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Salmonella-tainted eggs linked to U.S. government's failure to act

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Public health officials closed the books this month on an outbreak of salmonella illness that had sickened more than 1,900 people since May and led to the largest recall of eggs in U.S. history.

Two Iowa egg farms drew most of the blame, triggering a congressional investigation, a federal criminal probe and several lawsuits filed by victims.

What has not drawn much scrutiny is the role of the federal government, which recognized 20 years ago that salmonella in eggs posed a public health threat. Although federal inspectors have closely monitored meat and poultry production for the better part of a century, they have largely ignored eggs, another staple of the American diet. It was not until July, well after the recent outbreak was underway, that the government's first rules on safe egg production took effect.

Unlike other regulatory efforts, this one did not sputter under lobbying pressure by business. In fact, the \$4.4 billion egg industry had been seeking mandatory rules for years, despite the red tape and extra costs. Consumer groups wanted the regulation, and public health experts supported it, along with economists who said the benefits would far outweigh the costs.

But the proposal was thwarted by government itself - philosophical resistance to regulating business as well as rivalries and dysfunction at two federal agencies that share responsibility for keeping egg production safe.

Fractured oversight remains a problem today. There are more than 15 federal agencies and 71 interagency agreements dealing with food safety. Experts in public health and government accountability say that fragmentation weakens oversight, wastes tax dollars through redundancy and creates dangerous gaps.

Balkanization was a key factor in the government's failure to regulate eggs over the past two decades. The push for federal rules on egg production stalled in the

George H.W. Bush and Clinton administrations as the Food and Drug Administration and the U.S. Department of Agriculture dug into their own silos. It collapsed when the George W. Bush administration brought a renewed skepticism about regulation to the executive branch.

"The system certainly was at its worst," said Lester Crawford, a former FDA commissioner whose own bout with salmonella in 1986 turned the issue into a personal battle.

Crawford pushed for egg regulation while running the food safety program at the USDA from 1987 to 1991, and he said he was stunned by the lack of progress when he joined FDA as acting deputy commissioner in 2002.

"I went nuts. I was told it was ready to go and all we needed to do was say yes, so I said yes," Crawford said. He kept up the fight through 2005, when he left the agency.

Mark McClellan, who was FDA commissioner from 2002 to 2004, also supported egg regulation, but he said the proposal moved slowly because of its complexity and competing priorities.

"It was farm-to-table regulation, so there was lots to consider," he said. "It was going to affect the trucking industry, storage, food production, and small and large farms. . . . Then there was the issue of priorities. . . . It's not like one particular public health issue is unimportant, but with limited resources, you have to focus effort."

The regulations that took effect this year require farmers to buy chickens that are certified free of salmonella, test those chickens while they are laying eggs and, if there is a positive test, stop selling whole eggs.

But the rules were too late to prevent the outbreak this summer, when Shannon Sutton ate a contaminated egg at an omelet restaurant in July. Two days later, she was in a hospital bed counting the minutes between morphine injections to dull the abdominal cramps that racked her body.

"You just feel like you're dying," said Sutton, a 25-year-old mother of two from Salt Lake City, who was hospitalized for four days with severe diarrhea and vomiting. "It was so bad I couldn't talk or move or think of anything."

With medical costs estimated at \$25,000, Sutton has filed a legal claim against Wright County Egg, one of the nation's largest egg producers and the farm at the center of the outbreak.

When FDA inspectors paid their first visit to Wright County Egg after the outbreak, they found henhouses bulging with manure, mice and other hazards that can spread disease.

The company has defended its practices and said in a statement at the time that "the vast majority of the concerns identified in the FDA report already have been addressed through repairs or other corrective measures."

On Dec. 1, the FDA allowed Wright County Egg to resume selling eggs produced in two of its 73 henhouses, saying they were cleared of contamination. Hinda Mitchell, a spokeswoman for the company, expressed sympathy for the victims but declined to comment on the lawsuits.

An emerging threat

The threat of salmonella-tainted eggs did not exist a generation ago. But in the early 1980s, public health officials noticed an uptick in food poisoning cases linked to a particular strain of salmonella bacteria, which they traced to eggs.

By 1988, scientists had discovered that although other salmonella strains could be washed off egg shells, one type - Salmonella enteritidis - lived inside eggs.

Scientists think that this type, one of about 2,500 strains of salmonella, pass from the ovaries of an infected chicken into the eggs. It can be detected only through a laboratory test, and its discovery prompted new government warnings about the risks.

