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United Egg Producers

Al Pope
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Randy Green
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August 31, 1999

FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

RE: Docket No. 97N-0074

United Egg Producers (UEP), a national cooperative representing 80% of the nation's egg production, and United Egg Association (UEA), representing 95% of all eggs further processed, are pleased to have the opportunity to respond to the President's Council on Food Safety. UEP/UEA participated in the discussions at the July 15th meeting, reiterated its long sought goal in the development and implementation of its comprehensive farm-to-table egg safety program. Our membership has the most at stake in assuring consumers that their product is safe and wholesome. Our membership must bear the financial consequences of any outbreaks of salmonellosis associated with eggs. Egg products have an enviable record in that since the inception of the Egg Products Inspection Act nearly 30 years ago, not a single outbreak has been attributed to pasteurized egg products.

UEP/UEA has delineated its comments on the President's Council on Food Safety in relation to the stated goals and objectives of this first meeting.

Comments on the President's Council on Food Safety
Development of a Comprehensive National Food Safety Strategic Plan

Summary

"Purpose of the strategic plan: reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply."

97N-0074

UEP Headquarters
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"Vision statement: Consumers can be confident that food is safe. We protect public health through a seamless food safety system that uses farm-to-table preventive strategies and integrates research, surveillance, inspection, enforcement, and education. We use science- and risk-based approaches and work with public and private partners. We are vigilant to new and emergent threats and consider the needs of vulnerable populations. Food is safe because everyone understands and fulfills their responsibilities."

"Overarching Goal: To protect public health by significantly reducing the number of foodborne illnesses through science-based and coordinated regulation, inspection, enforcement, research, and education programs."

Comments on Purpose, Vision Statement and Overarching Goal

The purpose of these activities definitely should be to reduce disease. It is important that the Federal food safety strategy focus on actual hazards as opposed to theoretical risks so that the measurable incidence of disease associated with food and water decreases.

None of the objectives or strategies should ever promote a "risk-free" food as this is not possible; it is misleading and sets the consumer up for unrealistic expectations. Although the risk associated with eating will never be eliminated, the hazards can be controlled and minimized.

The comprehensive nature of the overarching goal is appropriate because all of these techniques are necessary to protect the food supply and the consumer. The inclusion of research and education is particularly important as it broadens the focus from government control to include partnership with the food industry and with consumers. It would be preferable if the overarching goal could include the concept of incentives and encouraging preventive actions – keeping pathogens out of the food supply is fundamental to protecting the food supply and should be encouraged and rewarded.

The biggest challenge with the philosophy is the need to integrate and coordinate with food industry production, processing and distribution. The approach of the council tends to focus on what can government do to control food industry actions as opposed to what government can do to enhance food industry actions. Funding programs that provide incentives to the food industry should be included in the council's considerations. Public funds for inspection is such an example as are funds for identification, diversion and indemnification of shell eggs if it is likely to cause disease.

Comments on Goals and Objectives

"Goal 1: Ensure the development and use of a comprehensive scientific and technological food safety knowledge base to support prevention, regulation, inspection, surveillance and education programs."

The strategies in this section should be collapsed into three categories: infrastructure, research, and communication and technology transfer. An infrastructure for food safety is needed and encouraged, but most of the strategies currently listed are research items and should go under the category of research. But the research isn't beneficial unless it is shared and applied with a vehicle for implementation, so a component on communication and technology transfer needs to be included.

Included in the research goals should be improvements in analytical detection techniques, the development of new technologies to eliminate pathogens and the study of the ecology of microorganisms in the agricultural production and processing environment. Consumer research, particularly with regard to developing effective educational methods, is also important. The role of risk assessment should be downplayed; it is only one of several important tools and does not warrant independent emphasis. Of particular importance is research involving foodborne disease outbreaks. The outbreak investigations themselves could be research tools if they were conducted accurately and with a uniform rigor and quality across the country. Research in the relationship between outbreaks and sporadic cases is needed as is the elucidation into the 60% of the agents of unknown etiology and unknown vehicles that are routinely reported with outbreaks. Finally, research priorities need to be based on hazards not risk. Research also needs to balance between known and unknown (or emerging) pathogens and between immediate and long-term needs.

"Goal 2: Improve the effectiveness of surveillance, outbreak investigation and response."

Accurate surveillance information is an asset to the food industry because accurate information narrowly and correctly identifies problems that need correction. Incomplete or inaccurate surveillance information, however, handicaps the food industry and consumers because it wastes resources and increases the cost of food. Outbreak investigations, when accurate and timely, highlight actions that can be effective in protecting the food supply. We feel that a more effective method of protection is available through validation of quality assurance programs so as to address food safety before it becomes a problem.

