U.S. DEPARTMENT OF AGRICULTURE

September 30, 2024

To Dairy Retailers,

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 efforts, FDA encourages dairy farmers to participate in the USDA voluntary Dairy Herd Status Programs as well as future 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 will take a One Health approach to reducing the risk to dairy cattle herds and other animal industries, as well as human health. Industry, state, and federal partners will gain more insight through coordinated and effective initiatives that collect data and reduce H5N1 circulation. By reducing the presence of the virus, we are working together to protect our nation's herds, flocks, people, and prosperity.

Participation by commercial milk producers and processors in voluntary surveillance and sampling programs is important step. The FDA and USDA are aware of concerns that commercial milk processors might decline milk from dairy producers identified as having or possibly having H5N1 infections in their herds. FDA and USDA, however, have demonstrated through two studies of products on retail shelves and a laboratory investigation of pasteurization that pasteurization is effective at completely inactivating 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 just as it is effective against the pathogens for 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 highly 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 assessment on a 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 then 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, completed in partnership with USDA, 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 and producer support programs are

available here: Dairy Herd Status Program | Animal and Plant Health Inspection Service (usda.gov). We ask for your assistance in educating consumers that the pasteurization process used for decades as part of our safe milk supply, is also effective in inactivating H5N1 in raw milk. FDA and USDA would be pleased to meet with retailers to answers any questions.

We remain committed to protecting the safety of our milk and food supply, ensuring consumer confidence, and promoting animal and human health throughout the United States.

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James J. Jones
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration

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Eric Deeble, VMD
Deputy Under Secretary
Marketing and Regulatory Programs
U.S. Department of Agriculture