New Jersey health officials, for example, enacted a "runny egg rule" in 1992, banning restaurants from preparing dishes with raw or undercooked eggs. The goal was straightforward: to kill salmonella and prevent illness. But the response was visceral.

Diners across the state openly scoffed at the rule. Johnny Carson turned it into material for his late-night routine. And then-Gov. Jim Florio, a Democrat, invited the media to a New Jersey diner where he defiantly ordered eggs over easy. Within months, the rule was rescinded.

For egg farmers, however, the problem was not so easily dismissed. Faced with bad publicity and multimillion-dollar liability claims, they voluntarily began testing for the bacteria, disinfecting henhouses, refrigerating eggs, removing manure and controlling rodents. But those farmers soon came to think that they were at an economic disadvantage against competitors who weren't spending money on prevention.

In the absence of federal regulation, some states began in the 1990s to enact their own rules, many focused on refrigeration. But the varying requirements created headaches for producers selling nationwide.

At the same time, public health officials and consumer groups were pushing for mandatory federal regulations. President Clinton ramped up the pressure when he devoted a 1999 radio address to contaminated eggs and announced that the FDA would lead efforts to eradicate salmonella in eggs over the next decade.

By the end of the Clinton administration, the United Egg Producers, a trade group representing 95 percent of the country's egg farmers, had come to the conclusion that the rules would create a consistent, level field.

"Nobody wants more regulation. That's just a fact of life. . . . I was resisting," said Ken Klippen, then the chief lobbyist for the United Egg Producers. But eventually, he said, he realized that new rules were coming and that his best bet was to negotiate fair terms for the farmers. "We were going to be regulated. This was going to happen, and the industry had to respond."

In the spring of 2000, a deal was struck. The egg industry agreed that the federal government would for the first time set rules for egg farms.

At a private meeting on the eighth floor of a sleek office building overlooking Washington's Union Station, Klippen, representing the egg farmers, shook hands with Richard Wood of Farm Animals Care Trust, who was negotiating on behalf of consumer groups. The regulators looked on, approvingly.

"This is how government and industry are supposed to work together," Judy Riggins, a policymaker at the USDA, whispered to Klippen.

And then, nothing.

For the next nine years, the government failed to deliver the rules.

A fractured bureaucracy

From the time scientists recognized the dangers of salmonella, regulators were unsure which federal agency should respond. Responsibility for safeguarding food is spread among multiple agencies. And when it comes to eggs, the roles get especially complicated.

The health of chickens falls under the USDA, but the FDA oversees the safety of whole eggs. Once an egg is broken and made into an "egg product," responsibility for its safety switches back to the USDA.

The USDA also oversees transportation of whole eggs, but the FDA dictates how they should be stored once they reach restaurants or stores.

Because salmonella wasn't making chickens sick, the USDA initially decided not to intervene. USDA inspectors are in packing facilities, but henhouses normally are the purview of the FDA. And the FDA rarely inspected henhouses.

The FDA has not routinely inspected egg farms because it has not established rules or standards, Deputy Commissioner Joshua M. Sharfstein said.

Over the past five years, the FDA has sent inspectors to just a handful of more than 4,000 egg farms in the country, according to agency records. In the case of one Ohio farm that recently detected salmonella in its henhouses and eggs, the only FDA inspection in the past five years took place in 2007, when inspectors visited the farm's office and not its henhouses, according to an FDA inspection report.

Early in the salmonella crisis, the USDA and FDA initiated the first of several failed efforts to collaborate on a solution.

"The government dysfunction over the salmonella problem really started with the turf issues," said Caroline Smith DuWaal, director of food safety at the Center for Science in the Public Interest.

Federal officials met with industry representatives, scientists and state public health officials and launched a consumer education campaign, stressing the safest ways to handle and prepare eggs. But the USDA and the FDA disagreed on the path forward and ended up working on separate strategies for handling eggs. Each deployed economists, scientists, lawyers and policymakers as the agencies shaped dueling proposals. Their rivalry to become the top agency for food safety was so intense, they refused to share their plans with each other until they were made public.

Despite formal agreements pledging to share information and work together, the FDA and the USDA were still not communicating as recently as this spring and summer.

From May to August this year, USDA officials did not pass along to the FDA concerns about sanitation problems that they had noted repeatedly in the packing houses at Wright County Egg, where they were grading eggs that were being packed in cartons. On daily reports, the egg graders noted dirty equipment, unsanitary cooler and storage areas, eggs left unrefrigerated overnight and the presence of bugs, among other deficiencies.

