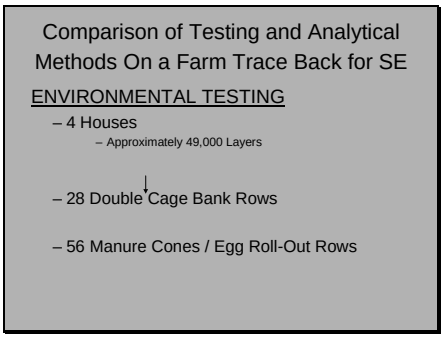
Appendix A

Slide 1



Slide 2



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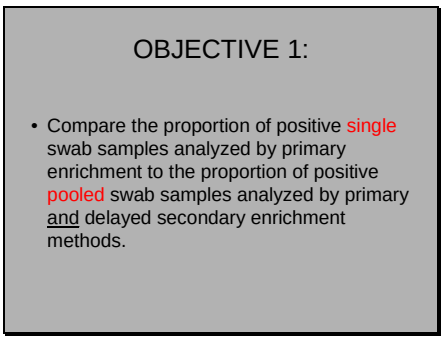

Slide 4

Primary Enrichment Results All Salmonella - Roll-Outs & Manure

	SINGLE SWAB	POOLED SWABS
% Positive	33.0	35.7
95% C.I.	(24.4 – 42.6)	(18.0 – 53.4)

Slide 5

Delayed Secondary Enrichment Results for All Salmonella - Roll- Outs & Manure

	SINGLE SWAB	POOLED SWABS
% Positive	33.0	71.4
95% C.I.	(24.4 – 42.6)	(54.7- 88.1)

Slide 6

Primary Enrichment Results for Group D Salmonella - Roll-Outs & Manure

	SINGLE SWAB	POOLED SWABS
% Positive	8.0	14.3
95% C.I.	(3.7 – 14.7)	(1.3 – 27.2)

Slide 7

Delayed Secondary Enrichment Results for Group D Salmonella - Roll- Outs & Manure

	SINGLE SWAB	POOLED SWABS
% Positive	8.0	17.9
95% C.I.	(3.7 – 14.7)	(6.1- 36.9)

Slide 8

OBJECTIVE 2:

- Compare the proportion of group-confirmed salmonella colonies per maximum of 5 suspect colonies on primary culture plates derived from single versus pooled swab samples.

Slide 9

Confirmed Salmonella Colonies per Maximum of 5 Suspect Picks for All Salmonellas

- Single Swab Sample Plates = 44/93
  = **47.3%**
- Pooled Swab Sample Plates = 18/33
  = **54.5%**
- CONCLUSION: No significant difference
  (Chi-Square Test for Homogeneity, *P > 0.05)*

Slide 10

Confirmed Salmonella Colonies per Maximum of 5 Suspect Picks for Group D Salmonella

- Single Swab Sample Plates = 11/30 = **36.7%**
- Pooled Swab Sample Plates = 9/17 = **52.9%**
- CONCLUSION: No significant difference (Chi-Square Test for Homogeneity, *P > 0.05)*

Slide 11

Salmonella Serotyping Results

Serotypes Found	N
S. cerro	18
S. enteritidis	15
S. schwartzengrund	9
S. thompson	3
S. infantis	1

Slide 12

Spatial Distribution of Group D Salmonella - Single v.s. Pooled Swabs

- **Positive Rows of Egg Roll-Outs**

Single	Pooled
4	29-32
22	
48	

- **Positive Rows of Manure Cones**

Single	Pooled
4	1-4
7	5-8
22	21-24
24	
37	
55	53-56

Slide 13

OBSERVATIONS

- 2,240 eggs, 40 eggs/row were negative for SE two weeks following environmental testing (20 eggs/pool)
- Single and pooled manure samples were highly correlated in identifying positive rows for SE
- Pooled swab culture plates gave similar confirmation for Salmonella groups as for single swab culture plates
- Pooling environmental swab samples was a valid screening method for detecting Salmonella

Appendix B

Print Name_____ **Signature**_____

California Egg Quality Assurance Program (CEQAP)
Certification Test

This is a take home test. We suggest that you read the questions first and then view the videotapes of the educational sessions. You should also view the USDA videotape on Biosecurity for the Poultry Industry (#1 - What is Biosecurity? and #3 - Egg Laying Operations). You are welcome to refer to any references which you have available. We recommend that you review the material in the California Egg Quality Assurance Program (CEQAP) Handbook which is available for $25 from the Pacific Egg & Poultry Association, 1521 "I" Street, Sacramento, CA 95814; phone 916/441-0801.

