



# United Egg Producers

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Stephen Sundlof, D.V.M., Ph.D.  
Director  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
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Dear Dr. Sundlof:

Almost three-and-a-half years ago, the Food and Drug Administration (FDA) published a proposed rule to establish on-farm regulations for the prevention and control of *Salmonella* Enteritidis (SE) in shell eggs. More than three years ago, United Egg Producers (UEP) provided extensive comments on the proposed rule, as well as suggestions for improving it. Now, FDA has stated its intention to publish a final rule in the near future. Because of changes in the pattern of SE outbreaks as well as changes in the agency's own situation, UEP feels it is important to reiterate and update some of our industry's views on this important matter.

### Outbreak Data Show Improvement and Decline in Egg Share of Outbreaks, Cases

UEP asked the Egg Safety Center (ESC), a scientific institute which is funded by the nation's egg producers, to update publicly available information from the Centers for Disease Control and Prevention (CDC) about SE, especially with regard to recorded outbreaks and the role of eggs in these outbreaks. ESC's report is attached to this letter.

Information published by CDC shows several important trends.

- **The total number of reported SE outbreaks has declined substantially since 1990, and the total number of cases (ill**



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- individuals) in the reported outbreaks has also declined.
- The **total number of egg-associated SE outbreaks** reported has likewise seen a substantial decline since 1990. The **number of cases attributed to eggs** (or clearly egg-associated) has declined.
  - The decline in egg-related outbreaks and cases did not simply mirror an overall decline in SE outbreaks. Rather, the **percentage of all SE outbreaks due to eggs** fell significantly, as did the **percentage of all cases in SE outbreaks due to eggs**.
  - During 1990-95, on average each year, eggs were implicated in 28.29% of **all outbreaks**. From 1996-2000, this percentage fell to 22.20%, and from 2001-2005, eggs were implicated in only 16.73% of all outbreaks.
  - On the same basis, the annual average percentage of **all cases in outbreaks** due to eggs was 34.24% in 1990-95, 31.30% in 1996-2000, and 12.17% in 2001-05.

Several charts in the ESC report demonstrate the declining share of CDC-reported outbreaks and cases due to eggs.

### **CDC Recognizes Progress and Industry and State Role**

Let us be clear: We are not saying that SE is no longer a problem. It is still a problem. *We are* saying that – as reported by CDC scientists in a 2004 journal article<sup>1</sup> – the implementation of quality assurance (QA) plans by the egg industry and the states, combined with other factors, has contributed to a decline in the number of SE outbreaks and in the importance of eggs to the overall SE problem.

CDC continues to recognize these efforts. On April 12, 2007, Dr. Robert Tauxe, deputy director of CDC's Division of Foodborne, Bacterial and Mycotic Diseases, stated that "previous efforts to decrease the incidence of *E. coli* 0157 in ground beef *and Salmonella in eggs have been successful*, but contamination of other foods may be the problem now," according to a CDC press release. (Emphasis added.)<sup>2</sup>

### **Putting the Problem in Context with FDA's Resource Challenges**

Again, we do not assert that the nation has solved the problem of SE, or of *Salmonella* more generally. FoodNet incidence data for *Salmonella* have not shown the declines reflected in outbreak data. But we believe it is time for FDA to put the risk of SE from eggs in context with risks from other foods, and also time for the agency to think realistically about the portion of its scarce resources it wishes to devote to regulating the egg industry.

Today, it is all but universally acknowledged that FDA – and the Center for Food Safety and Applied Nutrition in particular – suffers from severe budgetary strains. We need not repeat the litany of new challenges the agency faces, compared to declining internal resources. We do note that UEP has joined many other organizations in the food and agriculture industry in asking Congress to increase CFSAN's budget. In our view, the challenge of providing better and more thorough scrutiny of imported food in a globalized economy is especially critical, and cries out for expanded funding.



Yet we must also be realistic about how much new money Congress is likely to provide CFSAN in the short term. Meanwhile, the proposed SE rule stated that “**FDA intends to conduct annual inspections of egg farms**” in carrying out its oversight of industry compliance. In the same proposed rule, FDA provided a chart of “adjusted number of farm sites” that showed **4,079 sites for farms with 3,000 or more layers** (the category to be regulated under the proposed rule).

**With the agency’s budget squeezed; with a clear need to shift more resources to import inspection; with the percentage of SE outbreaks and cases in outbreaks due to eggs on a sharp decline — does FDA really want to add more than 4,000 individual inspections of farms to its existing workload?**

#### **FDA Should Adopt Suggestions Made by UEP in 2004 to Modify Proposed Rule**

A more sensible way to proceed, it seems to us, would be to adopt the major proposals UEP made in its 2004 comments on the proposed rule:

- Accept participation in **recognized state or industry QA programs** as fulfilling the requirements of FDA’s rule (establishing a process by which the agency would grant recognition to the plans, and also ensuring that testing and diversion requirements are consistent nationwide); and
- Where inspection outside a recognized state or industry QA program is necessary, **delegate inspection authority to USDA’s Agricultural Marketing Service (AMS)**, which can conduct the inspections as a supplement to the existing Shell Egg Surveillance Program, under which AMS already inspects egg operations four times a year.

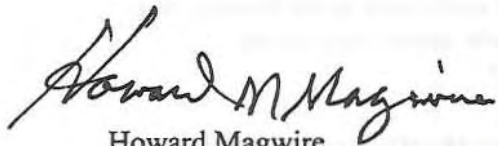
We believe the combination of a “recognition regime” and delegation of inspections to AMS would represent the best solution for FDA if the agency still intends to move forward with a final rule. In this case, UEP also wishes to reiterate strongly two points about the 2004 proposed rule:

- Incentives for producers to use **vaccination** should be added in order to achieve further reductions in SE, given the positive experience of several European countries with vaccination; and
- The initial concept of requiring all eggs to be **refrigerated within 36 hours of lay** remains unrealistic for off-line egg operations where eggs must be trucked to a packing station, and could potentially compromise food safety instead of enhancing it, as explained in detail in our 2004 comments, which also provided alternative refrigeration protocols that would be more practical without compromising product safety.

The significant expansion, since 2004, in contract farms that provide organic, cage-free or free-range eggs to packing stations makes the 36-hour issue still more significant than when UEP originally filed its comments.

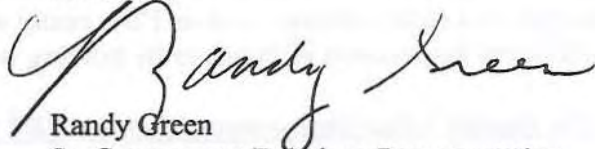
**Conclusion**

UEP continues to accept the need for federal action to control and prevent SE. However, many things have changed since 2004, for the industry and the agency alike. We encourage you to review the final rule with these comments in mind before it is published, and make any appropriate adjustments.



Howard Magwire  
Vice President, Government Relations

Sincerely,



Randy Green  
Sr. Government Relations Representative

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<sup>1</sup> Mumma, G.A., *et al.*, Egg Quality Assurance Programs and Egg-associated *Salmonella* Enteritidis Infections, United States. *Emerging Infectious Diseases*, Vol. 10, No. 10, October 2004.

<sup>2</sup> Centers for Disease Control and Prevention, "New Report Highlights Growing Foodborne Illness Challenges; E. coli 0157, Salmonella and Vibrio among Notable Concerns." CDC Media Relations Press Release – April 12, 2007.