

FDA Research Agenda for 2024 Highly Pathogenic H5N1 Avian Influenza

H5N1

Highly Pathogenic H5N1 Avian Influenza (H5N1 HPAI) was first detected in cattle in March 2024 and has now been reported in multiple states. Infection of dairy cattle is a relatively novel presentation of influenza, so there are significant research needs to be addressed to protect human and animal health. In response, the United States Food and Drug Administration (FDA) has initiated research efforts to address the impact and risk of this outbreak.

FDA, alongside our federal and state partners, is following a stepwise approach to our scientific analysis of commercial milk safety during the first-of-its-kind detection of HPAI H5N1 in dairy cattle. While our initial assessment of the milk safety system continues to be affirmed by sampling and testing of retail dairy products, there remain a number of collective activities being undertaken to ensure the continued effectiveness of the federal-state milk safety system. FDA is continuing to follow a sound scientific process to inform the agency's public health decisions related to food safety as outlined in the following research agenda.

FDA is completing its research and testing in partnership with both the U.S. Department of Agriculture's US National Poultry Research Center and Animal and Plant Health Inspection Service's National Veterinary Services Laboratory. Certain research studies will be completed in partnership with universities.

Objective 1: Understand characteristics of inactivation methods for H5N1 in dairy products

Investigating temperature thresholds and duration required to effectively neutralize H5N1 HPAI virus is necessary to better understand inactivation methods. FDA is working on multiple efforts to understand the effectiveness of pasteurization and other inactivation methods.

Focus area 1: Pre-Pasteurization Milk Samples. Testing pooled raw milk samples can be used as a basis to characterize potential virus levels that pasteurization may encounter. FDA is continuing to work with states on additional efforts to sample and build data on pre-pasteurization samples at different points in the milk production and processing system. FDA is also exploring innovative data management solutions like data trusts as a potential way to organize and aggregate dynamic data sources in different types of analyses.

Focus area 2: Bench-top Thermal Inactivation Kinetics Studies. Bench-top equipment studies will provide information on an estimation of the time and temperature needed for inactivation of H5N1 HPAI virus in milk and milk products.

Focus area 3: Continuous Flow Pasteurization Studies. Studies using continuous flow pasteurization equipment, reflective of those in commercial use, help confirm pasteurization parameters effective at inactivating H5N1 HPAI virus in milk processes.

Focus area 4: Raw Milk Cheese Aging. The purpose of these studies is to assess the survival of H5N1 HPAI virus in raw milk cheeses under various parameters over the aging process.

Objective 2: Determine the safety of retail dairy products

Ensuring the safety of retail milk is a primary objective given the high viral loads found in some affected unpasteurized milk. Evaluation of retail milk is critical for safeguarding public health and supporting confidence in the dairy supply chain.

Focus area: Retail Milk Sample Testing. Initial sampling of retail milk provided preliminary information on how much, if any viable H5N1 HPAI virus survives commercial processing. A second round of nationally representative sampling will further this effort. FDA expects to conduct additional post-pasteurization testing to continue to monitor these products in the future.

Objective 3: One Health interventions for H5N1 HPAI

H5N1 HPAI virus poses a threat to animal and human health as well as to agricultural economies. Addressing the challenges posed by H5N1 HPAI virus requires a multisectoral approach. The FDA is using a One Health strategy to mitigate the impact of H5N1 HPAI virus.

Focus area: One Health Interventions. Develop One Health interventions to prevent, control, or eliminate H5N1 HPAI in animals, milk, and the environment, for example, strategies to decrease the impact of H5N1 HPAI, interventions to prevent or control spread of H5N1 HPAI, and alternative viral inactivation and disposal methods for discard milk.