"Goal 3: Identify and manage food safety risks through protective standards, inspection and enforcement from farm to table."

Standards, inspections and enforcement need to be uniform, interpreted reasonably and evenly enforced across the nation. This can be accomplished by basing inspection on performance by rewarding those producers implementing quality assurance programs with HACCP provisions for monitoring critical points and better utilizing command-control inspection services where they are most needed. However, other options such as guidance and incentives should be included as part of this goal; sanctions are not the only way to motivate needed changes in behavior. Financial support or tax incentives at the production level should be considered. More emphasis needs to be placed on encouraging practices that prevent the transmission of pathogens through the food chain.

In addition to emphasis on "the farm," strategies need to be developed for the control of post-production practices because all food is vulnerable to mishandling. Specific risks need to be identified, including specific population groups and the accompanying specific interventions need to be developed.

"Goal 4: Ensure that all people who come into contact with food from farm to table are fully informed of the risks and measures to prevent or reduce the risk of foodborne illnesses."

This goal applies to everybody who eats, doesn't it? So it highlights the importance of education in protecting the food supply. Everyone needs to be aware of the *hazards* associated with food and the measures they can take to reduce risks. More fundamental education in food preparation is needed at both the consumer and food service levels. Proper food production must be accompanied by proper food preparation. As everybody eats and as many of those prepare food, food safety education should be a core component of public education.

"Goal 5: Create a national and to the extent possible an international seamless food safety system from farm to table."

An integrated system to ensure safe food need to be supported by funds, commitment and communication. Taxpayer support may be needed for inspection and the production of safe food may be associated with increased costs. In-shell pasteurization, for example, would add at least 2 cents per egg. A seamless system needs consistency and dependable programs of an ongoing nature. Communication is central to a seamless system; information needs to move within the government and between government and its partners with greater ease than is currently happening.

Attached is a copy of the egg industry streamlined, comprehensive inspection, grading, quality assurance farm-to-table egg safety program submitted for consideration and comment by the respective Federal agencies responsible for food safety programs..

Thank you for the opportunity to offer these comments.

Yours sincerely,

Al Pope
President

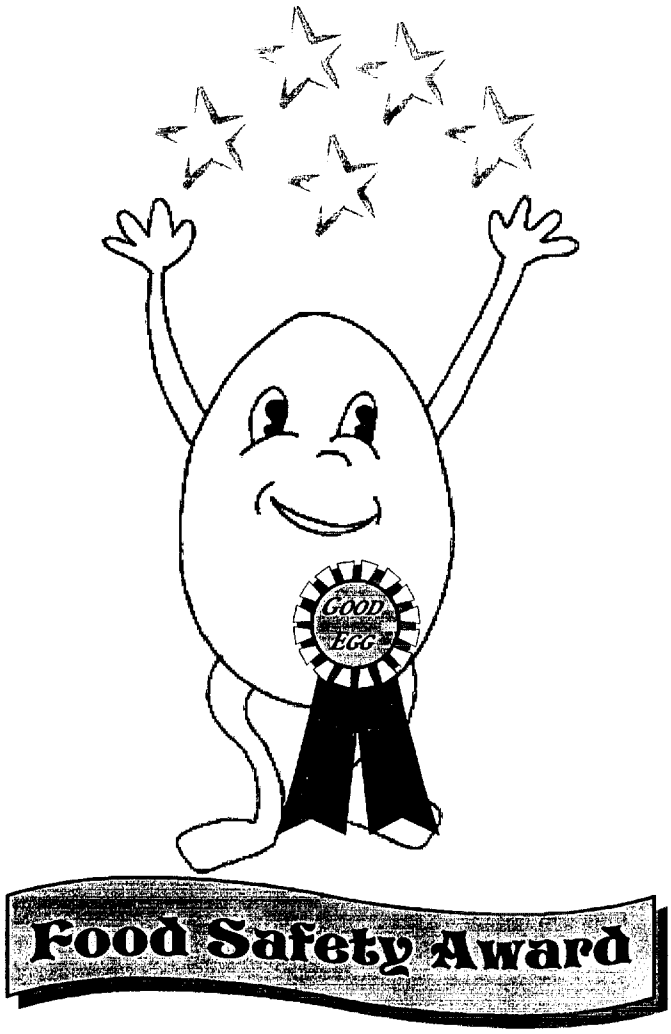
Ken Klippen
Vice President
Government Relations

Randy Green
Senior Government
Relations Representative

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: [illegible]

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.
II. 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.			
III. 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.			
IV. 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.			
V. 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:

Veterinary Services Representative's Signature

Company Representative's Signature

Date 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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