Be sure to answer all of the questions and mail this test to Ralph Ernst, Poultry Specialist, Department of Animal Science, University of California, Davis, CA 95616-8521. A score of 90% or higher is required for certification as a quality assurance supervisor for the CEQAP. You can repeat the test if you do not achieve certification on your first try.

Program Structure and Plan Development

1. **The California Egg Quality Assurance Plan specifies that participants <u>must</u> (check all that apply):**

____a. designate farm or processing plant representative as the official quality assurance supervisor(s) for the plan.
____b. develop a quality assurance plan for each farm or egg processing plant.
____c. submit the plan(s) to California Department of Food & Agriculture (CDFA) for approval.
____d. have the quality assurance supervisor(s) attend at least one continuing education session every two years.
____e. maintain the records required by your approved plan.
____f. disinfect all poultry houses monthly.
____g. send a copy of your plan to your regional USDA office for their files.
____h. administer a competitive exclusion product to replacement chicks at the hatchery.
____i. vaccinate pullets for *Salmonella enteritidis*.
____j. retain a veterinarian.
____k. use all medications and pesticides according to label directions or under veterinary supervision.
____l. develop a biosecurity program for the farm.
____m. maintain a flock health program.
____n. monitor for rodents at least once per month and maintain a record of results.
____o. enroll your farm/ranch in the National Poultry Improvement Plan.
____p. obtain feed from mills which follow "Good Manufacturing Practices and the

Recommended *Salmonella* Control for Processors of Poultry Feeds" as developed by the American Feed Industry Association.

True/False: circle the correct answer.

T F 1. Participation in the CEQAP is a USDA requirement.

T F 2. The CEQAP is funded primarily by fees charged to farmers.

T F 3. The CEQAP is a voluntary program, which was developed by a team from industry, government agencies and the University of California.

T F 4. Once I have been certified as a QA supervisor I will not be required to attend more educational meetings to maintain certification.

T F 5. Chickens subjected to stressful conditions have been shown to be more susceptible to *Salmonella* challenge.

T F 6. The records which you are required to keep for the CEQAP are primarily for the benefit of USDA and should not be used by the farm to make management decisions.

T F 7. Public health officials are concerned about *Salmonella* control in animal products because people can become seriously ill and even die from a *Salmonella* infection.

T F 8. In developing your flock plan be sure to make it specific to your farm or plant and your conditions.

T F 9. The QA Supervisor is responsible for annual training of ranch employees in appropriate biosecurity procedures and documentation of this training.

T F 10. Farm or ranch plans for the CEQAP are public documents and must be kept in the California Department of Food and Agriculture office.

T F 11. Some parts of this program may be modified in the future as new information becomes available.

T F 12. The CEQAP has an advisory committee composed of industry, agency and University people to provide guidance for the program.

T F 13. Oversight for the CEQAP is provided by the California Department of Food and Agriculture (CDFA).

T F 14. A veterinarian from the CDFA will visit all ranches at the appropriate intervals to assure that they are following their plan.

T F 15. You don’t need to keep the records specified in your farm plan unless someone calls and indicates that they will come to review your quality assurance program.

T F 16. Help in plan development can be obtained from U.C. Cooperative Extension Specialists or the plan consultant David Goldenberg.

Print Name_____ **Signature**_____

California Egg Quality Assurance Program (CEQAP)

Biosecurity, Cleaning and Disinfection Certification Test

True/False: circle the correct answer.

T F 1. For purposes of this quality assurance program, biosecurity is all of the measures taken to prevent entry of disease agents into your flocks.

T F 2. A biosecurity program has three major components, 1) farm isolation, 2) traffic control, and 3) sanitation.

