



TESTIMONY OF

JOSHUA M. SHARFSTEIN, M.D.

PRINCIPAL DEPUTY COMMISSIONER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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## INTRODUCTION

Good afternoon, Chairman Stupak and Members of the Subcommittee. I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner of the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss the recent *Salmonella* Enteritidis (SE) foodborne illness outbreak associated with shell eggs produced by Wright County Egg and Hillandale Farms of Iowa, Inc. Before discussing this outbreak, I would first like to thank you, Chairman Stupak, Chairman Waxman, Chairman Emeritus Dingell, Ranking Member Barton, Ranking Member Burgess, and other Members of the Committee, for your leadership in obtaining passage last year of comprehensive food safety legislation. We are hopeful that Congress will soon send legislation to the President for his signature.

FDA is the federal agency that is responsible for most of the U.S. food supply, except for meat, poultry, and processed egg products, which are overseen by our partners at the U.S. Department of Agriculture (USDA). While the production of eggs and egg-based products can involve many steps, different parts of the federal government work together in the effort to make sure the eggs and egg products that reach our tables are safe to eat. With regard to eggs, FDA has primary responsibility for the parts of the continuum that involve the production and packaging of shell eggs, which includes the shell eggs involved in the recent SE outbreak. USDA has primary responsibility to inspect processed egg products to prevent the distribution into commerce of adulterated or misbranded egg products, to ensure proper disposition of restricted shell eggs, and to voluntarily grade and certify shell eggs for quality, weight, condition, and/or other factors. USDA also oversees flocks that supply chicks to egg-laying operations.

We work closely with sister agencies, such as the Centers for Disease Control and Prevention (CDC) in HHS and USDA; with state, local, tribal, and foreign officials; as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia, to fulfill our mission to ensure the safety of FDA-regulated products.

While the scale of this most recent outbreak and associated investigation and recall activities have been quite challenging, FDA has moved with a great sense of urgency to protect consumers. To provide an idea of the scale of the recall, more than 500 million shell eggs distributed by Wright County Egg and Hillandale Farms of Iowa have had to be recalled. According to CDC, from May 1 to August 31, 2010, approximately 1,519 illnesses were reported that are likely to be associated with this outbreak. That makes this the largest recorded SE outbreak reported since the start of outbreak surveillance in the early 1970s.

In dealing with an outbreak situation, our mission is to track down the source of the contamination and get the affected product out of commerce as quickly as possible. We took action to alert consumers based on early indications that eggs were the likely source of contamination—before the first laboratory sample came back with a positive result for SE matching the outbreak strain.

FDA also conducted extensive outreach to inform consumers about the outbreak associated with shell eggs, the recall, and the steps consumers should take to help reduce their risk. To help consumers fully understand the products involved in the recalls, FDA posted a complete list of the recalled brands and created a searchable database for these recalls on the Agency's website, [www.fda.gov](http://www.fda.gov). We also provided information on [www.foodsafety.gov](http://www.foodsafety.gov). In addition, FDA briefed

organizations representing consumers and industry as well as our federal and state partners. We responded to hundreds of media inquiries, conducted numerous media interviews, and, between August 23 and August 30, held three media briefings to ensure that the public was well-informed.

A recent poll shows that these efforts were successful in getting a clear message to the public. A national poll conducted on August 27-30, 2010, by researchers at Harvard School of Public Health found that 84 percent of those surveyed were aware of the outbreak. Nearly three-quarters of Americans surveyed reported that they have confidence in the way public health officials handled the outbreak.

I would now like to provide a brief overview of FDA's activities to protect consumers by enhancing the safety of shell eggs and of the key events associated with this outbreak. In particular, I will describe FDA's egg safety regulation, which took effect for the biggest egg producers, on July 9, 2010, and our inspection plans to ensure compliance. We believe compliance with this regulation could prevent as many as 79,000 illnesses and 30 deaths per year due to SE.

## **FDA'S EGG SAFETY EFFORTS**

Egg-associated illness caused by *Salmonella* is a serious public health problem. Healthy people infected with *Salmonella* often experience fever, diarrhea, nausea, vomiting, and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (infected

aneurysms), endocarditis, and arthritis. *Salmonella* can also cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. We expect that implementing preventive measures established by FDA's new egg rule will reduce the number of SE infections from eggs by nearly 60 percent.

