

2413 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-0703  
(202) 225-3681

59 ELM STREET  
SECOND FLOOR  
NEW HAVEN, CT 06510  
(203) 562-3718

DURHAM/ MIDDLEFIELD/ MIDDLETOWN  
(860) 344-1159

WEBSITE: [HTTP://DELAURO.HOUSE.GOV](http://delauro.house.gov)



UNITED STATES  
HOUSE OF REPRESENTATIVES

ROSA L. DeLAURO

3RD DISTRICT, CONNECTICUT

CO-CHAIR, DEMOCRATIC STEERING AND  
POLICY COMMITTEE

COMMITTEE ON APPROPRIATIONS  
SUBCOMMITTEES  
RANKING MEMBER

LABOR, HEALTH AND HUMAN SERVICES,  
EDUCATION, AND RELATED AGENCIES  
AGRICULTURE, RURAL DEVELOPMENT,  
FOOD AND DRUG ADMINISTRATION,  
AND RELATED AGENCIES

October 4, 2018

The Honorable Scott Gottlieb, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
White Oak, RM 322346  
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

I write to express my concern regarding the Food and Drug Administration's (FDA's) oversight of shell eggs given two large, nationwide recalls so far this year alone.

FDA is responsible for ensuring that shell eggs are safe, wholesome, and properly labeled; the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) is responsible for the safety of eggs processed into egg products; USDA's Agricultural Marketing Service (AMS) sets quality and grade standards for shell eggs, such as Grade A; USDA's Animal and Plant Health Inspection Service (APHIS) manages the program that helps ensure laying hens are free from *Salmonella* at birth; and FDA oversees the safety of the feed that hens eat.

FDA issued a final Egg Safety Rule that went into effect on July 9, 2010 for egg producers with 50,000 or more laying hens. Under this rule, egg producers must implement safety standards to control risks associated with pests, rodents, and other hazards; they must purchase chicks and hens from suppliers who control for *Salmonella* in their flocks; and they must satisfy testing, cleaning, and refrigeration provisions to prevent *Salmonella*.

These large egg-producing facilities must also register with FDA and are required to maintain written plans summarizing their safety practices. Moreover, under this rule, FDA committed to inspecting more than 600 farms through 2011 to ensure that producers are complying with the rule's requirements. Starting on July 9, 2012, farms with fewer than 50,000 but at least 3,000 laying hens were required to comply with the Egg Safety Rule. At the time it was published, FDA estimated that the rule would prevent each year approximately 79,000 cases of foodborne illness and 30 deaths caused by consumption of eggs contaminated with *Salmonella*.

Nonetheless, there have been two very large outbreaks in shell eggs, resulting in the total recall of more than 206 million eggs. The *Salmonella* Braenderup outbreak, linked to eggs from Rose Acre Farms, caused 45 illnesses and 11 hospitalizations in 10 states. Inspectors at the farm where the contaminated eggs were produced found rodent infestation, ineffective pest controls, and unsanitary conditions that could contribute to the spread of pathogens such as *Salmonella*.

More recently, 38 people across 7 states have become infected with a strain of *Salmonella* Enteritidis that has been linked to Gravel Ridge Farms.

Given the potential for illness caused by shell eggs, as demonstrated by the aforementioned 2018 outbreaks, I am seeking written responses to the following questions:

1. How many inspections has FDA conducted since the 2010 regulation went into effect, and what have been the results of these inspections? What is the nature of the majority of the violations?
2. To what extent has FDA assessed the effectiveness of the egg safety rule in preventing foodborne illness?
3. To what extent has FDA collaborated with USDA agencies, including AMS, APHIS, and FSIS in overseeing shell eggs, since 2010 and especially during the 2018 *Salmonella* outbreaks?
4. How, if at all, does FDA coordinate with state and local health departments on monitoring safe handling and good manufacturing practices in shell egg processing plants? What inspection records from Gravel Ridge Farms exist, and can you provide them?
5. With regard to the 2018 outbreaks of *Salmonella* related to Rose Acre Farms and Gravel Ridge Farms, what challenges has FDA faced in identifying the cause of the outbreak, and what improvements could be taken to strengthen oversight of shell eggs and improve investigations of egg-related outbreaks of foodborne illness?

Thank you for your attention to this important issue. Should you have any questions regarding this request, please contact Christian Lovell of my staff at (202) 226-7393 or [christian.lovell@mail.house.gov](mailto:christian.lovell@mail.house.gov).

Sincerely,



Rosa L. DeLauro  
Member of Congress