T F 3. Dry cleaning is the recommended method for removing dried egg matter.

T F 4. Replacement chicks must be purchased from a hatchery which participates in the NPIP *Salmonella* monitoring program.

T F 5. Only necessary visitors should be allowed into chicken houses.

T F 6. Human and vehicle traffic probably pose the two greatest risks for introduction of disease agents to your farm.

T F 7. If you visit another poultry producer you should shower and change into clean clothing before visiting and before re-entering your bird facilities.

T F 8. If you visit other bird facilities you should always wear disposable boots or rubber boots (subsequently cleaned and disinfected) to protect your shoes from contamination.

T F 9. Experienced growers can **always** tell if chickens are infected with a virus by looking for signs of disease.

T F 10. Some visitors such as feed truck drivers are not likely to carry disease so it is all right to let them inside your laying houses.

T F 11. You should always clean equipment before attempting to disinfect it.

T F 12. The objective of sanitation is to reduce microbial load, exposure to pathogens and the risk of disease.

T F 13. Your farm well should be properly sealed and you should not locate manure piles, burial pits for mortality, or septic tanks close to your well.

T F 14. Chlorine is rapidly inactivated by dirt and works best on clean surfaces.

T F. 15. Household bleach is about 5% chlorine, but it is always best to check the label to determine the level of active ingredient when mixing chlorine solutions for disinfection.

T F 16. The main reason to avoid using pressure sprayers in laying houses containing hens is that the sprayers may get the birds wet.

T F 17. Hot water (200^{o}F) pressure spray is more effective at killing bacteria than cold water.

T F 18. It is best to have 2 to 4 days or more of down time following cleaning and disinfection, before birds are introduced.

T F 19. Rotating low pH with high pH compatible disinfectants has been shown to be more effective than continually using the same disinfectant.

T F 20. To know how much disinfectant you will need, use only the square footage of the house.

T F 21. The most common disinfectant used for *Salmonella enteritidis* control is carbolic acid which is a phenol.

T F 22. Formaldehyde is an excellent disinfectant but can only be used under carefully controlled conditions due to its human toxicity.

T F 23. The use of shower in/shower out facilities, foot pans, and disposable hats, boots and coveralls can all be part of a good biosecurity program.

T F 24. Stocking multiple ages in the same house is recommended because it will help develop early immunity in the younger birds.

T F 25. One good disease surveillance procedure is to monitor the flock by use of blood testing procedures.

T F 26. Environmental sampling for *Salmonella enteritidis* is a requirement of the CEQAP.

T F 27. Culturing of chick box papers is a recommended procedure to assure that you have obtained *Salmonella enteritidis* free chicks from the hatchery.

T F 28. Spilled feed can be allowed to build up throughout the life of a cage laying flock since it is on the floor where birds can’t reach it.

T F 29. One of the three major steps in cleaning and disinfection is removal of debris.

30. Examples of things to sanitize are (check all that apply):

____ a. visitors' boots
____ b. delivery trucks, bird crates or transport cages
____ c. equipment which has been on another farm
____ d. soil between buildings
____ e. wheels on delivery vehicles
____ f. waterers
____ g. fiber egg flats
____ h. manure piles
____ i. brooder houses

31. Infectious diseases can be spread from farm to farm by (check all that apply):

_____ a. people
_____ b. pets
_____ c. rodents
_____ d. wild birds
_____ e. chicken crates
_____ f. dirty equipment
_____ g. insects
_____ h. contaminated feed or feed sacks
_____ i movement of eggs or poultry
_____ j. rendering trucks and dead birds
_____ k. impure water
_____ l. dirty egg flats
_____ m. chicken dust or feathers
_____ n. manure
_____ o. dirty vehicles

32. Chlorination of the drinking water kills bacteria and inhibits growth of algae. If used, a level of _____ppm chlorine is recommended when measured in the most distant drinker for controlling coliform bacteria in the water.

Print Name_____ **Signature**_____

California Egg Quality Assurance Program (CEQAP)

Rodent Control Certification Test

Circle the correct answer:

T F 1. The house mouse, Norway rat and roof rat may be involved in spreading diseases to chickens and man.

