

## Washington Office

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## United Egg Producers

January 14, 2000

**Al Pope**  
President

**Ken Klippen**  
V.P. Government Relations

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Washington Counsel

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Mr. Joe Levitt  
Director  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204

Dear Mr. Levitt:

The United Egg Producers and United Egg Association (UEP and UEA) appreciate the opportunity to meet with federal officials to discuss the document *Egg Safety from Production to Consumption: An Action Plan to Eliminate Salmonella Enteritidis Illnesses Due to Eggs* (the "action plan"). We want to work with our federal, state and local governments in partnership with consumers toward the common goal of a safe food supply.

Members of the UEP and UEA account for the overwhelming majority of shell egg and egg products production in the United States. Therefore, our members have a keen interest in the action plan and will be directly affected by regulatory activities that result from it. The action plan recognizes the necessity for consistent national standards of quality assurance and egg safety. That is our goal too. We commend the President's Council on Food Safety for adopting this perspective.

We want to share some concerns that producers and processors have expressed as they have read and discussed the action plan. Most of these concerns take the form of questions, which if answered appropriately can reassure our industry. Our objective is cooperation rather than confrontation. At the same time, we must represent the interests of our members forthrightly. We must remain focused on the fact that the egg is a safe food which we want to make even safer.

**Testing:** The action plan emphasizes -- indeed relies on -- testing. It does not specifically propose other concrete steps (e.g., mandatory sell-by dates, a ban on repackaging) that could make a positive difference in the incidence of *Salmonella enteritidis* (SE). Is the government sufficiently aware that

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testing alone does not guarantee safety? In addition, the action plan does not fully answer certain critical questions – notably, whether diversion of eggs to breaking would be triggered only by a positive egg sample. We assume this to be the case, and certainly procedures of the Pennsylvania Egg Quality Assurance Program (PEQAP) and other analogous systems follow this model. However, a definitive statement in this regard would be extremely helpful.

**Funding:** Closely related to the issue of testing is that of funding. Is the federal government sufficiently interested in improving food safety to devote resources to the task? In particular, will the costs of extensive SE testing be paid through appropriated public funds, as is the case under the PEQAP and the federal government's existing *Salmonella* testing program in meat and poultry plants? Will any costs associated with the Food and Drug Administration's verification or validation of compliance with quality assurance plans be paid through appropriated public funds, as is the case under inspection systems for meat and poultry?

These are critical questions. We assume that it is not the government's goal to accelerate the consolidation and vertical integration of the egg industry. Please understand that if the government does not pay testing and inspection costs, *this industry will further consolidate* as smaller operations find themselves unable to bear the unfunded mandates imposed on them by government.

Funding issues do not end with the question of direct producer costs. If egg safety is truly a national concern, the government should be prepared to invest wisely in (1) grants to establish, maintain and improve recognized quality assurance (QA) programs for producers, (2) grants to create and carry out validation procedures for ensuring compliance with QA programs, and (3) grants for independent research in high-priority areas related to egg safety.

**Quality Assurance Programs:** In the short term, the federal government could take no more effective action than to establish standards for recognizing, monitoring and validating QA programs, including the establishment of protocols for third parties to validate and enforce compliance with recognized QA programs. We believe this task should take priority over the establishment of an extensive testing regime, in contrast to the timetable laid out in the action plan. In particular, we suggest that the agencies combine a regulation which establishes the standards described above with regulation on testing, endeavoring to propose both simultaneously. We make this proposal because what ultimately matters is what producers do to ensure safety and quality, not the tests they run. By putting testing ahead of QA programs, we fear, the President's Council has erred in establishing priorities.

**Consistent Enforcement:** Reliance on state agencies for certain functions is contemplated in the action plan. We have reservation about the wisdom of this course. Will the federal government insure that the agencies utilized are those with expertise in shell egg production? In addition, how will the federal government prevent inconsistent enforcement of the same standards in different jurisdictions?

**Inclusive Process:** We commend federal agencies for seeking outside advice and expertise.

However, we strongly urge that any advisory committees – including informal bodies – be geographically balanced, include non-government personnel, and include persons with extensive experience in and knowledge of the shell egg and egg processing industries.

