



Salmonella Outbreak in Eggs: An Update

by *Brendan Flaherty*

In July, the Food and Drug Administration's (FDA's) long-awaited "Egg Rule" was met with neither safer eggs nor food safety accolades, but with the largest *Salmonella* enteritidis outbreak in recorded history—the precise type of massive foodborne illness outbreak the regulatory reform was meant to prevent.¹ From May to October, more than 1,800 people were sickened by tainted eggs and more than half a billion eggs were recalled.²

The Centers for Disease Control and Prevention (CDC) along with state health departments, FDA and the United States Department of Agriculture (USDA), traced the outbreak

to two Iowa egg producers located about 100 miles apart: Wright County Egg and Hillandale Farms of Iowa. Although public health officials continue to search for the outbreak's precise cause, the investigation of these farms reveals much about an industry that grew and consolidated far faster than the safety regulations governing it.

Understanding the elements that contributed to the outbreak—from insanitary conditions on the farm to consolidated suppliers and regulatory gaps—should shed light on both what was wrong before the crisis and what should be done to prevent another. Final conclusions must wait until investigators pinpoint a cause. Even at this stage, however, the outbreak proves that mandatory inspections and testing were long overdue.

Salmonella and Eggs

Salmonella Enteritidis (SE) is one of the most common illness-causing serotypes of *Salmonella* in the United States and is most often associated with eggs. It thrives in the intestines of hens, can be present in their feces and excretions, and



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is easily transmitted by direct contact. Environmental contamination therefore poses the most obvious threat of shell egg SE contamination. SE can contaminate both the exterior of the egg shell and can enter the yolk through pores in the shell after an egg is laid. The longer an egg is in contact with contaminated materials—whether feces, feed, rodents or even containers—the higher the risk of trans-shell contamination. Traditional egg safety measures focused on the threat of direct environmental contamination by implementing egg washing and sanitizing steps, egg inspections and more rigorous sanitation of hen house and storage facilities.

A more insidious and widespread mode of transmission occurs when the hens' ovaries become infected with SE. Infected hens appear normal but pass SE into the egg before the shell is formed. An infected egg also appears completely normal. To combat this internal contamination, producers establish rigorous biosecurity protocols to prevent the introduction and spread of SE in their flocks. They may also test their flocks and eggs for SE, and vaccinate hens against certain SE strains. These measures, as with many of those targeting environmental contamination, were not mandatory under pre-Egg Rule regulations.

Fractured Regulatory Jurisdiction

Laying facilities lacked clear guidance on SE prevention in part because the problem falls in the crack between USDA's regulation of chickens and FDA's oversight of eggs. USDA has jurisdiction over the flocks that supply chicks and young hens, known as "pullets," to egg laying facilities and the laying flocks themselves.³ The department also inspects processed egg products and administers a voluntary program of grad-

ing and certifying shell eggs. To guard against infection in chicks and pullets, USDA's Animal and Plant Health Inspection Service administers a voluntary SE control program for hatcheries supplying hens to egg laying facilities. FDA responsibility covers egg laying, production and packaging. In the pre-Egg Rule regime, FDA did not inspect egg laying facilities and SE control plans within those facilities were not required.

Neither USDA nor FDA actively monitored hen health once the hens enter the laying facility and neither agency directly addressed attendant issues such as the composition and safety of chicken feed. The assumption was that if SE-free hens enter the laying facility and the facility follows even basic environmental safety measures, the eggs produced there should be safe. If environmental safety breaks down, however, and SE is introduced into the laying flock, neither the egg producer, USDA nor FDA would likely know until after an outbreak is traced back to the facility. By that point, as in this outbreak, the contamination may have become pervasive.

Egg Rule

Initially published in July of 2009, the Egg Rule became effective one year later for egg producers with 50,000 or more laying hens.⁴ Large producers such as these account for about 80 percent of the nation's egg production. Under the Egg Rule producers must now:

1. purchase chicks and pullets only from suppliers that monitor for SE in the flock;
2. implement pest control and biosecurity measures;
3. test the hen house environment for SE at specified intervals—positive test results trigger mandatory egg testing and environmental sanitizing;
4. refrigerate eggs during storage and

transport within 36 hours of being laid; and

5. maintain SE prevention plan and compliance records.

Most significantly, FDA has created an inspection program to ensure compliance with the Egg Rule requirements. As the outbreak illustrates, inspections are necessary to achieve full compliance. The central question looming over the Egg Rule, however, is the extent to which FDA will succeed where USDA did not: monitoring the health of the laying chickens.