T F 2. Rodents do not see well and use their sense of touch, smell, hearing, and taste as a primary mode of guidance.

T F 3. The cost of rodent damage to poultry operations can easily exceed the cost of a rodent management program if an effective monitoring and control program is not being used.

T F 4. Monitoring rodent populations is a very important part of a good Salmonella reduction plan.

T F 5. Rats or mice seldom use the same trail or runway.

T F 6. A rodent's home range is as far as it must travel to get food, water and harborage, and varies from site to site.

T F 7. Eliminating outside debris, old equipment piles, weeds and leaky faucets does not effect the extent of inside rodent populations.

T F 8. Multiple-capture mouse traps, such as the Victor tin cat or Ketch-all are effective in detecting and assisting in the control of mice.

T F 9. The best place to bait rodents is next to the feeders.

T F 10. Rodent baits must be used in accordance with label specifications.

T F 11. Anticoagulants are generally not associated with bait shyness problems while toxicants like zinc phosphide are.

T F 12. Non-anticoagulant baits like zinc phosphide, bromethalin and cholecalciferol are the best choice for clean out programs.

T F 13. Spilled feed can attract rodents.

T F 14. There is a regional variation in rodent food preferences. It is useful to try several bait types (pelleted, grain or block) to determine the most effective bait for your ranch.

T F 15. Roof rats can be distinguished from Norway rats by their longer tails, pointed nose and longer ears.

T F 16. Mice, unlike rats, can survive without water although they will drink water if it is available.

T F 17. Rats are good swimmers and may enter buildings through sewer pipes if vents are not rat proof.

T F 18. The house mouse, roof rat and Norway rat are often called comensal rodents.

T F 19. The gestation period for roof or Norway rats is about one year.

T F 20. Rodents can be most effectively observed in poultry buildings the first two hours after sunset and the last two hours before sunrise.

T F 21. Rats and mice defecate, urinate and shed hair everywhere they go.

T F 22. Bait shyness may be passed from parents to offspring for up to three generations.

T F 23. Rats can jump vertically more than 28 inches.

T F 24. Mice are more neophobic (afraid of new things in their environment) than rats.

T F 25. Use of 3/4 to 1 inch in diameter gravel, 6 inches deep and 8 inches wide, along foundations will prevent rodents burrowing under walls of houses.

T F 26. Pre-baiting is recommended with non-anticoagulent rodenticides.

Choose the single best response:

27. Rodent monitoring (inspections) can be done visually by looking for

a. rodents
b. rodent droppings
c. rodent burrows
d. rodent tracks
e. rub marks
f. gnaw marks
g. all of the above

28. The appearance of rodent droppings is important in distinguishing between rats and mice. Which is the correct statement?

    a. Rat droppings are 7/8 to1 inch long and house mouse 1/16 to 3/16 inch long.
    b. Rat droppings are 3/4 to 1-1/4 inch long and house mouse 3/16 to 1/2 inch long.
    c. Rat droppings are black and mouse droppings are brown.
    d. Rat droppings are 1/3 to 3/4 inch long and house mouse 3/16 to 1/2 inch long.

29. Exclusion of rodents from attics, insulated wall spaces, stored feed and other food or water sources can best be accomplished with

    a. steel wool
    b. 1 inch poultry netting
    c. 1/2 x 1/2 inch hardware cloth
    d. 1/4 x 1/4 inch hardware cloth or galvanized sheet metal

30. Multiple-capture mouse traps, such as the Victor tin cat or Ketch-all are very effective in detecting and assisting in the control of mice. Traps could be placed

    a. inside doorways
    b. beside all openings to the outside or between houses
    c. where rodent activity is observed
    d. in storage rooms
    e. all of the above

Print Name_____ **Signature**_____

California Egg Quality Assurance Program (CEQAP)

Flock Health Certification Test **True/False: circle the correct answer.**

T F 1. It is recommended that a sample of mortality be taken to a CAHFS laboratory for examination occasionally even if severe mortality is not observed.

T F 2. Growers should watch their birds for overt (external) signs of disease.

