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Docket No. 00N-0504

United Egg Producers (UEP) and United Egg Association (UEA) is pleased to comment on the President's Council on Food Safety/Egg Safety Action Plan, hereinafter referred to as the Plan. UEP is a national cooperative representing the interests of approximately 80% of all the shell eggs produced in the United States. UEA is a national association representing the interests of 95% of all the eggs further processed into liquid, dried, or frozen egg products.

The three general questions inviting comments to the docket were:
(1) Does the Plan comprehensively cover the problem of SE in eggs and measures for reducing this hazard?
(2) What are the costs in implementing the risk reduction components?
(3) What training is needed?
These comments will respond to each of these general questions.

(1) Does the Plan comprehensively cover the problem of SE in eggs and measures for reducing this hazard?

The egg industry considers food safety of paramount importance and supports the goal of the President's Council on Food Safety to protect the public health from all foodborne hazards through science-based objectives and action steps. The Federal food safety strategic policies must continually ask if the action steps will actually stop someone from getting ill.

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Protecting the food supply is an ongoing challenge because, although the risk associated with eating will never be eliminated, the hazards can be minimized. The objectives and action steps of the Egg Safety Action Plan are not comprehensive enough to meet the objectives of the Plan while other steps will raise the cost of food without protecting public health. These comments will detail areas of the Plan that need to be made more comprehensive and highlight those steps that do not contribute materially to the stated objectives.

The Plan does not address the ongoing practice of egg centrifugation at restaurants and bakeries in those States that have not banned the process or the machinery. The commingling of the shell with the internal contents in a centrifugal process do not allow the Food Safety and Inspection Service to examine each individual egg as required under the Egg Products Inspection Act. Furthermore, contamination that may be present on the shell's surface will recontaminate the liquid egg. This process of centrifugation at the bakeries and restaurants must be prohibited in the interest of food safety.

Science-based objectives and action steps in any regulation must be founded on accurate data

Any science-based objectives and action steps need to be truly rooted in scientific data and accurate information so that there is valid information for making informed decisions. The Plan calls for numerous stages of environmental testing. Testing at various stages without a specified purpose will raise the cost of food without protecting public health. UEP has revised its Streamlined, Grading/Inspection Program to include a testing component for a national uniform program of grading and inspection to verify the efficacy of quality assurance programs. UEP has developed such a plan and cites the One Dozen "eggsceptional ways" of improving egg quality and safety in these comments.[3]

The Plan has numerous examples of misinformation and misunderstanding which could lead to erroneous decisions. Even before the Plan's introduction, numerous quality assurance programs, developed by the egg industry, have contributed to a 48% decline in the rate of culture-confirmed SE cases reported (1 MMWR) to the Centers for Disease Control and Prevention (CDC) between the years of 1996 to 1999, and a 7% decline between 1998 and 1999. There is an opportunity to further this decline by increasing the participation in a nationally recognized quality assurance program. In the 1999 National Animal Health Monitoring Study [2] it was reported that 56.1% of farm sites were conducting a quality assurance program. Broadening the participation in quality assurance programs by establishing a national uniform program of grading and inspection for all egg producers will further the decline in the incidence.

UEP has revised its Streamlined, Grading/Inspection Program to include a testing component for a national uniform program of grading and inspection to verify the efficacy of quality assurance programs. UEP has devcloped such a plan, cites the One Dozen "eggsceptional ways" of improving egg quality and safety in these comments (3) and recommends the adoption of the UEP 5-Star Quality Assurance Program as the national standard.

What is the Risk?

Are eggs less safe than other protein-rich foods? This is the implication in FDA's proposed safe handling label. The President's Council on Egg Safety has identified egg safety as one component of this public health issue that warrants immediate federal, interagency action. The risk assessment has been determined by the SE Risk Assessment Final Report prepared by the Food Safety and Inspection Service as one SE-contaminated egg from the production of 20,000 eggs.4 This risk assessment is 0.005% which is several orders of magnitude lower than most animal products. Statistically, the likelihood of becoming ill from a contaminated egg is once in 84 years. This risk is very, very low. The Plan's action steps in developing labeling for egg cartons must be adjusted from its proposed discriminatory message. UEP has suggested that the Partnership for Food Safety Education's *Fight Bac!* campaign will further educate consumers in the proper way to handle all foods rather than warn against eating such products.

Misinformation with misleading results

When President Clinton made his radio address on December 11, 1999, he stated that there were 3.3 million infected eggs that could lead to human illness. This risk is overstated. The figure 3.3 million is based on the risk model of 1 egg in 20,000 eggs or 0.005%. This percentage of the nation's total egg production yields 3.3 million eggs, but the President's advisors neglected to point out to the President that nearly 30% of all eggs are broken into liquid form and pasteurized. Overstating the potential risks by 30% is a serious misstatement that has damaged the reputation of the egg and thus the egg industry this past year. The media coverage of the President's comments stated that foodborne illness accounted for 76 million people becoming ill every year, 300,000 would be hospitalized and 5,000 reported deaths. It was **not** pointed out that this is a combined figure for all foodborne illness, not just Salmonella, or Salmonella Enteritidis associated with eggs. We must take extreme care as both the Government and the Industry are faced with making critical decision based on information. We need accurate data.

It is vital to recognize that the most important priority for any Federal food safety strategic plan is credible information. Real, not hypothetical, numbers need to be used in making decisions leading to policy. The MMWR of February 4, 2000 provides the number of outbreaks and number of deaths attributed to Salmonella Enteritidis infection associated with eating raw or undercooked eggs.

The deaths reported during that 14 year period was 79 (less than 6 per year....no where near the 5,000 deaths reported), of which 64 or 81% occurred in health-care facilities. The information about the majority of deaths occurring in health-care facilities was not included in the Plan with the net effect that major newspapers and other forms of media attributed the 5,000 deaths annually to eating SE-contaminated eggs. Any loss of life is unacceptable, however, risk communication must be accurate to prevent the continued disparaging of any commodity. Greater efforts need to be directed toward accurate risk communication.

The Importance of educating consumers demands immediate implementation

A broadly-based policy is more likely to be effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the farm-to-table continuum. In the Plan the burdens of immediacy are placed on the egg industry through a comprehensive testing program (Section 1.1.1) while federal responsibilities provide for more generous timelines.

Objective 8 provides for the education of individuals using science-based materials. This must be a high priority items with a more aggressive action step. The Partnership for Food Safety Education, of which the Food and Drug Administration as well as the US Department of Agriculture Food Safety and Inspection Service participated in the *Fight Bac!* campaign development. This campaign is working. *Fight Bac*! has reported successes in penetrating consumer awareness through the development of its science-based educational material. The *Fight Bac!* campaign should be the foundation for the immediate implementation of better consumer education programs toward improving our responsibilities of safer foods, replacing the Plan timeline loosely defined as 2000-2005.