Wright County Egg and the USDA noted that, in each case, the problems were corrected by farm employees in time for the day's egg packing and grading. "If anything rose to the level indicating that we were going to withdraw grading services, we would tell the FDA," said Caleb Weaver, a USDA spokesman. "But nothing rose to that level."

But some of the eggs that the USDA graders were judging carried salmonella. The eggs were shipped by the thousands to retailers and restaurants across the country.

Skepticism about rules

Bureaucratic infighting was one obstacle to egg regulation. But another formidable barrier permeated the debate for years: a strong philosophical bias against government intrusion into kitchens, businesses and farms.

That was particularly true during the George W. Bush administration, when officials repeatedly expressed concern that the rules could hurt small businesses and end up dictating how Americans should eat their eggs.

It took the FDA until 2004 to get proposed rules through the Department of Health and Human Services and to the Office of Management and Budget, which has final say over new regulations. There, the FDA faced a new set of old questions.

"Essentially, they said, 'Show us how many people are sick, dying and hospitalized, and show us your rule is worth the cost,'" said William Hubbard, associate FDA commissioner from 1991 to 2005.

The FDA thought it had a compelling case. The rules would cost farmers \$82 million a year but could save \$1.4 billion in medical costs and lost productivity

by preventing 79,000 illnesses and 30 deaths a year. Still, OMB "didn't think there were enough bodies in the street," Hubbard said.

Several former FDA officials interviewed said senior officials in the Bush administration, still reeling from the terror attacks of 2001, were most concerned about the threat of bioterrorism and mass casualties. Eggs seemed almost quaint and certainly not urgent.

"We'd get blank stares," said Steve Roach of Farm Animals Care Trust, which represented consumer groups in briefings with OMB. "We would go in and say, 'There's still a lot of people getting sick.' They'd just say, 'Thank you for presenting.'"

Susan E. Dudley, administrator of the Office of Information and Regulatory Affairs at OMB from 2007 to 2009, said when it came to egg regulation, her agency was following a cost-benefit approach that had been embraced by every administration since Ronald Reagan.

The fact that the egg industry was on board didn't sway Dudley. "One needs to be skeptical when an industry seeks regulation, because it often confers competitive advantage. It could be over other companies or over international firms," she said. "And it often raises costs and it's consumers who get hurt."

She also said the White House was concerned that federal rules would devastate small farmers without substantially reducing illnesses.

In 2008, the United Egg Producers wrote to OMB, reiterating support for federal action and lobbying to shape any impending rules.

But later that year, the industry and others were surprised when the FDA suddenly withdrew the rule that it had proposed four years earlier.

David Acheson, former associate commissioner of foods at the FDA, said OMB officials insisted that the rules be reworked to prevent harm to small businesses that prepare food, such as nursing homes. FDA already had included exemptions for small farmers.

"The feeling was: Take it off the fire altogether, fix it and then bring it back," Acheson said. "It wasn't going to fly under the current administration, which was a waning administration."

Howard Maguire, who was the egg industry's main lobbyist in 2008, said OMB had pushed FDA officials to take the proposal off the table.

"People inside the FDA said it was purely politics and they were told to back off," he said. "It wasn't relief for us. It was frustration because this thing just kept hanging over our heads."

Several months later, Obama administration officials arrived at the FDA to find a package of egg regulations, endorsed by industry and consumer groups, awaiting action. The administration published the standards, which took effect in July.

This fall - armed with the new regulations and acting in the wake of the most recent outbreak - FDA inspectors began visiting the nation's 600 biggest egg farms. Among the first farms were those with ties to Wright County Eggs, including Ohio Fresh Eggs.

Under the new rules, Ohio Fresh had tested and found *Salmonella enteritidis* in a henhouse and in eggs. FDA inspectors reviewing the farm's paperwork discovered that the company had mistakenly shipped nearly 300,000 eggs to Cal-Maine Eggs, the country's largest egg producer and distributor, which recalled them Nov. 5.

In a statement, Ohio Fresh Eggs apologized for the mistake and said, "We are redoubling our efforts to ensure thorough and ongoing training of our workers so that this situation is not repeated."

Despite the error, FDA officials were satisfied. The problem had been caught early. And no one became sick.

But even with the regulations in place, FDA officials said, after the outbreak this year, they recognized a problem of poor communication between agencies. The FDA is now training USDA inspectors to spot food-safety problems and report them to the FDA. And officials have pledged yet again to try to bridge the gaps between agencies.

Staff researcher Lucy Shackelford contributed to this report.

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