T F 3. The California Veterinary Diagnostic Laboratory System (CAHFS) maintains four laboratories in California that accept poultry. These are located in Davis, Turlock, Fresno and San Bernardino.

T F 4. The CAHFS laboratories are full service laboratories, which can provide post mortem examination, microbiology (culture of samples), virology, clinical chemistry, serology and chemical analysis.

T F 5. The CAHFS is supported by the State of California to maintain disease surveillance and assist the livestock industries in control of disease problems.

T F 6. You can't use the CAHFS laboratory if you don't have a consulting veterinarian.

T F 7. The CAHFS laboratories don't test feed for mycotoxins, feed samples would have to be sent to a private laboratory.

T F 8. An emergency disease plan should include knowing who you are going to call for diagnostic and treatment help, how the flock(s) are going to be isolated and who needs to be notified.

T F 9. The diagnostic laboratory (CAHFS) is only of value in obtaining a post-mortem evaluation of sick and dead birds.

T F 10. Once good flock health programs are in place, written records become unnecessary.

T F 11. It is not necessary to vaccinate for all diseases possible. At times using unnecessary vaccines can be harmful to the flock.

T F 12. Good health management depends on a sound knowledge of the nature and origins of diseases.

T F 13. Some infectious disease agents are so virulent (able to cause disease) that

they can overcome almost all preventive measures.

T F 14. It is important to feed good quality, balanced diets to maintain healthy birds.

T F 15. Stress can be caused by extreme heat or cold, lack of food or water, overcrowding, changing penmates, excess ammonia in the air, vitamin deficiencies or mineral deficiencies.

T F 16. Chickens experiencing stressful conditions are more likely to get sick if they are exposed to pathogenic bacteria.

T F 17. The CEQAP requires that you keep a daily record of mortality in your flock(s).

T F 18. Maintaining healthy stock is one method of assuring that eggs produced on your facility will have a minimum of bacterial contamination.

T F 19. One of the bird's natural defense systems--the beating cilia lining the trachea--can be destroyed by high ammonia levels in houses.

T F 20. Reliable information sources such as a consulting veterinarian, Cooperative Extension, your local diagnostic laboratory and your supplier of vaccines and medications are essential to effective health management planning.

T F 21. All of the significant diseases are caused by infectious agents.

T F 22. Vaccines must be stored properly and used by the expiration date on the package but a few weeks after the expiration is all right.

T F 23. Diseases that do not cause obvious signs of disease in a flock are of no significance.

T F 24. The area for accumulating dead birds for disposal should be as far as possible from your bird housing.

T F 25. Employing a qualified consulting veterinarian and nutritionist is recommended and should allow the producer to optimize flock productivity and product quality.

T F 26. Management plays no role in the occurrence of ammonia blindness in a pullet grow-out operation.

T F 27. Vaccinating and beak trimming service crews should be left to do their jobs without interference.

T F 28. Salmonellosis is an example of a disease with numerous potential origins (e.g. breeders, hatchery, contaminated premises, biological or mechanical

carriers, etc.).

T F 29. Many poultry health problems are caused by errors in management rather than by bacteria or viruses.

T F 30. It is unreasonable to expect the diagnostic laboratory to have knowledge of producer needs and perspectives.

Print Name_____ **Signature**_____

California Egg Quality Assurance Program (CEQAP)

Insect Vector Control Certification Test

Circle the correct answer:

T F 1. The Northern Fowl Mite can complete its entire life cycle on chickens.

T F 2. Larvae of the darkling beetle (*Alphitobius diaperinus*) have been found to harbor a number of disease organisms including Fowl Pox, Newcastle Disease, *E. coli* and *Salmonella*.

T F 3. Red mites and fowl ticks are blood-sucking parasites, which live in the environment and feed on birds (usually during the night).

T F 4. The lesser house fly (*Fannia canicularis*) can reproduce at lower temperatures than the common house fly (*Musca domestica*).

T F 5. The common house fly has been shown to transmit several disease agents.

T F 6. The continued use of insecticides for fly control on poultry farms may lead to insecticide resistance problems.

T F 7. To be effective, fly control programs should be based on good manure management (e.g. manure drying or composting).