The Outbreak

In May, the Minnesota Department of Health notified the CDC of a cluster of SE cases linked to a single Mexican restaurant. Epidemiological study showed that chile rellenos prepared with shell eggs were the likely source. The eggs served at the restaurant were then traced back to Hillandale Farms. At the same time, microbiological genetic subtyping known as pulsed-field gel electrophoresis (PFGE) revealed that the illness-causing strain was SE pattern 4.⁵ The PFGE pattern—akin to a genetic fingerprint—for the illness-causing strains were loaded to PulseNet, a nationwide database used for bacterial illness surveillance. PulseNet allows public health investigators to compare PFGE patterns across the country and thereby quickly identify common-source bacterial outbreaks.

By July, the CDC used PulseNet and other surveillance techniques to detect a four-fold increase in illnesses caused by SE across the nation. Further epidemiological investigation identified shell eggs as the food source associated with the dramatic uptick in cases. The CDC alerted FDA and USDA of its investigation.

Through PulseNet, six separate clusters of SE pattern 4 outbreaks in California were soon identified and all

linked to Wright County Egg. Similarly, three additional Minnesota clusters were linked to Iowa egg producers and the CDC launched an in depth analysis of all identified clusters of SE in the United States.

At about the same time, FDA focused on tracing the illness-causing eggs from restaurant to producer. By August 9, FDA contacted Wright County Egg and began inspections on August 12. The company issued its nationwide recall on August 13. Additional traceback data led to Hillandale Farms. FDA inspected that facility on August 19 and Hillandale issued a nationwide recall on August 20. After the recalls, the number of SE cases nationwide returned to baseline.

The Farms

Under the pre-Egg Rule regime, neither FDA nor the Iowa Department of Agriculture had ever inspected the Wright County or Hillandale production facilities. When they did in late August 2010, they found numerous conditions and practices allowing for the introduction and transfer of SE into and between the hen houses.

Part of the DeCoster Egg empire,⁶ Wright County Egg is the larger operation of the two. The company has five egg production facilities with a total of 73 laying barns that house 5.8 million hens producing about 1.4 billion eggs per year.⁷ The inspection reports from Wright County Egg show that frogs, mice, flies and wild birds were living in and around the hen houses.⁸

The manure pits below the hen houses were full to the brim, with manure piling up to 8 feet high. Inspectors observed that in some houses, “the outside access doors to the manure pits...had been pushed out by the weight of the manure, leaving open access to wildlife or domesticated animals.” The report cites unsealed holes in

many of the hen houses as well as doors and entryways with gaps, allowing access to outside wildlife. In some laying houses, chickens that had escaped from their cages were wandering in the manure pits and using the manure piles to access the egg laying area.

Investigators observed workers at the Wright County facility moving directly from one house to another without wearing protective clothing, without changing clothing, and carrying equipment that had not been sanitized when being transferred between houses.

Inspections of the feed mill at Wright County, located in the same vicinity as the egg laying facilities, also revealed numerous biosecurity problems. Wild birds were roosting in the mill, bins holding raw feed ingredients had rusted holes in them and feed tank covers were missing or ajar. All these conditions can allow pathogens from wild birds to end up in the feed. This, in turn, can contaminate the hens in the laying houses and the eggs those hens lay.

Hillandale Farms’ Iowa facilities are smaller, but the company purchases feed and pullets from Wright County Egg. FDA observed similar conditions at Hillandale,⁹ including unsealed holes where rodents could enter the laying houses, standing water near manure pits and uncaged hens tracking manure from the pits into egg laying areas.

Although the problems cited in the Hillandale report did not appear as extensive as those cited in the Wright County report, microbiological samples taken from both facilities were PFGE matches to the illness-causing outbreak strain. Samples from the hen houses and the feed mill at Wright County Egg yielded positive results for SE, as did samples of the egg wash water at Hillandale Farms. In all, FDA collected almost

600 samples from both facilities and has thus far matched 17 to the PFGE pattern of the outbreak strain of SE.

Based on the FDA inspection reports, neither facility appeared close to meeting the requirements of the Egg Rule. The year between initial publication and the time of the outbreak had little apparent impact on day-to-day operations. The lesson here is that without meaningful inspections and enforcement, little will change.

Congressional Hearing

This was never clearer than during the House Committee on Energy and Commerce hearing on September 22. Leaders from both Hillandale and Wright County Egg testified, although Hillandale president Orland Bethel asserted his Fifth Amendment rights against self-incrimination and refused to testify. In striking contrast, the owner of Wright County Egg, Austin “Jack” DeCoster, and his son and Wright County COO Peter DeCoster, faced a barrage of questions.

Jack DeCoster initially apologized and, quite correctly, pointed out that his company consolidated and increased the scale of production without modernizing safety procedures. DeCoster testified that “we were big before we started adopting sophisticated procedures to be sure we met all of the government requirements.”¹⁰ Once confronted with graphic pictures showing manure spilling out of a Wright County Egg hen house door, dead rodents, and manure-encrusted dead chickens, the DeCosters, flanked by attorneys, did not fare so well but also did not shed much light on the precise source of contamination.