A more inclusive process should also improve the quality of data on which the government relies. For example, in some meetings with federal officials, we have been told that the recent – and highly encouraging – 44% decline in salmonellosis associated with SE is only applicable to one region of the country. As the attached paper from the Egg Nutrition Center points out, this assertion is simply mistaken.

**Economics:** Will federal rulemaking include an economic impact analysis? In our view, this step is essential. For example, at the moment in-shell pasteurization is too costly to be widely utilized, so almost all egg producers will find themselves implementing the plan’s “Strategy I.” Will the government assess questions including (but not limited to) the likely impact of regulations on further consolidation within the industry; on industry profitability; on consumer costs; and on relative supplies of shell eggs and eggs for processing?

**Labeling:** We have elsewhere commented extensively on the FDA’s proposed warning label for shell eggs, the needless alarm which we believe it would cause, and our support for an alternative label that would mirror themes of the FightBAC campaign, in which agencies of the President’s Council have participated.

We must say forthrightly that for many producers, the FDA’s final rule on the warning label will be an important – perhaps conclusive – indication of how fairly and reasonably the remainder of the action plan will be implemented. The warning label as proposed by FDA is ill-advised, inappropriate and injurious to the interests of our members. It must be changed.

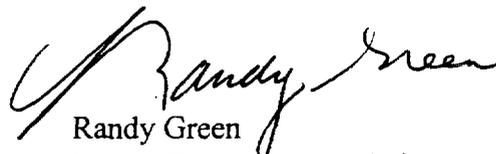
We will subsequently provide more extensive comments, and supply relevant agencies with appropriate data as they have requested. For now, we wish to stress both our desire to work together with the agencies, and our dedication to maintain the economic viability of our industry. We will be staunch advocates of both our members’ legitimate economic concerns and our industry’s belief that a fair national system of quality assurance and inspection is in the public interest.

Thank you for your attention to this letter. We look forward to working with you.

Sincerely,



Ken Klippen  
Vice President  
Government Relations



Randy Green  
Senior Government Relations  
Representative

cc: Lou Carson



# ENC

# EGG NUTRITION CENTER

## MEMORANDUM

TO: Ken Klippen  
 FROM: Jill Snowdon *JAS*  
 DATE: January 14, 2000  
 RE: Decline in human incidence of *Salmonella* Enteritidis (SE)

The statement that the decline in salmonellosis from SE is only in limited areas of the country is incorrect. There are three federal sources of data on salmonellosis in the US as well as data recorded by the states. All salmonellosis data bases show a continuing decline in human disease from SE. Data review follows.

### Salmonella Surveillance System

This a nationwide, passive surveillance system in operation for several decades and is considered particularly valuable in monitoring trends in salmonellosis. Data is published by CDC annually; the most recent data is for 1998. There is a 56% decrease across the nation from a rate of 3.9 per 100,000 in 1994 to 2.2 in 1998. Trends on a regional basis show a decline of over 60% (although the peak year varies). The remaining regions in the country have a disease rate below 2 per 100,000.

Region	Peak year	Rate in peak year	Rate in 1998	Percent decline
Mid-Atlantic	1989	10.5	4.6	66%
Pacific	1994	7.1	2.7	62%
New England	1995	10	3.5	65%

The *Salmonella* Surveillance System also records the number of isolates that are due to a particular serovar (such as Enteritidis). The percentage of isolates recorded from SE was below 7% through the late 1970's. It peaked, in 1994, near 27% and in 1998 is down to 17.5%. This is another indicator that this disease incidence is on the decline.

### FoodNet data

The FoodNet surveillance system actively records data in limited geographic areas (called catchment areas) across the country. In 1998, the size of the catchment area was over 20.5 million persons or 7.7% of the US population. In 1998, 7 sites were monitored in the states of Connecticut, Minnesota, Oregon, California, Georgia, Maryland and New York. It is believed that active surveillance records all of the incidents of illness where laboratory testing was

CROSS FILE SHEET

File Number:

98N-1230/ *c 815*

See File Number:

97P-0197/ *c 816*  
96P-0418/ *c 815*