Based on data from the Centers for Disease Control and Prevention (CDC), most SE outbreaks occur in commercial venues. The Plan under the subheading Egg-Handling Practices provides the basis for the urgency in the immediate implementation of science-based educational material by stating, "the presence of SE bacteria in a raw egg, alone, does not guarantee illness upon consumption. However, the likelihood of developing SE infection increases when the egg is not handled safely by permitting the bacteria to multiply and a greater number of bacteria to be ingested with the food." In 1997, seventy-one percent of the SE outbreaks were in food service or institutional settings. Clearly, food service establishments need additional education on how to store and prepare food. The sooner this is developed, the sooner we will reap the rewards of further reductions in the incidence of Salmonella associated with eggs and other foods.

In analyzing the 2,423 outbreaks involving 77,373 cases of foodborne illness reported to the CDC between 1988 and 1992, the most common practices contributing to foodborne disease included improper holding temperatures and poor personal hygiene of food service workers. Addressing these food handling practices by reminding all consumers that there is a risk if a food is mishandled or not prepared properly could result in food that is not safe to eat.

We can and must work together on educating consumers. Without a clearly focused timeline on this vitally important step of educating consumers and handlers undermines the efforts of the Plan. Although not the only line of defense, educating the consumer in proper food handling and preparation is the final line of defense.

Cited epidemiology must be current and accurate

In reporting the rate of isolation of SE from infected humans, the Plan cited the years from 1976-1994 to acknowledge an increase in the rate of illness from 0.5 to 3.9 per 100,000 population. It also reported regional trends for the years 1990-1994, indicating a decrease in the Northeast with increases elsewhere. This is correct information for that time period, however this information is misleading as the more current information from CDC shows **a decline in every region** of the country. The MMWR reported from 1996-1998, the rate of culture-confirmed SE cases reported declined from 3.6 to 2.2 per 100,000. Every effort should be made in reporting accurate and up-to-the-minute epidemiology information so that action steps can be solidly-based.

Industry demographics must be accurate
Every egg producer must be included in the Plan

In reporting the demographics of the US egg industry, the Plan noted the estimated value of layers at nearly $1 billion. In 1999 the value of the laying flock would be more accurately reported at $1 per bird. With an average flock size nationwide of 269 million layers this would have yielded a value of less than one-third of the reported value in the Plan. Additionally, the demographics represented the egg industry as 5,000 producers with 3,000 or more hens and another 65,000 farms having less than 3,000 egg-laying hens. The USDA in cooperation with the American Egg Board collects the most current statistics on the number of egg-producing farms with 3,000 or more hens showing this total at less than 700 farms. The actual number of farms is only 14% of the number referenced in the Plan.

Accurate industry demographics is imperative for accurate decision-making. The Plan will exclude farms with 3,000 or fewer laying chickens. It is reported that these farms can produce up to three-quarters of a million eggs annually for each farm. Therefore, the potential exists for millions of eggs to be produced each year by farms excluded by the Plan. This creates a significant opportunity for potential foodborne disease problems with a large number of eggs entering the marketplace without any quality assurance surveillance. The grading and inspection program must be uniform and apply to every egg producing farm in the country irrespective of the number of laying chickens on that farm.

Flaws in the objections and action steps of the Egg Safety Action Plan

The Overarching goal calls for the elimination of SE illnesses associated with the consumption of eggs by 2010. The Egg Safety Action Plan has set an interim goal of a 50% reduction in egg-associated SE illnesses by 2005. Is there a consensus among epidemiologists that complete elimination of Salmonella is possible? In the Plan it states, "Salmonella of various serotypes are commonly found in the digestive tracts of animals and frequently contaminate our environment." If Salmonella is *commonly* found in the digestive tracts of animals, how can any amount of effort totally eliminate it? To establish a goal that will not succeed is to plan to fail with further damaging consequences for the disparaged egg and reduce the credibility of both the egg industry and the Government.

Objective 1 calls for the reduction of the number of SE-containing eggs marketed to the consumer. In subsection 1 the nationwide SE reduction program details a rigorous testing program and diversion of eggs to pasteurization upon discovery of a positive. Is this diversion the result of a positive SE test? This is an important factor as other vectors can contribute to the presence of SE in the environment. Science has shown that mice may be carriers with each fecal pellet possibly containing 25,000 SE organisms. One mouse may deposit 100 pellets in a single night. Testing can help verify that a good quality assurance program is working and that should be the goal rather than ***testing*** be the goal.

Section 1.2 establishes a HACCP-based system for shell egg processing with the specifics being founded in quality assurance programs. This action step should precede Section 1.1.1 on environmental testing. Testing should be the validation of the effectiveness of a quality assurance program. You cannot "test" your way to safety, but you can manage those hazards that will reduce the incidence of Salmonella associated with eggs through a good quality assurance program.

Economic Impact of Testing

What does it cost to conduct environmental testing to the degree specified in the Plan. The area dimensions in a "row" will vary depending on the size and design of the chicken house, the space allocation per chicken, the number of tiers of cages, even the number of houses considered in one flock. The use of drag-swabs must be associated with an optimum dragging area for scientific optimization. In making an assumption to gauge the economic impact of this degree of verification proposed in the Plan, a base of 260 million laying chickens in the nation, a "row" could represent 2,000 chickens or 130,000 rows.

AMS in cooperation with the National Egg Regulatory Officials currently utilize a work force representing 50% of USDA's AMS workforce who already have experience in processing, sanitation inspection, refrigeration enforcement, monitoring quality assurance plans, enforcing the Egg Products Inspection Act and determining the quality of eggs through hand candling. This proven track record for enforcing consistent grading standards through the AMS voluntary shell egg grading service demonstrates the degree of effective communication necessary between industry and government to achieve success. This organizational structure must be the level of enforcement and verification of egg safety standards. To develop a training program through State agencies is not a good utilization of taxpayer funds when a proven system is already in place. This would duplicate what is already done daily. This recommendation is the most efficient, most effective and the least cost in achieving this objective.

HACCP, Vaccines and New Technologies

Objective 1.2 establishes a HACCP-based system (Hazard Analysis of Critical Control Points) for shell egg processing. The egg industry is supportive of policies and procedures that are HACCP-like in their implementation. Reductions in the incidence of Salmonella have resulted from HACCP-like quality assurance programs and public health surveillance systems. To see the rate of disease decrease four years in a row is heartening to agencies, egg producers and consumers. The egg industry is optimistic about continuing this trend as it further develops stringent quality assurance plans. Practical techniques that are economically feasible, such as the use of vaccines for controlling Salmonella, are eagerly sought by the egg industry. Every effort should be made to facilitate the sharing of technologies that will contribute to a decrease in a foodborne disease. The egg industry and private vaccine manufacturers have submitted data and information on the use of vaccines in preventing the shed of SE organisms in the egg to the Food and Drug Administration with no response. European countries have added the use of vaccines in effective SE control programs. The interagency coordination necessitates that this lack of response be addressed and corrected so that transfer of technology be facilitated.

Labeling should educate consumers, not frighten them with "cigarette-style" wording

Objective 1.4 notes the finalization and implementation of refrigeration and labeling regulations for eggs from processor to consumer. The egg industry supports providing safe handling labels that reflect science-based education of consumers into proper food handling and preparation. What is the rationale for the development of the FDA proposed safe handling label that uses language substantially more alarmist than the language required by the FSIS for labeling meat and poultry? The Los Angeles Times, January 5, 2000 stated that the language was "cigarette-style wording".