One of the most insightful moments of the hearing came from Representative Diana DeGette of Colorado, who pointed out that both Peanut Corporation of America—the source of a 2009 nationwide

Salmonella outbreak linked to peanut products—and Wright County Egg used the same “independent” auditor, AIB:

Ms. DeGette: Mr. DeCoster, your company hires a private auditing company to audit Wright County Farms annually, correct?

Mr. Peter DeCoster: Yes, ma’am.

Ms. DeGette: And this company is AIB, which is a private, for-profit food-safety auditing firm, correct?

Mr. Peter DeCoster: Right. They are --

Ms. DeGette: Thank you. Okay. And if you will turn to Tab 5 of the notebook in front of you, on June 7th and 8th, 2010, your farm was actually inspected by AIB, correct?

Mr. Peter DeCoster: Yes, ma’am.

Ms. DeGette: And AIB actually issued a superior certificate to the farm, correct?

Mr. Peter DeCoster: Yes, they did.

Ms. DeGette: So AIB audited your company in 2008 two times, four times in 2009, and at least one time in 2010. And every time, you were found to be superior. Is that correct?

Mr. Peter DeCoster: Yes. This is an inspection of the processing facility --

Ms. DeGette: Uh-huh.

Mr. Peter DeCoster: -- and not of the chicken barns.

Ms. DeGette: Okay. And what I wanted to talk about with Tab 7, if you’ll look at that, unbelievably to this committee, in 2009 AIB was the same auditor that audited the Peanut Corporation of America and also gave them a superior recommendation. Do you see that in your notebook, as well?

Mr. Peter DeCoster: Yes, ma’am.

Ms. DeGette: So here’s the thing, is both the Peanut Corporation of

America and Wright County Egg paid AIB to audit their companies and receive superior ratings right before both companies sold products that sickened thousands of people with Salmonella. And, Mr. Chairman, I bring this up to say that just relying on third-party auditors is not going to guarantee consumer safety, which is why, getting back to all of our point, we need to pass this bill.¹¹

The bill she references, the FDA Food Safety and Modernization Act (S.510), is currently stalled in the Senate. FDA Principal Deputy Commissioner Joshua Sharfstein, who also testified at the hearing, took the opportunity to join DeGette in stressing the importance of this bill. “Although, with regard to eggs, FDA has issued requirements for egg producers to implement preventive measures... such preventive controls are needed for other FDA-regulated foods as well,” Sharfstein said. He pointed to the following provisions in the pending legislation that would help the administration focus on preventive controls, which he said is “more efficient and effective than the current approach of addressing each commodity individually.”¹²

- The bill would allow FDA to more quickly trace contaminated products to the source.
- It would allow FDA to check companies’ safety records *before* problems occur.
- FDA would be able to require companies to identify and resolve food safety hazards.
- FDA would have mandatory recall authority.
- There would be new civil penalties and increased criminal penalties that

FDA can use as enforcement tools.

Despite embodying egg safety measures that have been well-known for a decade, the Egg Rule has yet to be truly tested. The investigation of the 2010 outbreak showed how far some huge egg production facilities were from compliance with even basic Egg Rule requirements. The outbreak also highlighted the importance of a legitimate inspection regime and the importance of expanding FDAs reach to hen health within egg production facilities. ▲

1 Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33030.
2 <http://www.cdc.gov/salmonella/enteritidis/> Last visit Oct. 20, 2010.
3 See http://www.fsis.usda.gov/factsheets/focus_on_shell_eggs/index.asp Last visit October 20, 2010.
4 21 C.F.R. § 118, et seq. (2010).
5 <http://www.cdc.gov/salmonella/enteritidis/#investigation> Last visit Oct. 20, 2010
6 Neuman, William, *An Iowa Egg Farmer and a History of Salmonella*, New York Times, Sept. 21, 2010
7 <http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM224399.pdf> *The Outbreak of Salmonella in Eggs: Hearing Before House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce*, 111th Cong. (2010) (Testimony of Peter DeCoster, Wright County Egg COO) [Hereinafter Congressional Hearing]
8 <http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM224399.pdf> FDA 483 Inspection of Wright County Egg
9 <http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM224399.pdf> FDA 483 Inspection of Hillandale Farms
10 <http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM224399.pdf> Congressional Hearing, Testimony of Austin DeCoster
11 <http://energycommerce.house.gov/documents/20100930/transcript.09.22.2010.oi.pdf> Congressional Hearing preliminary transcript
12 <http://energycommerce.house.gov/documents/20100922/Sharfstein.Testimony.09.22.2010.oi.pdf> Congressional Hearing, Testimony of Joshua Sharfstein, FDA Principal Deputy Commissioner