

United States Senate
WASHINGTON, DC 20510

May 2, 2024

Commissioner Robert M. Califf, M.D.
U.S. Food and Drug Administration
10902 New Hampshire Avenue
Silver Spring, MD 20993

Secretary Thomas Vilsack
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, D.C. 20250

Director Mandy Cohen, M.D., M.P.H.
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Commissioner Califf, Secretary Vilsack, and Director Cohen:

I am alarmed by reports about the rapid spread of the bird flu virus (H5N1), and concerned that your agencies are not moving quickly enough to understand and contain the outbreak. It is critical that you work swiftly to get ahead of this emerging situation and reassure the American public that they – and our food supply – remain safe. Given your agencies' recent experience with the COVID-19 pandemic and baby formula shortage, I am concerned that once again our federal government and its interagency process appears to be caught flat-footed.

On March 25, 2024 the United States Department of Agriculture (USDA) confirmed the first case of H5N1 in dairy cattle.¹ Subsequently, on April 1, 2024, the Centers for Disease Control and Prevention (CDC) confirmed the second-ever human case of this strain in the United States.² Thankfully, cases of human-to-human transmission have not yet been reported.³ But, I am concerned by the FDA's recent report that one in five samples of milk now contains fragments of the virus.⁴

The responsibility of protecting American consumers and livestock from threats like bird flu is a joint effort between the USDA, the Food and Drug Administration (FDA), and the CDC. Critical questions remain unanswered regarding the transmission and spread of the virus, requirements for testing livestock, and the safety of our milk and beef supply in the United States.⁵

¹ USDA, [*Federal and State Veterinary, Public Health Agencies Share Update on HPAI Detection in Kansas, Texas Dairy Herds*](#)

² CDC, [*U.S. Case of Human Avian Influenza A\(H5\) Virus Reported*](#)

³ National Library of Medicine, [*Recent Changes in Patterns of Mammal Infection with Highly Pathogenic Avian Influenza A\(H5N1\) Virus Worldwide*](#)

⁴ FDA, [*Updates on Highly Pathogenic Avian Influenza \(HPAI\)*](#)

⁵ USDA, [*APHIS Requirements and Recommendations for Highly Pathogenic Avian Influenza \(HPAI\) H5N1 Virus in Livestock For State Animal Health Officials, Accredited Veterinarians and Producers*](#)

It is essential that you move to fill the existing gaps in our public health knowledge by conducting sound science and quickly disseminating accurate information. Please submit your agency's responses to the following questions as soon as possible, and no later than May 10, 2024.

1. What specific steps are your agencies currently taking to contain the bird flu outbreak and ensure it does not spread further among humans?
2. Are your agencies confident that the commercial milk and beef supply is safe for consumption? If not, what additional testing is necessary to confirm that this is the case and when will that testing be completed?
3. What risks do the high levels of inactivated virus found in milk pose to humans? Could the virus be reactivated?
4. USDA is currently only mandating testing in lactating cattle prior to interstate transport.⁶
 - a. Why has USDA limited testing only prior to interstate transport?
 - b. What percentage of dairy cattle are not transported across state lines? Are the current testing requirements missing a critical percentage of infected cattle and allowing the outbreak to spread?
 - c. USDA announced that it is testing beef samples, but only in states with confirmed outbreaks.⁷ Given confirmed asymptomatic infections and other indications that the outbreak may be more widespread than we know,⁸ why is USDA not rapidly testing beef in all 50 states?
5. Are USDA, FDA, and CDC conducting proactive, joint surveillance and sharing information across agencies to proactively detect unusual bird flu activity in wild animals, livestock, or humans? Are there federal programs, like the CDC's National Wastewater Surveillance System (NWSS), that are tracking or have the capacity to track existing and emerging infectious diseases on farms?
6. What steps are you taking to proactively inform and protect agricultural frontline workers on H5N1 precautionary measures, actions needed in the case of an exposure, and symptoms?

⁶ USDA, [*Federal Order Requiring Testing for and Reporting of Highly Pathogenic Avian Influenza \(HPAI\) in Livestock*](#)

⁷ Reuters, [*US to test ground beef in states with bird-flu outbreaks in dairy cows*](#)

⁸ CBS News, [*U.S. orders cow testing for bird flu after grocery milk tests positive*](#)

7. Federal researchers have identified a genetic mutation in a recently confirmed case of bird flu in a dairy cow that suggests the current strain of H5N1 in the U.S. has adapted to spread better in mammals.⁹
 - a. Which federal agencies are currently conducting assessments on the capability of H5N1 to continue mutating and present increased risk to humans?
 - b. Are studies being conducted on the likelihood of genetic adaptation that allows for human-to-human transmission?

Sincerely,

A handwritten signature in blue ink that reads "Mitt Romney". The signature is fluid and cursive, with the first name "Mitt" and last name "Romney" clearly distinguishable.

Mitt Romney
United States Senator

⁹ CBS News, [*U.S. orders cow testing for bird flu after grocery milk tests positive*](#)