The sterner warning proposed by FDA and the use of additional inflammatory adjectives and other wording not required for meat and poultry may have the effect of implying to consumers that eggs are less safe than meat and poultry. For the purposes of these consumers purchasing decisions, it is irrelevant that the two labels are required by two different agencies. FDA has participated in the Partnership for Food Safety Education through the *Fight Bac!* program. Dr. Susan Alpert, Director of FDA's Food Safety Initiative, reported at the Partnership for Food Safety Education meeting on March 1, 2000 in the Russell Senate Office Building, Washington, DC along with Dr. Catherine Woteki, Under Secretary for Food Safety at the US Department of Agriculture that the *Fight Bac!* message was achieving success in educating the general public. Using the *Fight Bac!* label as the basis for educating consumers in safe handling instructions on egg cartons and cases would serve the goal of expanding on this educational effort. **The *Fight Bac!* slogan is simple, direct and a positive message that is easily understood and calls the consumer "to action".** With the interagency consumer research and development of the *Fight Bac!* slogan, this label is the most logical in achieving the purpose of educating consumers.

Funding

No mention is made in the Plan as to how this program is to be funded. Will the egg industry find itself in a position of enforcing an unfunded mandate? To be consistent with every inspection program calling for Salmonella-testing presently enforced by federal statute, public funds are used to pay the cost of inspection. Meat and poultry industries are paying for e. Coli testing, but Salmonella is paid for by taxpayer dollars. To segregate the egg industry from every other inspection program by insisting on an unfunded mandate is discriminatory. Whatever program is enforced by federal regulatory authority, it should embrace the consistent practice of public funding. To do otherwise would be construed a tax, be discriminatory, and would further contribute to the consolidations and further decline in the number of farms already taking place in the egg industry.

The egg industry is supportive of indemnifying egg producers who must divert their eggs to a breaker. The level of indemnity would be based on the market value during the time of diversion less what the egg producer receives from the breaker for those eggs to be pasteurized.

Answers to Specific Questions Posed in the Federal Register Notice

4.) Are the following appropriate and adequate components for a nationwide SE reduction program: Bio-security, SE-negative feed, chicks from SE-monitored breeders, flock health monitoring program, cleaning and disinfection of houses, rodent/pest control, monitored water supply? Yes, these components are important in the validation procedure.

Many quality assurance programs presently in operation call for these components. An additional provision should be comprehensive training in the program addressing the implementation of each segment on a consistent basis, nationwide.

5.) How effective do you think each component would be? Which component(s) do you think will provide the most risk reduction? Each component is a link in the chain for preventing the introduction of *Salmonella* into the egg laying complex.

6.) Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? Nearly 60% in the egg industry do perform environmental tests, as confirmed by the National Animal Health Monitoring System, Part II, January 2000, page 38. The study confirmed that 59.8% conducted testing after layers were placed but before the last 4 weeks of production, and 59.2% during the last 4 weeks of production. Additional testing must be justified for a specified purpose otherwise the simple act of testing will only raise the cost of food without protecting public health. In the event an environmental test proves positive, additional testing would occur, as specified in the UEP 5-Star Quality Assurance Program.

7.) In the event that an environmental sample for SE is positive, what, if any, additional steps should a producer be required to take with the positive flock/house and with the next flock that will be placed in that house? Two series of steps are recommended; one calling for the use of vaccines and the other if vaccines are not used. If vaccines are used, and the environmental tests are SE positive, then extra cleaning and disinfecting procedures should begin immediately upon depopulation. The replacement flock would be vaccinated with an approved live or killed SE vaccine prior to the onset of lay. A review of the components of the Quality Assurance Program should be conducted to identify potential problems. A third party walk through of the facility will also be conducted utilizing a representatives from the extension service, State Veterinarians, USDA/AMS, USDA/APHIS, University QA specialist or equivalent. And egg testing of pooled samples of 480 eggs would be conducted. If egg tests are found to be positive then egg diversion to pasteurization should be implemented until the first additional egg tests provide negative results. Lastly, 2-3 weeks prior to flock depopulation, environmental testing should again be conducted. In the event the producer chooses not to vaccine and the layer house is found to be SE positive at 2-3 weeks prior to depopulation, again a review of the steps in the Quality Assurance Program and a review of the records would be conducted to identify any potential problems. A third part inspection of the facility would also be conducted. Environmental testing of the facilities would be conducted at 30 weeks of age and again, if and, when the flock is molted. Environmental testing of molted flocks should be tested once hens have been returned to production. If environmental tests are positive, then eggs must be diverted to pasteurization until egg tests of 480 egg samples have indicated a negative test. Environmental testing will be conducted 2-3 weeks prior to depopulation.

8.) Where vaccines have been used, is there a correlation between vaccine use and reduction of SE in eggs? See answer to number 7 above.

9.) In the event eggs from an SE-positive layer flock are diverted from the table egg market, what measures should be implemented to ensure those eggs are pasteurized? Any eggs diverted to the breakers will be pasteurized. Loads destined for the breakers are tagged so that any loads determined to be positive will be identifiable and will be pasteurized.

10.) In the event eggs from an SE-positive layer flock are diverted to the production of liquid, frozen, or dried egg products, should the eggs be handled or processed differently? *Salmonella* is heat sensitive so the process of pasteurization will kill the pathogens.

11.) Do customer specifications exist that prohibit the processing of SE-positive eggs for egg products? There exist some breaking facilities that may not accept SE-positive eggs for pasteurization even though the heat process kills the pathogens. This would cause serious consequences for those egg producers who are in a position where they must divert their production to the breakers due to the identification of *Salmonella*-positives. Diverting those eggs to a landfill may also require a moisture-absorbing additive prior to acceptance at a landfill. The losses for a producer in this predicament is substantial.

The series of questions relating to specific costs for various components in the quality assurance programs were answered during the public meetings in differing areas of the country.

15.) Are there any methods by which a packer/processor can determine how old eggs are when they are received? No. While we may not be able to determine the exact day each egg is laid, AMS has been operating a grading service that serves as a barometer of both age and quality of shell eggs.

16.) When packing shell eggs for the consumer, will the use of only new primary packing materials increase marketing costs? Only new material is used when packing shell eggs for the consumer.

17.) Are the proposed components of the national standards for packing and processing of shell eggs and egg products appropriate and adequate to reduce the risk associated with SE? No. The Plan is not comprehensive enough. For example, the Plan indicates that research should be conducted on the practice of repackaging and re-selling of eggs that have been returned unsold from grocery stores. We should not study the practice. We should ban the practice!

The Plan should also provide stronger incentives to implement the promising vaccination programs. For example, if a human illness outbreak should warrant an FDA traceback to the farm, then those layer houses using a vaccination program as a component of the total Quality Assurance Program would be exempt from environmental tests and only egg tests would be conducted. The Plan requires too much testing than is necessary. Diversion of eggs should only occur if *Salmonella* is determined in egg samples. Afterall, it is the eggs that are sold to the consumer and hence that is the ultimate product to be sampled as is true in other commodities such as meat and poultry. The Plan does not address the ongoing practice of egg centrifugation at restaurants and bakeries in those States that have not banned the process or the machinery. This process of centrifugation at the bakeries and restaurants must be prohibited to stop the commingling of the shell's surface with the internal contents of the egg.