FDA has been concerned about egg safety for more than a decade and has worked hard to put into place preventive controls on farms that would prevent foodborne illness outbreaks, like the one recently associated with Wright County Egg and Hillandale Farms of Iowa. The egg safety regulation we published in July 2009 requires virtually all egg producers with 3,000 or more laying hens to implement measures designed to prevent SE contamination. The regulation became effective for the largest egg producers—those with 50,000 or more laying hens—on July 9, 2010. These producers account for about 80 percent of egg production. The requirements will become effective for smaller producers with at least 3,000 laying hens but fewer than 50,000 laying hens by July 9, 2012. This rule is part of a coordinated strategy between FDA and USDA's Food Safety and Inspection Service to ensure that egg safety measures are consistent, coordinated, and complementary.

Among other things, the regulation requires egg producers to adopt preventive measures and to use refrigeration during egg storage and transportation. Specifically, under the rule, egg producers whose shell eggs are not processed with a treatment such as pasteurization must:

- buy chicks and young hens only from suppliers who monitor for SE bacteria;
- establish rodent, pest control, and biosecurity measures to prevent the spread of bacteria throughout the farm by people and equipment;

- conduct testing of the poultry house environment for SE. If the tests find the bacterium, a representative sample of the eggs must be tested over an eight-week time period (four tests at two-week intervals); if any of the four egg tests is positive, the producer must further process the eggs to destroy the bacteria, or divert the eggs to a non-food use;
- clean and disinfect poultry houses that have tested positive for SE; and
- refrigerate eggs at 45 degrees Fahrenheit during storage and transportation no later than 36 hours after the eggs are laid (this requirement also applies to egg producers whose eggs receive a treatment, such as pasteurization).

In addition, the rule requires egg producers to maintain a written SE prevention plan and records documenting their compliance. FDA has published draft guidance and intends to issue additional guidance to help egg producers comply with the rule.

To ensure that important safety measures established by our egg safety rule are being implemented properly, FDA has announced a comprehensive inspection program. We plan to inspect all facilities now covered by the rule, which produce 80 percent of the country's eggs, to identify potential problems before they cause illnesses. Over the next 15 months, our investigators and their partners at the state level will inspect about 600 egg producers—those with 50,000 or more laying hens—to determine if their facilities are in compliance with the egg safety requirements.

As noted earlier, we expect that industry's compliance with this rule will significantly reduce the risk of SE infections, preventing an estimated 79,000 cases of illness and 30 deaths per year.

Within weeks of the egg safety rule's becoming effective in July, we saw evidence of why this additional regulation is so badly needed. I would now like to walk through the key events of the investigation that led us to discover the sources of this outbreak.

## **RESPONSE TO RECENT OUTBREAK**

The first phase of the outbreak response was the initial epidemiological investigation. In late July, CDC became aware of a four-fold increase in cases of *Salmonella*. CDC's consultation with states identified multiple investigations of restaurant-associated clusters of illnesses due to SE. Data from these investigations identified a range of theories for what could be behind the outbreak. One of these theories—but not the only one—was shell eggs. FDA was made aware of the scale of the situation and of these various hypotheses in late July.

This began a second phase—narrowing down the suspects and identifying the source of the outbreak. During this phase, FDA, CDC, state departments of health, and others involved in outbreak response, worked together to rule out certain theories and track the eggs to their source. In late July and early August, FDA and CDC officials identified three clusters of illnesses with the strongest epidemiological connections to a common source of eggs.

FDA initiated discussions with Wright County Egg in early August to relay that some information from these investigations suggested that Wright County Egg may be a common source of shell eggs in several clusters of illnesses and to begin collecting information. On August 11, although we did not have any confirmatory laboratory testing at the farms, FDA and CDC believed the evidence was clear enough to take action to protect the public, and we held

further discussions with Wright County Egg that resulted in the firm initiating a voluntary recall. Wright County Egg issued a press release to announce the recall on August 13. FDA posted this recall information on its website the same day.

We then began a third phase of intensive on-site investigations at Wright County Egg and assessments of whether other egg farms or foods were implicated in the illnesses to be sure we were fully protecting the public. Based on further tracebacks of illness clusters and our investigation at the Wright County Egg farms, we found two other Wright County Egg layer facilities with shared feed and other common risk factors. This led FDA to immediately work with Wright County Egg to remove these shell eggs from distribution, resulting in additional recalls, which Wright County Egg announced on August 18.

Shell eggs from Wright County Egg were sold to distributors and wholesalers in 22 states, who then distributed the shell eggs further throughout the country and to Mexico, the Bahamas, and the Turks and Caicos Islands. According to Wright County Egg, 380 million of their shell eggs are being recalled under many different brand names.

