



U.S. DEPARTMENT OF AGRICULTURE

September 30, 2024

To the Dairy Processing Industry,

The Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and our federal and state partners continue to work diligently through an all-of-government response to the outbreak of Highly Pathogenic Avian Influenza A (H5N1) in dairy cattle. As part of these ongoing efforts, FDA encourages dairy farmers to participate in the USDA voluntary Dairy Herd Status Program and other voluntary H5N1 monitoring studies being discussed between FDA, USDA, and state regulatory partners – including the Silo Sampling Study coordinated by FDA, the National Conference on Interstate Milk Shipments, and USDA. These programs take a One Health approach to inform ideas and ways to reduce the risk this virus poses to dairy cattle herds and other animal industries, as well as human health. Industry, state, and federal partners will gain better insight into this virus through coordinated and effective initiatives that collect information and reduce H5N1 circulation. Reducing the circulation of this virus protects our nation’s herds, flocks, people, and prosperity.

The FDA and USDA are aware of concerns that commercial milk processors might reject milk from dairy premises identified as having or possibly having H5N1 infections in their herds. This concern could discourage participation in voluntary surveillance and sampling programs intended to expand knowledge of the disease and inform programs to reduce circulation of H5N1. Participation by commercial milk producers and processors is critical. FDA and USDA have demonstrated through two studies of products on retail shelves and a laboratory investigation of pasteurization using real-world equipment that pasteurization is effective at completely neutralizing H5N1 in milk and dairy products made from pasteurized milk.

The FDA and USDA are confident that pasteurization is effective at inactivating H5N1 in raw milk as it is for the pathogens against which we began pasteurizing raw milk 100 years ago. Based on the information currently available during this outbreak, our commercial milk supply is safe. FDA expects that the Grade “A” Pasteurized Milk Ordinance (PMO) requirements and existing quality management systems will ensure that clinically ill cows producing abnormal milk will be segregated from the milking herd, thus reducing the potential level of H5N1 virus in raw milk produced. As with many bovine pathogens, asymptomatic and pre-symptomatic shedding can occur, and thus raw milk bound for processors might not be free of virus. FDA’s High Temperature Short Time (HTST) pasteurization study showed it was completely effective in inactivating the levels of viable virus found in a multi-state sampling of raw, pre-pasteurized milk bound for pasteurization.

FDA initially assessed the commercial, pasteurized milk supply as safe in late March 2024. FDA based this initial assessment on a critical review of existing scientific literature, data on pasteurization’s effectiveness against pathogens previously identified in raw milk, and FDA’s century of real-world evidence from the United States milk safety system. Further, FDA was aware of a study that showed pasteurization against H5N1 in egg products was effective in inactivating the virus at times and temperatures typically lower than those used in milk pasteurization. FDA confirmed its initial assessment through three pivotal studies: a sampling study of 297 commercial pasteurized retail products, an HTST pasteurization validation study, and a sampling study of

167 commercial pasteurized retail products. These studies confirmed that pasteurization inactivates H5N1 and protects public health.

FDA's pasteurization study, published in the [Journal of Food Protection](#), as well as the retail dairy product sampling test results can be found on FDA's HPAI website here: [Updates on Highly Pathogenic Avian Influenza \(HPAI\) | FDA](#). More information on USDA's voluntary herd status program is available here: [Dairy Herd Status Program | Animal and Plant Health Inspection Service \(usda.gov\)](#)

We respectfully request that you consider educating your customers that the pasteurization process, used for decades to kill harmful pathogens, is also effective in inactivating H5N1 in raw milk. FDA and USDA are eager to hear from and meet with processors if there are questions regarding FDA's assessment of the ability of the milk safety system, including pasteurization, to address H5N1.

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