The remainder of the questions in the Federal Register notice call for answers that would vary from farm operation to farm operation.

The National Animal Health Monitoring System has scheduled the release of additional data in the Fall of 2000 that may prove useful in providing additional information to these questions. It is recommended that final Administration action await the release of that data.

Uniform, national grading/inspection program with action steps to reduce SE

United Egg Producers is herewith submitting its ONE DOZEN "eggsceptional" ways for a uniform, national grading/inspection program that incorporates action steps to improve egg quality and safety:

1) Quality Assurance Program based on HACCP provisions at the farm and shell egg packing plants and enforced by USDA/AMS or USDA/APHIS.

2) Uniformity among all egg producers and packers in addressing food safety.

3) A streamlined monitoring program for grading/inspection and surveillance of shell egg plants administered by USDA/AMS.

4) Change from continuous inspection to a "continuous monitoring of performance standards" program for shell egg plants.

5) Requirements for shell egg refrigeration at storage and transportation.

6) Requirements regarding repackaging of shell eggs.

7) Requirements regarding the "dating" of shell eggs.

8) A validation testing component with incentives for using a SE vaccine. 5

9) Uniform traceback procedures of shell eggs.

10) Documentation, verification and third party validation procedures.

11) Taxpayer funded - consistent with Meat & Poultry Inspection programs.

12) Indemnification to producers who divert eggs from the table egg market to pasteurization as a result of the flock being SE positive

Conclusion

UEP is proposing that all shell egg packing plants come under a **uniform, grading/inspection program**. One, that is less than a continuous inspection program, but on an "as needed" performance basis. This would allow for inspection services to be utilized where they are most needed. The program would provide grading and inspection services to include monitoring for food safety and quality assurance program performance as listed above in the One Dozen "Eggsceptional" ways to improve egg quality and safety including plant sanitation and good manufacturing practices. The quality assurance program would apply to both egg production and packing plants at every location throughout the United States.

UEP and UEA thanks you for this opportunity to present these comments.

Yours sincerely,

Carl Lofgren
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References:

1. CDC Mortality and Morbidity Weekly Report, February 17, 2000
2. USDA/APHIS/VS National Animal Health Monitoring System
   Part II: Reference of 1999 Table Egg Layer Management in the U.S., January 2000
3. United Egg Producers uniform, grading/inspection program
4. FSIS Salmonella Enteritidis Risk Assessment, Shell Eggs and Egg Products,
   Final Report, June 12, 1998
5. United Egg Producers Testing Component for Validation of Quality Assurance
   Food Safety Program.

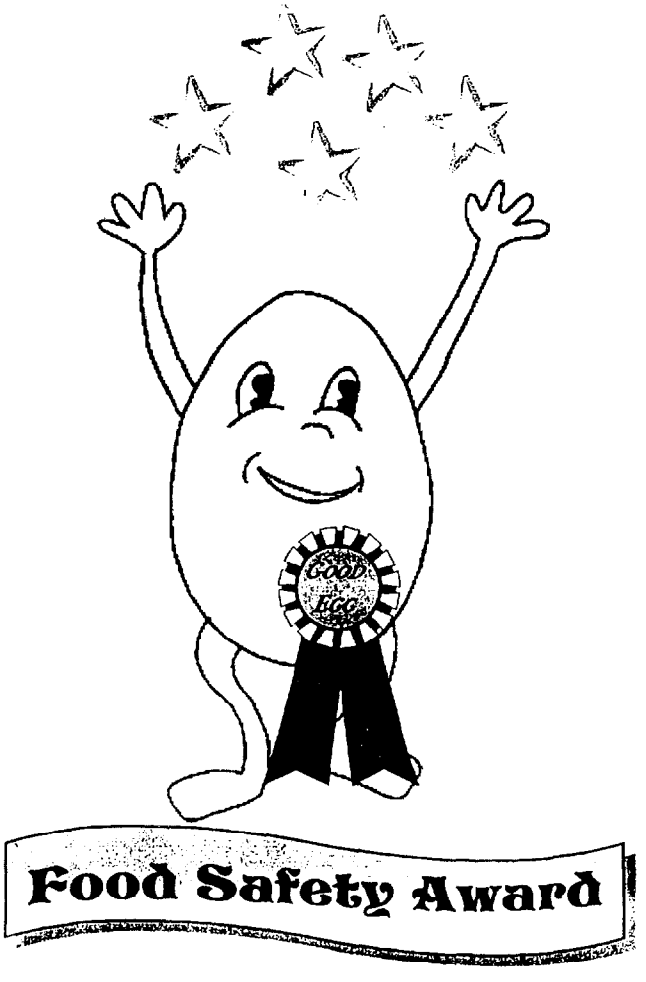
Enclosures:

1. United Egg Producers Streamlined Grading/Inspection Program

DISCUSSION PAPER

CONCEPTUAL FRAMEWORK FOR:

A STREAMLINED NATIONAL COMPREHENSIVE GRADING/INSPECTION/QUALITY ASSURANCE FOOD SAFETY PROGRAM FOR SHELL EGGS



SUBMITTED FOR CONSIDERATION BY

UNITED EGG PRODUCERS BOARD OF DIRECTORS

AUGUST 1999

DISCUSSION PAPER

"A COMPREHENSIVE STREAMLINED GRADING, INSPECTION, QUALITY ASSURANCE FOOD SAFETY PROGRAM FOR SHELL EGGS"

"It's a program whose time has come" - A program of integrity in that it applies to all U.S. egg production in a uniform comprehensive way. A program that responds to the needs and concerns of consumers, industry and regulatory officials.

For the first time, this bold and innovative proposed program incorporates or embraces all the multi-agency responsibilities and resources, adds the cooperation and leadership of the industry, to achieve an effective food safety program for shell eggs.

The egg industry has repeatedly responded, in a pro-active way since food safety concerns were first raised in 1988. Some of the industry initiatives include:

- **Established the S.E. Task Force and obtained funding from Congress**
- **Called for breeder testing through NPIP**
- **Supported eggs being on FDA's potentially hazardous food list**
- **Proposed and supported a National Refrigeration Law**
- **Recommended liquid pasteurized egg product be used in food service and institutional settings**
- **Developed vaccines**
- **Sponsored HACCP workshops for egg production and processing**
- **Published egg handling and preparation tips for food service and consumers**
- **Established the S.E. Risk Assessment Working Group**
- **AEB became a founding member in partnership with the White House on President Clinton's Food Safety Initiative**
- **Developed food safety (Quality Assurance Programs) for egg production and processing**

The industry has on numerous occasions stepped up and submitted testimony on a variety of issues. It has, among other things, made repeated requests related to modifying the proven ineffective traceback program, encouraged the adoption of a uniform national quality assurance program, and the approval of vaccines as well as submitted research priorities.

Let's take a look at the conceptual framework of such a program.

DISCUSSION PAPER – CONCEPTUAL FRAMEWORK FOR:

STREAMLINED GRADING/INSPECTION/QUALITY ASSURANCE FOOD SAFETY PROGRAM FOR THE SHELL EGG INDUSTRY

United Egg Producers (UEP), proposes that the egg industry in cooperation with those government agencies charged with the responsibility of food safety, grading, and inspection, consider a comprehensive farm to table approach for the purpose of achieving the ultimate food safety program.