Through additional traceback and FDA investigational findings, Hillandale Farms of Iowa was identified as another potential source of contaminated shell eggs contributing to the outbreak.

On August 20, Hillandale Farms of Iowa initiated an additional recall of eggs that went to grocery stores, distributors, and wholesalers in 14 states; these entities then distributed the shell eggs further throughout the country. On August 20, FDA issued an alert to consumers about the Hillandale Farms recall. As we mentioned earlier, in all, more than 500 million shell eggs are now involved in these nationwide recalls.



FDA has conducted an extensive investigation at both Wright County Egg and at Hillandale Farms of Iowa. The investigation involved a thorough assessment of compliance with the new egg safety rule, including an assessment of the operating conditions, an extensive review of records and procedures, and the collection of hundreds of environmental samples for FDA laboratory analysis.

On August 27, FDA announced that multiple positive samples that match the DNA fingerprint of the outbreak strain of SE had been collected from both Wright County Egg and Hillandale Farms of Iowa. On August 30, FDA made its inspectional observations, also known as FDA 483s, available on our website and briefed the media on these observations. Our investigators found significant objectionable conditions observed at poultry houses, such as the presence of live and dead flies that were too numerous to count, as well as maggots at Wright County Egg and live rodents and structural damage that allowed rodents, birds, and potentially other animals to enter poultry houses at both companies.

FDA is continuing to evaluate information relating to conditions on the implicated egg farms, analyzing investigative samples, and ensuring that appropriate controls and corrections are fully established. All eggs being produced on the implicated farms are being sent to facilities for treatment to destroy any SE that may be present. We also are monitoring the recall by conducting audit checks at consignees of the recalled shell eggs throughout the entire distribution chain, including, but not limited to, retailers, wholesalers, and distributors, to make sure the recalled shell eggs are being removed from the market. As of September 10, with assistance from state agencies, approximately 2,170 recall audit checks have been conducted. Although recall audit activities are continuing, the firms' recall efforts thus far appear to be effective in

removing recalled products from the market. FDA is also currently reviewing the findings of our investigation to evaluate what enforcement actions may be appropriate.

## **NEED FOR COMPREHENSIVE FOOD SAFETY LEGISLATION**

The Administration, through the President's Food Safety Working Group, has highlighted the need to modernize our food safety laws to provide key tools for FDA to keep food safe. The legislation pending in Congress would transform our nation's approach to food safety from responding to outbreaks to preventing them. It would do so by holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination. Although, with regard to eggs, FDA has issued requirements for egg producers to implement preventive measures, and FDA will be conducting inspections to ensure those measures are being implemented to protect consumers, such preventive controls are needed for other FDA-regulated foods as well. Such explicit authority to require preventive controls is a basic and critical component of an effective food safety system and is more efficient and effective than the current approach of addressing each commodity individually.

Other key provisions included in the pending food safety legislation would give FDA better ways to more quickly trace back contaminated products to the source, the ability to check firms' safety records before problems occur, clear authority to require firms to identify and resolve food safety hazards, and resources to fund additional inspections and other oversight activities. Pending legislation would also give the Agency mandatory recall authority, and other strong enforcement tools, like new civil penalties and increased criminal penalties for companies that fail to comply

with safety requirements. The legislation also would strengthen FDA's ability to ensure the safety of imported food.

There is broad bipartisan support in Congress for this legislation as well as broad support from the food industry and from consumer and public health organizations. We commend the House for passing a strong and comprehensive food safety bill and appreciate the hard work that has been done in the Senate. The stakes are too high to continue with the existing limitations in our food safety system. We hope this Congress will take the historic step of enacting comprehensive food safety legislation to give FDA the resources and tools necessary for a modernized food safety system.

## **CONCLUSION**

In conclusion, FDA has worked closely with its food safety partners to quickly investigate this outbreak, contain it to prevent further illnesses, and provide timely and clear information for consumers. To help prevent future egg-related outbreaks, we will be carrying out a large-scale inspection program to ensure that the new requirements to adopt preventive measures to prevent SE are being implemented. Our efforts to ensure egg safety are one step in our ongoing work to carry out the recommendations of the President's Food Safety Working Group to upgrade our food safety system for the 21<sup>st</sup> century by prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

While we have made great progress to improve the safety of our nation's food supply, the task ahead of us is equally great. I look forward to working with you to address both the issues raised today and any other matters of concern.

Thank you again for the opportunity to discuss the recent SE outbreak. I would be happy to answer any questions.