T F 8. The lesser house fly (Fannia) is about 2/3 as large as the house fly (Musca) and often adults are seen hovering in shady areas.

T F 9. All common fly types reproduce from eggs which hatch into larvae; the larvae change into pupae and adults emerge from the pupal case.

T F 10. When conditions are ideal the house fly cycle can be completed in 7 to 10 days.

T F 11. The pupal case of the lesser house fly is smaller than that of the house fly and is flatter with small projections along the sides.

T F 12. The Lesser Mealworm beetle (sometimes called litter beetle) and the Mealworm beetle are often found on poultry farms.

T F 13. Many of the ectoparasites (external parasites) of poultry are shared by many bird species (e.g. wild birds like sparrows).

T F 14. The scaly leg mite lives on the legs of birds and makes the legs look scaly.

T F 15. Using wire on the sides of your poultry houses, which excludes wild birds, can assist in keeping your birds free of external parasites.

T F 16. Chickens don't get lice or fleas so you don't need to worry about these two parasites.

T F 17. Mosquitos can transmit Fowl Pox.

T F 18. Fly baits can be useful in a fly control program.

T F 19. Permethrin is an insecticide labeled for control of external poultry parasites and flies.

20. The most common pest fly around poultry ranches in the winter, which can often be seen hovering in shady areas is,: (check correct answer)

___a. the house fly (Musca)
___b. the lesser house fly (Fannia)
___c. the flesh fly (Calliphoridae)
___d. the black dump fly (Ophyra)

21. The following external parasites may feed on chickens. (check all that apply)

___a. Northern fowl mites
___b. Roost, chicken or red mites
___c. Lice
___d. Bedbugs
___e. Fleas
___f. Mosquitos
___g. Ticks
___h. Scaly leg mite

22. Larvadex is an effective insecticide that kills (check correct answer)

___a. adult house flies
___b. larval house flies
___c. pest beetles
___d. northern fowl mites

23. The only biological control organism for fly control that is available for purchase is (check best answer):

___a. the Carcinops beetle
___b. predaceous mites (uropodid and macrochelid)
___c. parasitic wasps
___d. Entomophthora fungus

24. Which of the following can affect manure moisture and drying of manure under the cage row? (check best answer)

___a. genetic strain of bird
___b. cage density
___c. puddles of water near the house
___d. height of the manure
___e. weather
___f. house design
___g. air flow
___h. all of the above

25. Which of the following is likely to achieve the best prevention of adult fly emergence when the manure contains heavy concentrations of all developmental stages of the house fly? (check best answer)

___a. immediate removal followed by thin bed drying
___b. immediate release of parasitic wasps
___c. application of concentrated larvicides
___d. immediate removal followed by windrow composting at temperatures greater than 115^{o}F.
___e. immediate removal to a pile covered by a plastic tarp

Appendix C

Economic impact of the Salmonella enteritidis control program to the Egg Industry in California

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Salmonella enteritidis is not considered to be a significant cause of morbidity or mortality in commercial layer flocks. The major threat to the producer is that the farm will be implicated in a trace back investigation following a human illness due to S. enteritidis and the associated cost in fulfilling the regulatory compliance. For the industry as a whole there is the negative publicity from the public perception that eggs are linked to human salmonellosis. This risk associated public perception could translate in to a financial loss for the egg industry. Alternatively, if the producer chooses to implement an S. enteritidis control program, there may be a reduced risk of human salmonellosis, improved consumer confidence and the industry will benefit from sustained product demand and financial gain. However, implementing a S. enteritidis control program in a commercial layer flock is not simple and it could certainly increase production costs. There is no previous documentation dealing with the economic impact of the S. enteritidis control program. The purpose of this paper is to present two cost estimates: 1) an S.enteritidis control program for the California Egg Industry and 2) the loss of income incurred by a producer in the absence of a S. enteritidis monitoring program based on a retrospective study.

