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## United States Senate

COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

April 11, 2022

The Honorable Robert M. Califf  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Califf:

I am deeply concerned about a new report into longstanding, significant delays and dysfunction across food safety efforts at the U.S. Food and Drug Administration (FDA). Americans rely on the FDA to ensure the food they are eating and feeding their families is safe. The FDA's failure over decades to regulate and enforce food safety standards, on issues ranging from bacteria in vegetables to arsenic in baby food, has put the health of Americans at risk. I am calling on you to make these issues a priority and take immediate action to ensure the FDA is doing all it can to fulfill all aspects of its mission to protect the health and safety of the American people.

According to a recent media report based on over 50 interviews, the FDA's food safety efforts have received little attention within the agency and have been beset by delays and management challenges for years.<sup>1</sup> Despite overseeing nearly 80 percent of the American food supply, the FDA's predominant focus, the investigation found, has been on drugs and devices, while food safety issues have not been prioritized by senior leadership. Over the last decade, the food safety program has languished with delays across inspections and the development and issuance of safety standards. As one former acting FDA Commissioner put it, the food program is "on the back burner" at the agency. Other officials described the program as "impossible," "broken," "byzantine," and "a joke."

This report highlighted several delays in regulatory action that have endangered the public health. Over a decade after the Food Safety Modernization Act was implemented, the FDA has yet to issue safety standards required by the law, and hundreds of people have been sickened due to foodborne illness. Despite recognition within the agency of the danger of toxic elements in baby food, the FDA has not imposed strict safety standards, even as report after report has identified unacceptably high levels of lead, arsenic, mercury, cadmium, and other toxins in baby food. The agency has not even finalized long-term voluntary reduction targets for sodium in food, despite a recommendation to do so in 2010.

I am further concerned by the agency's failure to ensure timely inspections and recalls, which are critical for ensuring food is free of bacteria and other harmful contaminants. According to the

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<sup>1</sup> <https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/>

report, the number of FDA food safety inspections has generally decreased over time. Inspections are also often delayed. For example, I have sought answers from both Abbott Nutrition and the FDA regarding potential bacterial contamination of Abbott’s infant formula, which has been associated with multiple hospitalizations and deaths.<sup>2</sup> The FDA first received a report of these issues in September 2021, but failed to initiate an inspection of the manufacturing plant until January, before a voluntary recall in February.<sup>3</sup> The FDA has since found serious sanitation issues at the facility.<sup>4</sup> FDA inspections for facilities manufacturing other food products have also failed to identify the causes of bacteria in produce, and the agency has often waited months prior to issuing product recalls.<sup>5</sup>

These delays actively endanger the health and safety of the American people. Every year, approximately one in six Americans get sick and 3,000 die from foodborne diseases.<sup>6</sup> Exposure to toxic metals and chemicals like arsenic, lead, and cadmium – especially for children – have been linked with a higher risk of serious illness, lifelong impairment, and death.<sup>7</sup> The effects of poor nutrition are also significant. For example, a new analysis focused just on salt intake estimates the FDA’s delay in finalizing sodium targets in food may result in over 260,000 deaths.<sup>8</sup>

You have the opportunity to address these longstanding issues and reform the way FDA handles these longstanding food safety and nutrition issues. During your confirmation hearing, you committed to me you would “hit the ground running” and prioritize consumer and patient protection issues.<sup>9</sup> I am calling on you to fulfill that promise and take immediate action to ensure the FDA’s food safety efforts are robust, timely, and effective in keeping the American people healthy and safe.

In addition, I request the following information no later than April 25, 2022:

1. What steps are you taking or planning to take to improve the FDA’s food safety efforts, including the timeliness and rigor of regulatory and enforcement activities?
2. The recent news report highlights significant, years-long delays in addressing water used to grow produce, toxic substances in baby food, and sodium levels in food. Has the FDA assessed the causes of these delays? If so, please provide the results or findings of any such assessment. If not, please explain why such assessments have not been conducted and if there are any plans to do so.
3. The report indicates that an organizational change made under the Trump Administration may have further hampered FDA’s food safety efforts. What steps, if any, are you

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<sup>2</sup> Letter from Senators Patty Murray and Bob Casey to Abbott Nutrition (Feb. 24, 2022); Briefing from FDA Staff (March 16, 2022).

<sup>3</sup> <https://www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226>

<sup>4</sup> <https://www.fda.gov/media/157073/download>

<sup>5</sup> <https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/>

<sup>6</sup> <https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>

<sup>7</sup> <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food-a6772370847/>

<sup>8</sup> <https://www.ahajournals.org/doi/abs/10.1161/HYPERTENSIONAHA.121.18475>

<sup>9</sup> <https://www.help.senate.gov/imo/media/doc/Califf2.pdf>

considering to ensure the FDA's organizational structure supports timely and effective decision-making on food-related issues?

4. For each year over the past ten years, how many:
  - a. Food safety inspections has the FDA conducted? Please provide a breakdown by inspection type;
  - b. Food and food packaging samples did the FDA test for toxic elements? Please provide a breakdown by food and packaging type. Please provide the results of any such tests for any products intended for infants or young children.

Thank you for your attention to this matter. Please direct any correspondence pertaining to this request to Yelena Tsilker at [Yelena\\_Tsilker@help.senate.gov](mailto:Yelena_Tsilker@help.senate.gov).

Sincerely,

A handwritten signature in blue ink that reads "Patty Murray". The signature is written in a cursive, flowing style.

Chair  
U.S. Senator Committee on Health, Education,  
Labor, and Pensions

cc: Senator Richard Burr  
Ranking Member