UEP, a national cooperative representing approximately 80% of the shell egg industry and on behalf of its Board of Directors hereby submits the following proposal.

This conceptual framework will include at least *ONE DOZEN* "Eggceptional" ways to improve egg quality and safety. They include:

1. **Quality Assurance Program based on HACCP provisions at the farm and shell egg packing plants.**
2. **Uniformity among all egg producers and packers in addressing food safety.**
3. **A streamlined monitoring program for grading/inspection and surveillance of shell egg plants administered by USDA/AMS.**
4. **Change from continuous inspection to a "continuous monitoring of performance standards" program for shell egg plants.**
5. **Requirements for shell egg refrigeration at storage and transportation.**
6. **Requirements regarding repackaging of shell eggs.**
7. **Requirements regarding date of "pack" for shell eggs.**
8. **Requirements regarding "expiration date" for shell eggs.**
9. Uniform traceback procedures of shell eggs.
10. Documentation, verification and third party validation procedures.
11. Taxpayer funded – consistent with Meat & Poultry Inspection programs.
12. Indemnification to producers who divert eggs from the table egg market to pasteurization as a result of the flock being S.E. positive.

While UEP has, in the past, provided testimony in opposition to the creation of a new "single food safety agency", we now will submit a proposal that a "single food safety agency" be establish for the egg industry under the auspices of USDA/AMS Poultry Grading Branch.

The USDA/AMS Poultry Grading Branch currently offers a Voluntary Resident Shell Egg Grading Service to the shell egg packing plants of which only about 30% of the nation's eggs are packed. Additionally, USDA/AMS provides and administers a quarterly inspection program for all shell egg packing plants in the U.S.

We will propose that ALL shell egg packing plants come under a mandatory streamlined grading and inspection program. One, that is less than a continuous inspection basis but instead, on an "as needed performance basis". The program provides grading and inspecting by size and quality of shell eggs. Additionally, the program will monitor for food safety/quality assurance programs including plant sanitation and good manufacturing practices. This quality assurance program would apply to both egg production and packing plants.

We will propose that as part of this mandatory program that no eggs packed for the ultimate consumer may be older than 21 days from the date of lay.

We will propose that as part of this mandatory program that those eggs packed for retail sales must carry an "expiration date" or "sell by date" of no more than 30 days from the packing date.

We will propose that any eggs returned to the packer from grocery stores, store warehouses, and institutional accounts be prohibited from repackaging. These eggs will be diverted from the table egg market to the further processing market for pasteurization.

We will propose that all egg packaging carry a label that says "Keep Refrigerated". The refrigeration requirement will be consistent with the law being implemented on August 27, 1999 by USDA that requires all eggs packed for the ultimate consumer to be stored and transported at 45 degrees ambient temperatures.

We will propose that all eggs sold in retail carry a Safe Handling Instruction Label that says, "Keep Refrigerated – Eggs are not to be eaten raw or undercooked".

We will propose that all eggs sold to institutional accounts carry on the egg case or the invoice a Foodservice Safe Handling Instructions that says, "Some eggs may contain bacteria that could cause illness if the product has been cross-contaminated, mishandled or cooked improperly. For your protection, follow these safe handling instructions."

We will also propose that all egg production farms and shell egg packing plants follow the provisions of a HACCP type program such as the "5-Star" Total Quality Assurance Program developed by UEP.

The "5-Star" Program identifies five (5) critical points in the production and packing process to be monitored. Those points are:

- Poultry House Cleaning and Disinfecting
- Rodent and Pest Elimination
- Proper Egg Washing
- Biosecurity
- Refrigeration

Additionally, the program includes a testing component for validation to be sure the program is working. The program will also require that record keeping forms be kept on each of the five points.

We will propose that third party monitoring of the producer/packer "5-Star" Total Quality Assurance HACCP type program be provided by either USDA/AMS Poultry Grading Branch and or USDA/APHIS Veterinary Services. This monitoring will include the provisions as outlined in a MOU between UEP and APHIS, dated July 21, 1999 and is included as an attachment to this proposal.

We will propose that the current FDA traceback program for S.E. is replaced with one submitted by UEP to FDA in May 1999 and is now included as an attachment to this proposal.

We will propose that indemnification be provided to producers whose flocks have been found to be positive with the S.E. bacteria. This is similar to animal health threats i.e. avian influenza and the federal government's program for indemnification human health threats i.e. salmonella should be included in programs for indemnification at the dollar value of difference between the shell egg market value and breaking stock egg value.

We will propose that this program be taxpayer funded. USDA currently provides funding to carry out inspection programs for meat and poultry inspection and egg product inspection. Funding should be provided, likewise, for the grading and inspection program for shell eggs.

Conclusion: It is in the best interest of egg producers and packers to implement programs that provide the best science based food safety programs possible for our consumers. It is also in the best interest of government to work with the egg industry to centralize all egg inspection and food safety programs into one agency that has a successful history of providing quality service to both the shell egg and egg product industry. There is no value in creating a new agency that may have very little if any experience in the egg industry and thereby waste time in the training of new inspectors.

Our proposal simply makes common sense by utilizing, in a streamlined way, resources that are already in place. Efficient, effective use of these resources is what we propose.

One of the failures of the current FDA traceback program may be in the program's design. To be effective in achieving the goal of reducing foodborne illness, any on-farm program should begin before a human illness outbreak occurs, and serve to prevent, to the extent possible, an outbreak in the first place and certainly to reduce the inherent risks associated with foodborne illness.

We call upon government to join in and further help the egg industry by conducting a review and evaluation of programs in food preparation at the food service level. We also call upon government to review and evaluate recommendations for educating consumers on food preparation in the home.

We believe that the streamlined comprehensive program being proposed by UEP addresses most, if not all, the concerns expressed by consumers, government agencies and the industry.

The egg industry remains committed to the implementation of food safety programs and looks forward to cooperatively working with government to achieve the goals set forth in the program being proposed by UEP.

APHIS Agreement No. 99-9114-0497-MU

MEMORANDUM OF UNDERSTANDING
Between
UNITED EGG PRODUCERS (UEP)
And
UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

ARTICLE 1 - PURPOSE

This Memorandum defines the procedures which UEP and APHIS will follow when APHIS personnel are asked to serve as third party monitors of UEP's 5-Star Total Quality Assurance Program. The personnel who will be providing this service are the field Veterinary Medical Officers (VMO's) and Animal Health Technicians (AHT's) assigned to the Veterinary Services (VS) Area Offices.

ARTICLE 2 - BACKGROUND

In a letter dated April 7, 1998, UEP requested that APHIS personnel provide third party monitoring of UEP's 5-Star Total Quality Assurance Program. In a Decision Memorandum signed May 15, 1998, Veterinary Services Deputy Administrator Joan M. Arnoldi indicated the Agency's willingness to provide this service to the U. S. layer industry, provided an appropriate protocol could be devised. This protocol is defined in this Memorandum of Understanding. Our intention to enter into this Memorandum of Understanding was communicated to UEP in a letter dated March 23, 1999, from Dr. Craig Reed, APHIS Administrator.