Cost estimates for Control Program

The limitations in estimating costs for a S.enteritidis control program stem from the many variations in flock sizes, age, type of housing and equipment, environmental conditions, and management practices. However, the great majority of California producers have joined the California Egg Quality' Assurance Plan (CEQAP) and subscribe to common basic core program components. Therefore in estimating costs, components such as cleaning and disinfection, rodent control and testing for S. enteritidis etc. are required by the plan and assumptions are made that they are practiced by all participants. It is recognized that these farm practices existed long before the S. enteritidis problem but producers became more vigilant following the implementation of CEQAP. Cost estimates for rodent control and cleaning and disinfection were based on 2 companies' expenditures; a large company with a capacity of 1,776,900 birds, and a mid size company with a capacity of 63,000 birds.

Assumptions:

There are 32 companies, 100 farms, and 1000 houses with 23 million laying hens in California with an average of 23,000 birds per house. 85% of the companies hire veterinarians; and 25% of the annual veterinary services, 50% of the rodent control and 25% of the cleaning and disinfection efforts are estimated for a S. enteritidis control (monitoring) program. 8% of the laying hens are vaccinated. Annual Se monitoring cost estimates for the state of California Egg Industry Cost of S. enteritidis testing:

16 swabs per house (4 pools), 10 houses per farm $451 per pool, for 1000 houses = $45 X 4 X 1000	$180,000
Cleaning and Disinfection $1927 per house (25% estimated for the Se program) = $1927 X 1000 (25%)=. $481,750 (18 months) For 12 months =67%($481,750)	$322,772
Rodent Control $1 327 per Farm (50% estimated for the Se program) = $1 327 X 100 (50%).	$66,350
Vaccination for S. enteritidis 14 Cents per bird, 8% of 23,000,0000 birds $0.14 X 1,840,000	$257,600
Consultation Professional fee, $12,00O/yearlcornpany (25% est., for Se) 32 companies, 85% hire veterinarians= 27 $3000 X 27.	$81,000
**Total	**$907,722**

The Cost of not monitoring for S. enteritidis

When shell eggs are implicated in human salmonellosis, a trace back investigation is initiated by regulatory agencies. The cost of compliance with the regulatory protocol is very expensive because eggs are diverted to pasteurization or the infected flock is depopulated. Unlike some of the zoonotic diseases such as brucellosis and tuberculosis in cattle, there are no indemnities paid if the producer chooses to depopulate the infected flock. If the producer chooses to divert eggs for pasteurization the shell egg premium will be lost (by as much as 50%). Indirect income losses to the producer include lack of replacement pullets for example, if replacement pullets are not planned several weeks in advance the producer may incur cost of idle capital; other indirect costs may include the cost of purchasing eggs in the open market to fulfill existing contract obligations. Other costs include laboratory testing, liability claims, increased insurance premiums, decreased consumer confidence, etc.

Income loss associated with *S*. enteritidis phage type 4 outbreak in a commercial layer chickens (19 months follow up)- A Retrospective Study

In May of 1994 S. enteritidis phage type 4 (Se PT4) was isolated from five of six 27-week old layer chickens submitted for necropsy from a flock of 43, 000. Bacteriologic and epidemiological investigations on the farm revealed that 5 of the eight flocks (n=176,000) were infected. The prevalence of Se PT4 in randomly selected healthy birds ranged from 1.7% (cage birds) to 50% (free range birds) and the prevalence in culled birds (kept in dirt floor houses) ranged from 14 to 42%. The estimated overall prevalence of group D Salmonella was 2.28 per 10,000. The estimated prevalence of group *D* Salmonella in eggs from caged birds in three infected houses ranged from 1.5 to 4.1 per 10, 000, whereas in 2 houses of free range birds, prevalence was 14.9 to 19.1 per 10,000. Three of the 8 flocks on the farm remained negative for Salmonella throughout the observation period (May 2 1994 to December 1995). The producer voluntarily diverted eggs for pasteurization and there was no human illness associated with this outbreak and no trace back investigation was initiated.

