

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

May 27, 2020

The Honorable Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hahn:

We write regarding the U.S. Food and Drug Administration's (FDA) efforts to ensure the supply of safe food in the United States during the coronavirus disease 2019 (COVID-19) pandemic. As the Committee continues its longstanding oversight of food safety, we appreciate FDA continuing to keep us apprised of actions the agency is taking to maintain food safety and address food supply disruptions during the pandemic.

FDA plays a critical role in ensuring the safety of the nation's food, overseeing nearly 80 percent of the food supply in the United States, and as the pandemic has progressed, FDA has taken steps to continue to fulfill this important role.¹ In an attempt to balance the need to monitor food safety with the need to protect facility inspectors, FDA suspended routine in-person inspections of domestic and foreign facilities while continuing "mission critical" domestic inspections.² Additionally, FDA has responded to food supply chain disruptions resulting from COVID-19, releasing temporary guidance for some food packaging, labeling, and distribution during the pandemic, and recently issuing a Memorandum of Understanding with the U.S. Department of Agriculture regarding FDA's role in monitoring the nation's food supply.³ The demand for eggs, for instance, has shifted during the pandemic as individuals are

¹ Government Accountability Office, *Food Safety: A National Strategy is Needed to Address Fragmentation in Federal Oversight* (Nov. 13, 2017).

² U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections* (Mar. 18, 2020) (press release).

³ U.S. Food and Drug Administration, *FDA Provides Flexibility to the Food Industry to Support Food Supply Chain and Meet Consumer Demand During COVID-19* (accessed May 27, 2020) (www.fda.gov/news-events/fda-voices/fda-provides-flexibility-food-industry-support-food-supply-chain-and-meet-consumer-demand-during); U.S. Food and Drug Administration, *USDA, FDA Strengthen Food Supply Chain Protections* (May 19, 2020) (press release).

purchasing more eggs directly from supermarkets, and large-scale food service operations, like restaurants and schools, are buying fewer eggs.⁴ FDA's temporary guidance gives producers the flexibility for eggs previously packaged and labeled for food service operations to be sold to retail establishments instead.⁵

Nevertheless, the potential spread of harmful foodborne pathogens does not stop while the nation responds to the COVID-19 pandemic. COVID-19 is not known to spread through food, but foodborne illnesses in the United States remain a public health challenge.⁶ Each year, an estimated nine million people in the United States get sick from foodborne diseases caused by known pathogens.⁷ In 2020, FDA has already conducted investigations of two foodborne pathogen outbreaks, one of which remains ongoing, that has resulted in 87 illnesses and four deaths.⁸ Just last week, FDA released a report on its investigation into *E. coli* outbreaks tied to romaine lettuce that began in September 2019 and resulted in 188 people falling ill.⁹

Following FDA's suspension of routine inspections in March, the average number of inspections per month dropped from 900 to just eight in April.¹⁰ Consumer protection advocates are concerned this reduction makes an already weak inspection system even weaker, while other experts believe the ultimate impact will be limited as the food companies themselves are the primary testers, not FDA, in assessing the safety of its product.¹¹ We too are concerned about the impact the suspension of inspections will have on the safety of our nation's food supply, and want to know more about how FDA is preparing for the inspections to resume.

FDA's responsibility to implement the Food Safety Modernization Act (FSMA) also continues, despite the COVID-19 pandemic. In recent months FDA has taken steps to address areas of FSMA still

⁴ *Id.*

⁵ *Id.*

⁶ U.S. Food and Drug Administration, *FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19* (accessed May 27, 2020) (www.fda.gov/news-events/fda-voices/fda-offers-assurance-about-food-safety-and-supply-people-and-animals-during-covid-19).

⁷ Interagency Food Safety Analytics Collaboration, *Foodborne Illness Source Attribution Estimates for 2017 for Salmonella, Escherichia coli O157, Listeria monocytogenes, and Campylobacter Using Multi-Year Outbreak Surveillance Data, United States* (Sept. 2019).

⁸ U.S. Food and Drug Administration, *Outbreaks of Foodborne Illness* (accessed May 7, 2020) (www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks-foodborne-illness).

⁹ U.S. Food and Drug Administration, *FDA Released Report on Investigation into Fall 2019 Outbreaks of Illnesses Tied to Romaine Lettuce* (May 21, 2020) (press release).