ARTICLE 3 - AUTHORITIES

In accordance with the Act of February 28, 1947, as amended (21 USC 114d-1), APHIS has the authority to cooperate with public and private organizations to protect poultry.

ARTICLE 4 - OBJECTIVES

The objective of UEP's 5-Star Program is to provide the egg layer industry with a voluntary, hazard analysis and critical control point (HACCP) based program to assist egg producers, egg processors, and egg marketers in their efforts to reduce the risk of *Salmonella enteritidis* (SE) contamination of eggs. The objective of APHIS in this agreement is to provide independent verification that a UEP member is complying with the provisions of the program. This is in accordance with APHIS's larger goal of protecting the health of U. S. domestic animal populations.

ARTICLE 5 - MUTUAL AGREEMENT

UEP and APHIS mutually agree to the following procedures for verifying the activities of UEP members participating in UEP's 5-Star Total Quality Assurance Program (hereafter referred to as "the Program"):

A request for auditing services should be made by a UEP member (hereafter referred to as "the Participant") to the APHIS Area Veterinarian in Charge (AVIC) for the State in which the egg production facility or egg processing plant is located.

Upon receiving an audit request, the AVIC will assign a VMO (hereafter referred to as "the Auditor") to conduct the audits. The Participant will furnish the Auditor with a standard operating procedure used by the Participant in implementing the Program. The assigned Auditor and the Participant will cooperatively develop an Auditing Plan which is specific for the Participant's designated facility and which incorporates, as a minimum, the general auditing procedures outlined herein. The Auditing Plan will define the specific facilities, records, and procedures to be audited, and the frequency at which audits will occur. The Auditing Plan will be signed by the Participant, the Auditor, and the AVIC prior to the initiation of any auditing activities. The Auditing Plan may be suspended and all auditing activities may be terminated upon written request by either the Participant or the Auditor.

The Participant will agree to be audited at frequencies, dates, and times which are mutually agreeable to the Participant and the Auditor (quarterly audits are recommended). The Auditor will assess the Participant's level of compliance with the Program and will identify any specific areas that need improvement. Audits may include a review of records pertaining to the Participant's monitoring and verification activities, interviews with employees responsible for monitoring the specific points of the Program, and visual inspection of facilities and procedures. Audits may be performed by or with the assistance of an AHT, following the establishment of the Auditing Plan.

APHIS will provide an Auditor to review any part of the Program in any facility upon request by a Participant. However, APHIS believes that the expertise of VS personnel is strongest on the farm in the area of poultry health, and that the USDA's Agricultural Marketing Service (AMS) has greater expertise in egg processing plants. Therefore, APHIS encourages Participants to utilize VS Auditors in egg production facilities and non-official egg processing plants, and to utilize AMS Auditors in official egg processing plants where an AMS Resident Grader is already stationed.

ARTICLE 6 - UEP RESPONSIBILITIES

Participants are responsible for the following activities:

6.1. Access:

The Participant will provide the Auditor with access to the materials and facilities deemed necessary to conduct a complete audit, within the scope of this agreement and the signed Auditing Plan.

6.2. Poultry house cleaning and disinfecting:

The Participant will provide the Auditor with a list showing the location of each flock and the schedule for depopulation, cleaning, disinfecting, and repopulating the houses. The list should also include the name and telephone number of a contact person at each location. Additionally, the Participant's records should include monitoring worksheets showing the production facility name and location, flock number, cleaning dates, person responsible for cleaning, cleaning procedure, types and strengths of detergents and disinfectants used, and (if applicable) a record of environmental sampling culture results.

The Participant will clean each laying house after a flock is removed, using either a wet or dry cleaning method as outlined in the Program. Disinfection of SE negative or unknown status houses is optional and at the Participant's discretion. In the event of a positive environmental culture for SE, the Participant will maintain a record of special cleaning and disinfection for both the positive depopulated flock and the replacement flock.

6.3. Rodent and pest elimination:

The Participant will establish a rodent and pest elimination program for all areas of the facilities identified in the Auditing Plan. Regardless of the method of control, the Participant will provide the Auditor with records which document the control program activities and which demonstrate the overall effectiveness of the program. Monitoring worksheets should identify the facility, the flock number, the name and address of the rodent and pest control company (if applicable), and the dates and results of control program activities. These documents could include bait station location maps, schedule of bait applications, and rodent and pest activity observations.

6.4. Proper egg washing:

The Participant will maintain records which document that wash water temperature, pH, sanitizing rinse temperature, sanitizing rinse concentration, and water change interval comply with the criteria listed in the Program. The Participant may use computer printouts and recording charts to document these conditions, provided the facility has a system in place to assure the accuracy of such equipment. The Participant should provide the Auditor with monitoring worksheets which list the dates, times, and names of persons assessing the temperatures and pH levels. Separate worksheets are to be maintained for each washer.

6.5. Biosecurity:

The Participant must document that the following four biosecurity measures are conducted:

a. Day old chicks must be received from hatcheries participating in the National Poultry Improvement Plan (NPIP) "U.S. *Salmonella enteritidis* Monitored Program."

b. The Participant must provide the Auditor with copies of NPIP Form 9-3 certifying that all breeder flocks which supply chicks and pullets to the facility participate in the NPIP program.

c. The Participant must document either that feeds contain no animal protein, or that any animal protein used in feeds is from a source participating in the Good Manufacturing Practices of the Animal Protein Producers Industry (APPI) Salmonella Education/Reduction Program.

d. The Participant must document that all medications, feed additives, and pesticides have been used as directed by the manufacturer.

The Participant's records should also include the dates and names of persons conducting or monitoring each of these activities.

6.6. Refrigeration:

The Participant will maintain records which document that cooler room and transport vehicle temperatures are maintained according to the criteria listed in the Program. Cooler room temperatures should be evaluated near the highest level of product storage, but not in front of cooling units. Transport vehicles should be evaluated by measuring the temperature of air blowing directly from the cooling unit. Automatic temperature recording devices may be used, provided the Participant has a system in place to assure the accuracy of such equipment. All records should include the dates, times and locations of the temperature recordings, as well as the name of the person recording or monitoring these temperatures.

6.7. Validation testing:

The Program provides the Participant with the option of conducting environmental tests for SE at the production facility. If the Participant chooses to do so, environmental samples should be collected between two and three weeks prior to flock depopulation, in accordance with the Program criteria and the protocol described in the facility Auditing Plan. The Participant should maintain records which identify the date, the name of production facility, the person responsible for sample collection, the flock number, where samples were taken, the name and location of the laboratory, the date samples were submitted to the laboratory, and the test results. If the Participant serves as his or her own environmental sample collector, the Participant should notify the Auditor of the dates when samples will be collected, so that the Auditor can monitor the collection of at least one sample set per year.

If the validation test results are negative, then no further action is required by the Participant under the Program. If the validation test results are positive for SE, the Participant should notify the Auditor so that a cleaning and disinfecting inspection can be scheduled following depopulation of the flock. Also, the Participant should initiate with the Auditor a joint review of the Program at the facility to identify areas for improvement.

6.8. Reporting and post audit activities:

The Participant is solely responsible for complying with the provisions of the Program. The Participant should correct any areas of noncompliance identified by the Auditor as quickly as possible.