Estimated loss of income associated with Se PT4:

The different age layer flocks were kept in 8 different houses and produced regular or specialty type eggs. For estimating loss, one price was chosen for all the eggs (large price +50 Cents) produced on the farm. At the start of the outbreak egg production was about 92% and a mortality of 0.2% per week was estimated thereafter until the flock was removed or marketed. Three flocks were never infected during the observation period (19 months). The other flocks became positive intermittently and eggs were treated according to protocol. This entailed testing 1000 eggs from a positive flock four times (every 2 weeks). During this testing period, eggs were diverted to pasteurization. If eggs became negative for four consecutive times, the producer was allowed to sell shell eggs and the flock was monitored for the rest of the production life by sampling 480 eggs every 3 months. If at any time eggs became positive, diversion to pasteurization would resume and eggs would be tested every 2 weeks (1 000 eggs per house). The net loss from each flock was calculated by subtracting the sum of the sampling cost and the income from pasteurized eggs from the original value. Diverted eggs were estimated to be 5O%of the shell egg price (Table 1). At the start of the outbreak the producer opted to hire a veterinarian and additional cost was incurred.

Table 1. Estimated Loss of Income (US $) Associated with Se PT4 Infection of Laying Flocks

Flock ID	Original value of eggs	Cost of eggs used for testing	Net value of eggs	Income from eggs	Net Loss
1	1,493,957	1,253	1,492,704	156,250	1,337,706
2	761,830	844	760,986	94,344	667,486
3 Not infected	387,147	407	386,740	386,740	407
4 Not infected	246,842	329	246,513	246,513	329
5 Not infected	1,200,175	329	1,199,846	1,199,846	329

6	305,779	1,247	304,505	32,212	273,567
7	76,061	960	75,101	12,026	64,034
8	63,953	1,148	62,805	10,400	53,553
Total	4,535,744	6,544	4,529,200	2,138,331	2,397,413
Total net loss	Original value minus income from diversion (4,535-2,138,331)= 2,397,413				
Other costs	Flock vaccination for SE				2,195
	Professional fee				4,500
Grand Total					$2,404,108

Laboratory costs related to the outbreak:

Collection of Samples (time)
31 trips, 3hrs each trip, $1001hr=$300 X31 …….....…. $9,300
Cost of necropsy and Salmonella culture of laying hens:
- 655 birds @ $30 per bird…….....…. $19,650
- @5% positive for group D Salmonella
- 33 isolates serotyped ($1 2 each) and phage typed($l1.00 each)
- - - 33 X $23 = ...……..……. $759
Cost of environmental testing:
Drag swabs. 180 @ $45 each…….....…. $8,100
13 % (23 isolates) serotyped at $1 2 each. .....……..... $276
Rodent and other feral animal sample culture.58 @ $30each…….…… $1740
Group D Salmonella was serotyped ($12 each) and phage typed ($11 each)
12 isolates @$23 each…….…… $ 276
Feed Samples. 7 @ $30 each .....…… $210
One isolate of Salmonella serotyped @.$l 2……..... $12
Tank Water samples 8 @ 30 each. $240
Cost of serotyping 6 isolates ($1 2 each) .....…… $72
Cost of testing eggs
85,360 eggs, pool of 20 eggs
4268 pools @ $17 per pool
4268X $1 7=. .....…… $72,556
Cost of serotyping and phage typing=$23 each
58 group D Salmonella isolates =$23 X 58 .....…. $1,334
Cost of testing Moore swabs (creek water) for Salmonella
40 swabs @$30 each…….....…. $1,200
68 Salmonella isolates were serotyped
68 @$I2 each .....……..... $816
Total4 Salmonella enteritidis were phage typed
4 @$11 each…….…… $44
Total. .....…….. $116,585

Grand Total .....…… $2,520,693

Conclusion

The *S. enteritidis* monitoring cost estimates outlined in this study would pale in to insignificance should the egg industry experience negative consumer confidence like what occurred in Europe in the 1980's. The 1994 Se PT4 outbreak in California caused significant financial loss to a producer and resulted in an estimated additional $5 million loss to the industry due to a short-term trade embargo. It has also alerted the California Egg Industry to reinforce the importance of the Se monitoring program. It is imperative for the producer to weigh all the decision-making factors whether to divert eggs or not. In this study the producer took a great risk and allowed the sampling process to continue in the hope that eggs would be negative. The loss would have been greatly reduced should he discontinued sampling of eggs and decided to depopulate the flocks.