¹⁰ *Inspections, citations, recalls slashed: Coronavirus is testing America's food safety net*, USA Today (May 11, 2020).

¹¹ *Id.*

to be implemented, such as by issuing a proposed rule for a food laboratory accreditation program.¹² Further, on March 5, FDA issued a 2020 Leafy Greens Shiga toxin-producing E. coli (STEC) Action Plan to enhance prevention and response related to foodborne illnesses in these produce.¹³ The plan includes advancing a proposed rule for agricultural water, which stakeholders have been calling for in the wake of deadly outbreaks, such as among romaine lettuce.¹⁴ In addition, prior to the emergence of COVID-19 in the United States, FDA had planned to release the blueprint, “New Era of Smarter Food Safety” in March 2020.¹⁵ The initiative, announced a year ago, was intended to help create a more digital and traceable system, and foster new food safety cultures on farms and in food facilities.¹⁶ However, according to FDA Deputy Commissioner for Food Policy and Response Frank Yiannas, efforts within the agency had to shift to the pandemic response, delaying the roll-out and execution of the blueprint.¹⁷

The pandemic has also severely disrupted food supply chains. We are disturbed by reports of farms destroying millions of pounds of foods they can no longer sell due to closures of schools and businesses, while, at the same time millions of Americans who have lost their jobs are facing food insecurity.¹⁸ This is alarming and we request information about how FDA is monitoring and addressing supply chain issues. While FDA’s temporary guidance now allows eggs typically packaged for food service operations to be sold directly in retail establishments, some farmers are still having to euthanize thousands of egg-laying chickens.¹⁹ More must be done to allow food producers and operators the flexibility to sell or donate their food products to other entities in the supply chain.

¹² U.S Food and Drug Administration, *FSMA Proposed Rule on Laboratory Accreditation* (accessed May 27, 2020) (www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-laboratory-accreditation).

¹³ U.S. Food and Drug Administration, *2020 Leafy Greens STEC Action Plan* (Mar. 5, 2020).

¹⁴ *Id.*; PEW Charitable Trusts, *Romaine Lettuce Contamination Reinforces Need for Agricultural Water Quality Rule* (Jan. 7, 2019).

¹⁵ *FDA food safety leader says all OK despite fewer inspections amid pandemic*, Food Safety News (Apr. 17, 2020).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Dumped Milk, Smashed Eggs, Plowed Vegetables: Food Waste of the Pandemic*, New York Times (Apr. 11, 2020); Feeding America, *The Impact of the Coronavirus on Food Insecurity* (Apr. 22, 2020).

¹⁹ *Id.*; *Farmers are Euthanizing Thousands of Chickens Despite Surging Egg Demand*, Vice (Apr. 24, 2020).

The Honorable Stephen Hahn, M.D.

May 27, 2020

Page 4

Given the ongoing threats COVID-19 poses to the global food supply chain and the availability of safe food in the United States, we request responses to the following by June 10, 2020:

1. What information or guidelines will FDA use to determine when to restart routine in-person surveillance of domestic food manufacturing facilities and inspections of foreign food facilities or imports? Please detail any metrics that will be used in this assessment.
2. How, if at all, will FDA's response to COVID-19 impact FDA's planned actions under the 2020 Leafy Greens STEC Action Plan, including the development of a proposed rule for agricultural water?
3. What impact, if any, will the delayed release of the "New Era of Smarter Food Safety" have on FDA and the food industry's efforts to adopt new technologies, strong tracing capabilities, and foster a new culture around food safety? Does FDA intend to incorporate any lessons learned from its response to COVID-19 into the blueprint prior to its eventual release? If so, please detail how the COVID-19 response will influence the development of this blueprint.
4. How is FDA monitoring supply chain disruptions that result in food loss and waste, and working with food producers to mitigate such losses? Please detail FDA's engagement efforts with industry and other stakeholders.

Thank you for your attention to this matter. We look forward to the response and further updates as the nation faces additional consequences of COVID-19. For any questions about this request, please contact Jesseca Boyer of the Majority staff at (202) 225-2927.

Sincerely,



Frank Pallone, Jr.
Chairman



Diana DeGette
Chair
Subcommittee on Oversight
and Investigations