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U.S. Rejected Hen Vaccine Despite British Success

By **WILLIAM NEUMAN**

Faced with a crisis more than a decade ago in which thousands of people were sickened from [salmonella](#) in infected eggs, farmers in Britain began vaccinating their hens against the bacteria. That simple but decisive step virtually wiped out the health threat.

But when American regulators created new egg safety rules that went into effect last month, they declared that there was not enough evidence to conclude that vaccinating hens against salmonella would prevent people from getting sick. The [Food and Drug Administration](#) decided not to mandate vaccination of hens — a precaution that would cost less than a penny per a dozen eggs.

Now, consumers have been shaken by one of the largest egg recalls ever, involving nearly 550 million eggs from two Iowa producers, after a nationwide outbreak of thousands of cases of salmonella was traced to eggs contaminated with the bacteria.

The F.D.A. has said that if its egg safety rules had gone into effect earlier, the crisis might have been averted. Those rules include regular testing for contamination, cleanliness standards for henhouses and refrigeration requirements, all of which experts say are necessary.

However, many industry experts say the absence of mandatory vaccination greatly weakens the F.D.A. rules, depriving them of a crucial step that could prevent future outbreaks.

Salmonella bacteria is passed from infected hens to the interior of eggs when they are being formed. The salmonella vaccines work both by reducing the number of hens that get infected and by making it more difficult for salmonella bacteria to pass through to the eggs.

“They are the only thing I’m aware of that really controls the problem from the inside out, at the source,” said Ronald Plylar, the former president of a company that developed an early salmonella vaccine.

Many people in the American egg industry say they believe that the current outbreak and recall will tip the balance and force nearly all producers in the United States to begin vaccinating hens to reassure consumers.

The F.D.A. said it considered mandatory vaccination very seriously. “We didn’t believe that, based on the data we had, there was sufficient scientific evidence for us to require it,” said Dr. Nega Beru, director of the agency’s Office of [Food Safety](#).

However, Dr. Beru says that the new rules encourage producers to vaccinate if they think it will help fight salmonella.

Another F.D.A. [food safety](#) official, Nancy S. Bufano, said that despite the success of vaccination in Britain, the agency thought that because the vaccines used in the two countries were not identical, it made comparisons difficult.

Vaccine company executives, however, said the differences were minor and the drugs used in both countries were equally effective.

The drop in salmonella infections in Britain was stunning.

In 1997, there were 14,771 reported cases in England and Wales of the most common type of the bacteria, a strain known as Salmonella Enteritidis PT4. Vaccine trials began that year, and the next year, egg producers began vaccinating in large numbers.

The number of human illnesses has dropped almost every year since then. Last year, according to data from the Health Protection Agency of England and Wales, there were just 581 cases, a drop of 96 percent from 1997.

“We have pretty much eliminated salmonella as a human problem in the U.K.,” said Amanda Cryer, director of the British Egg Information Service, an industry group.

The F.D.A. estimates that each year, 142,000 illnesses in the United States are caused by consuming eggs contaminated with the most common type of salmonella. It has said the new rules would cut that by more than half. People who eat bad eggs that have not been cooked thoroughly to kill the bacteria can get [diarrhea](#) and cramps. Rare cases can be fatal.

There are no laws mandating vaccination in Britain. But it is required, along with other safety measures, if farmers want to place an industry-sponsored red lion stamp on their eggs, which shows they have met basic standards. The country’s major supermarkets buy only eggs with the lion seal, so vaccination is practiced by 90 percent of egg producers, according to Ms. Cryer.

Thomas Humphrey, a food safety professor at the University of Liverpool, said that producers in the United Kingdom turned to vaccination after other measures, similar to those now required by the F.D.A., failed to show significant results.

One-half to two-thirds of American farmers already inoculate their flocks, according to industry estimates, and that number is likely to increase. While the new federal rules do not require vaccination, they do require testing for salmonella. If henhouses are found to be contaminated, then eggs must be tested. If eggs are tainted, then they would have to be broken and pasteurized, which would mean producers would get much less money for their eggs.

The F.D.A. has estimated that it would cost farmers about 14 cents a bird to vaccinate, or about \$31 million to cover hens at all the large farms in the country. But vaccine company executives said the cost can be just a few cents a bird, depending on the type of vaccine and how many doses are given. A single bird can lay about 270 eggs in its lifetime.

After the current outbreak, “many producers that were trying to decide whether or not to vaccinate will now vaccinate,” said David Zacek, the chief executive of Lohmann [Animal Health International](#), one of three companies that produce the vaccines in the United States.

The two companies involved in the recall, Wright County Egg and Hillandale Farms, said that they began introducing vaccinated birds to their Iowa operations last year. But the companies have seven separate facilities in Iowa with a total of about 7 million birds, and it can take up to a year and a half to replace all the hens on a large farm.

The companies would not say how many of their birds had been vaccinated when the outbreak started this spring. Wright County said that currently about three-quarters of its birds have been vaccinated and Hillandale said it has now vaccinated about 80 percent.

Industry experts said that in a typical facility, eggs from different laying barns are commingled when they are sorted and packed, so it is possible that eggs from vaccinated and unvaccinated hens can be shipped out together.

“That’s how a farm can be moving in the right direction but still only be partially protected,” said Dr. George Boggan, technical service veterinarian for CEVA, the vaccine company that works with Wright County Egg.

The F.D.A. began working on its new egg rules more than a decade ago, and a review of agency documents suggests that officials formed a negative opinion about the effectiveness

of vaccines early on. That opinion failed to change as time passed and evidence mounted that vaccines significantly reduced the occurrence of salmonella.

Many small-scale trials show vaccines are effective. But the F.D.A. said that only large-scale field trials could prove that a vaccine would work in the real world of commercial henhouses.

One such trial cited by F.D.A. officials was a 1999 Pennsylvania study that found little difference in salmonella levels between some vaccinated flocks and an unvaccinated control group. "Currently there is no vaccine that has been shown to be efficacious in the field," the agency wrote in a public summary of its views last year.

However, Dr. Sherrill Davison, the lead researcher on that 1999 study, said that the F.D.A.'s assessment did not reflect advances made since then.

"That data was very preliminary data that used vaccine technology from the beginning of these programs, and that technology has changed and our understanding of how to administer them has changed," she said.

Dr. Davison was involved in creating a pioneering egg safety program in Pennsylvania that was the model for the federal rules that went into effect this year. While the Pennsylvania program is voluntary, she said the vast majority of producers there vaccinate their birds.

"I personally believe it is essential for the program," she said.