ARTICLE 7 - APHIS RESPONSIBILITIES

Auditors are responsible for the following activities:

7.1. Access:

Upon selection by the AVIC, the Auditor will make a courtesy telephone call to the Participant, introduce himself or herself, and make a calendar appointment for the initial interview. A schedule for the subsequent audits will be developed as part of the Auditing Plan.

Auditors will take all necessary sanitary precautions when entering or exiting a facility or when moving from one area of a facility to another area of that facility. These precautions may include washing hands, using foot baths, changing outer garments, and any other biosecurity measures required by the Department or the Participant.

The Auditor will bring any verification equipment necessary to complete the audit. This equipment may include a pH meter or equivalent measuring device, various thermometers, and any other necessary recording or testing devices. The Auditor will take care to assure that this equipment is cleaned and disinfected upon entry and exit of the premises.

If requested by the Participant, the Auditor will arrange for training of the Participant's personnel on a reasonable, timely basis. Such training may cover the topics of biosecurity, rodent and pest control, environmental sampling, or other production issues covered by the Program.

7.2. Poultry house cleaning and disinfecting:

The Auditor will review the cleaning records discussed in Article 6.2. The auditor may also visit a facility following a depopulation to visually assess the adequacy of the cleaning and disinfecting procedures. Such an inspection is recommended annually, and, when possible, should be scheduled to coincide with a regularly scheduled quarterly audit. The Auditor will record his or her findings on the Audit Checklist.

7.3. Rodent and pest elimination:

The Auditor will review the rodent and pest control documents discussed in Article 6.3., and will visually assess the effectiveness of the pest control program. The Auditor may inspect the production, egg processing, egg cooling, material storage, and feed production facilities, and any other facilities identified in the Auditing Plan. The Auditor will record his or her findings on the Audit Checklist.

7.4. Proper egg washing:

The Auditor will review the records and worksheets described in Article 6.4., and will verify, using the appropriate instruments, that the wash water and rinse water temperature, pH, and chlorine concentration are within the acceptable ranges defined by the Program. The Auditor will record his or her findings on the Audit Checklist.

7.5. Biosecurity:

The Auditor will review the records and documents described in Article 6.5. The Auditor may also assess the Participant's biosecurity program by visual inspection and by interviewing the appropriate plant employees. The Auditor will record his or her findings on the Audit Checklist.

7.6. Refrigeration:

The Auditor will review the records discussed in Article 6.6. The Auditor will also measure the cooler room and transport vehicle temperatures using the appropriate verification equipment. For cooler rooms, the Auditor will calculate an average ambient temperature from measurements taken near the highest level of product storage and at five separate locations in each cooler, excluding areas around doorways or directly in front of cooling units. The Auditor will record his or her findings on the Audit Checklist.

7.7. Validation testing:

If the Participant conducts environmental testing for SE, the Auditor will review the testing records described in Article 6.7., and record his or her findings on the Audit Checklist. If the Participant serves as his or her own environmental sample collector, the Auditor should monitor the collection of at least one sample set per year. After being notified by the Participant of a test result positive for SE, the Auditor should conduct a cleaning and disinfecting inspection following depopulation of the flock. Also, the Auditor should assist the Participant in a joint review of the Program at the facility to identify areas for improvement.

7.8. Reporting and post audit activities:

The Auditor will deliver an original, completed, Audit Checklist to the Participant following each audit. One copy of this document will be retained by the Auditor, and one copy each will be delivered by the Auditor to the AVIC and to the UEP 5-Star Program Administrator.

The Auditor will retain his or her copy of the Audit Checklist for 1 year after the close of the fiscal year in which it was created. The AVIC will retain his or her copy of the Audit Checklist for 2 years after the close of the fiscal year in which it was created.

ARTICLE 8 - STATEMENT OF NO FINANCIAL OBLIGATION

Signature of this Memorandum of Understanding does not constitute a financial obligation on the part of APHIS. Each signatory party is to use and manage its own funds in carrying out the purpose of this Memorandum of Understanding.

ARTICLE 9 - LIMITATIONS OF COMMITMENT

This Memorandum of Understanding and any continuation thereof shall be contingent upon the availability of funds appropriated by the Congress of the United States. It is understood and agreed that any monies allocated for purposes covered by the Memorandum of Understanding shall be expended in accordance with its terms and in the manner prescribed by the fiscal regulations and/or administrative policies of the party making the funds available. If fiscal resources are to transfer, a separate agreement must be developed by the parties.

ARTICLE 10 - CONGRESSIONAL RESTRICTION

Under 41 U.S.C. 22, no member of, or delegate to, Congress shall be admitted to any share or part of this Memorandum of Understanding or to any benefit to arise therefrom.

ARTICLE 11 - AMENDMENTS

This Memorandum of Understanding may be amended at any time by mutual agreement of the parties in writing.

ARTICLE 12 - TERMINATION

This Memorandum of Understanding may be terminated by either party upon sixty (60) days written notice to the other party.

ARTICLE 13 - EFFECTIVE DATE AND DURATION

This Memorandum of Understanding will be in effect upon final signature and will continue until twenty-four (24) months from the date of signature. That twenty-four (24) month period will be considered a Pilot Program, during which time no User Fee will be charged by APHIS for this auditing service. At the end of the Pilot Program, APHIS and UEP will assess their respective need and desire to renew this Memorandum of Understanding. If the parties agree to renew this Memorandum, an evaluation will be made by APHIS of the appropriate User Fees which may be charged for auditing services under a renewed Memorandum. APHIS will take into account any current fees charged by USDA AMS for similar auditing services when setting User Fees to be charged by USDA APHIS.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICES

NAME: THOMAS E. WALTON

TITLE: Associate Deputy Administrator

SIGNATURE: T Walton

DATE: 8/3/99

UNITED EGG PRODUCERS

NAME: GENE W. GREGORY

TITLE: Senior Vice President

SIGNATURE: Gene W. Gregory

DATE: July 21, 1999

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

United Egg Producers 5-Star Total Quality Assurance Program Audit Checklist

Name and address of company:
Name of company representative:
Producer name & address:
House name or number:

Date of audit (month, day, year):
Records audit? Yes___ No___
On-site audit? Yes___ No___
Flock number:

I. Cleaning & Disinfecting Poultry Houses	In compliance	Not in compliance	Comments &/or explanation
A. A documented cleaning and disinfection procedure is provided.			
B. Worksheets monitoring the procedure are complete, accurate, and current prior to bird placement.			
C. Cleaning Procedure: Wet___ Dry___			
D. Detergents Used: Yes___ No___			
E. Disinfectant Used: Yes___ No___			
F. Fumigation Used: Yes___ No___			
G. Cage frames, cages, belts, conveyors, floors, walls, and ceilings thoroughly cleaned (& disinfected) as warranted by the *Salmonella enteriditis* status of the house.			S. e. negative & unknown status houses not required to disinfect every time, but can be done if wanted.
I. Rodent and Pest Elimination			
A. A documented & effective rodent and pest elimination program is provided.			
B. Worksheets monitoring the program are complete, accurate, and current.			
C. Adequate precautions have been taken to prevent the entrance of birds, rodents, and insects.			
II. Egg Washing			Mark not applicable if not used on this farm
A. Worksheets monitoring the washing and sanitizing process are complete, accurate, and current.			
B. Wash water temperature(s) maintained at a minimum of 90° F.			
C. Temperature(s) of sanitizing spray maintained at a minimum of 90° F.			
D. Sanitizer concentration level(s) maintained at 50 PPM or above of chlorine or its equivalent.			
E. Wash water pH maintained at a minimum of 10.			
F. Wash water changed approximately every 4 hours and not to exceed 5 hours.			
. Biosecurity			
A. A documented biosecurity program is provided.			
B. Records documenting compliance with program requirements are complete, accurate & current.			
C. Chicks & pullets produced from breeder flocks and hatcheries participating in the NPIP program.			
D. Participant provides certification regarding the source of animal protein if used in feed.			Animal protein? ___Yes ___No
E. Certification provided indicating that all medications, feed additives, and pesticides are used according to manufacturers instructions.			
Refrigeration			
A. Worksheets monitoring cooler and transporting temperatures are complete, accurate, and current			temperature never exceeds 60° F at any time
B. An average ambient air temperature of 55° F or below is maintained in on-farm coolers.			
C. Egg transport vehicles (farm to processing plant) are producing air temperature of 55° F or below			
D. An average ambient air temperature of 45° F or below is maintained in processing plant coolers			temperature never exceeds 50° F at any time

E. Egg transport vehicles (processing plant to wholesale and retail distributors) produce air temperature of 45° F or lower.			
VI. Validation (optional)			
A. A documented environmental sampling program is provided.			
B. Worksheets monitoring the environmental sampling program are complete, accurate, and current.			
C. Environmental testing is conducted according to outlined procedures.			

Where items are not in compliance, enumerate them individually and describe in detail why they are not in compliance. The production company assumes the responsibility for correction to compliance.

Item:	Description:

erinary Services Representative's Signature

Company Representative's Signature

of signature: _____

Date of signature: _____

PROPOSED TRACEBACK FOR SALMONELLA ENTERITIDIS (S.E.)

Submitted By:
United Egg Producers
May 1999

PROTOCOL FOR S.E. TRACEBACK
AS PROPOSED BY UNITED EGG PRODUCERS

When a public health investigation uncovers food handling abuses, food service workers carrying the S.e. bacteria, cross contamination, etc., a traceback to the farm should not be warranted.

1. If a traceback is deemed necessary then shipping records or other evidence will be required which assures the producer and FDA that eggs from the producer's flock was the source that caused the human illness outbreak.

2. An outbreak investigation report should be provided to the producer by the FDA or the State Health Department before any testing is conducted of the producer's facilities. The investigation report should include the phage type of S.e. that caused the illness. (If upon investigation, the same phage type is not found on the farm, then it must be concluded that the farm was not the cause of the human illness.)

3. Confidentiality and media avoidance should be guaranteed to the producer until proven results are known.

4. In consideration of the fact that an egg producer can not hide evidence such as the poultry house, chickens, or eggs, any producer that may be implicated in a human illness outbreak will be given a minimum of 48 hours notice before FDA or State Health Departments arrive at the farm.

5. A federal standard of traceback protocol should be written and followed by both FDA and State Health Departments and a copy provided to the egg producer prior to any testing of the producer's facility.

6. In recognition that producers have used every means known to control S.e. and to encourage more producers to use such programs, FDA will end the traceback if the investigations finds either one of the following conditions:

   (a) For those farms implementing a Quality Assurance/Food Safety program that includes vaccinations for S.e., the investigation will be considered complete. If, however, FDA determines that the investigation should continue, then the environmental tests will be eliminated and go directly to egg tests.
   (b) For those farms implementing a Quality Assurance/Food Safety program that includes validation testing of the program and has tests results indicating an S.e. negative environment at the approximate time of the

human illness outbreak and recordkeeping that all components of the program are being monitored, *will be exempt* from environmental testing of the facilities and egg testing by FDA or State Health Departments.

7. If it is determined that a traceback is warranted, the investigation should first determine whether a Quality Assurance/Food Safety program has been implemented by the producer. Farms that have not implemented a Quality Assurance/Food Safety program and have been implicated in a human illness outbreak will be expected to cooperate with FDA or State Health Departments in a traceback that includes testing of the environment or of the eggs.

8. Environmental testing is not an accurate predictor of the status of the eggs. Eggs, however, from the layer house should be diverted to pasteurization or hard cooking until test results are known of the eggs.

9. Environmental testing should only be taken from manure pits. In the absence of manure pits, swabs from the manure belts or scraper boards may be used.

10. Eggs from environmentally positive houses should be tested at the rate of 1% of one day's production regardless of the size of the individual layer house.

11. Eggs from environmentally positive houses should be diverted and egg testing should be conducted as many times as necessary until the first S.e. negative test report is confirmed. No further testing or diversion should be required.

12. Producers whose layer house is found to be environmentally S.e. positive must agree to implement a Quality Assurance/Food Safety program immediately. The producer shall have the right to implement any Quality Assurance/Food Safety program so long as the program has the ability to directly address the problem.

13. Houses that have been tested as environmentally S.e. positive, must upon depopulation of the flock, take extra steps in their cleaning and disinfecting procedures. A third-party inspection of the facility should be conducted. This third-party inspection may be conducted by representatives from any of the following:

State Veterinarian
USDA/AMS Poultry Grading Service
USDA/APHIS/VS

Submitted to FDA – May 1999

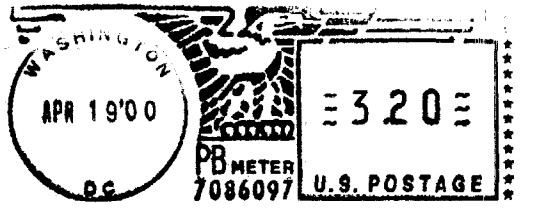
FAILURE OF CURRENT TRACEBACK PROGRAM

It was learned during the January 1998 SeRA II Risk Assessment/Working Group meeting in Atlanta, Georgia that FDA is following the same proposed 1993 rule for an egg traceback as USDA/APHIS previously did. Since we are operating without a final rule, it was suggested by many of the attendees that a new protocol be developed.

There is no evidence that the current S.e. traceback program has provided any reduction in foodborne illness outbreaks associated with eggs. This failure is perhaps built into the program's design, as it takes effect after the outbreak has occurred, rather than before an outbreak. To be effective in achieving the goal of reducing foodborne illness, any on-farm approach should begin before an outbreak occurs, and serve to prevent to the extent possible, an outbreak in the first place, and certainly, to reduce the inherent risks associated with foodborne illness.

Since it is the goal of the egg industry and government to reduce foodborne illness from eggs, we believe the most important thing the egg industry can do for food safety generally, and S.e. specifically, is to have producers implement Quality Assurance/Food Safety programs.

Quality Assurance/Food Safety programs have been shown to reduce the likelihood of S.e. and other potential foodborne pathogens in egg production facilities. Since reducing foodborne illness outbreaks is the goal of food safety regulators, programs that measurably reduce bacterial pathogens will likewise enhance food safety and help reduce foodborne illness.



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