

June 6, 2024

Dear State, Territorial, Local and Tribal Health Partners:

We are grateful for your continued partnership as we collectively work to address new developments related to the presence of High Pathogenic Avian Influenza A H5N1 (HPAI H5N1) in dairy cattle. The assistance and feedback we have received from our regulatory partners at state Departments of Agriculture and Health is invaluable.

We share a common goal of ensuring the safety of our nation's milk supply. To that end, we are providing our latest thinking and science-based recommendations on unpasteurized, raw milk with respect to HPAI H5N1 virus. Evidence demonstrates that cattle infected with the HPAI H5N1 virus shed the virus in their milk. All raw milk produced from herds with HPAI H5N1 infections has the potential to contain infectious HPAI H5N1 virus since it will not be subject to pasteurization.

Given the current and potential future risks that HPAI H5N1 virus poses to our nation's public health, as well as the health of our nation's food-producing animals and wildlife, it is important to work together to minimize additional exposure of humans and other animal species to the HPAI H5N1 virus to reduce the potential for additional HPAI H5N1 infections and reduce the virus's opportunity to adapt to new hosts. Because raw milk has the potential to contain viable (live) HPAI H5N1 virus, it represents a potential route of consumer exposure to the virus. Based on the limited research and information available, we do not know at this time if the HPAI H5N1 virus can be transmitted to humans through consumption of raw milk and products made from raw milk from infected cows. However, exposures on affected farms are associated with three documented cases of H5N1 illness in dairy workers.

While the introduction into interstate commerce of raw milk for human consumption is prohibited under the FDA's authority<sup>1</sup>, we know that a number of states permit the intrastate sale of raw milk for human consumption, with varying structures and requirements to these state programs. Because of our concerns related to HPAI H5N1 virus in raw milk, we are providing the following recommendations for states as we continue to work together to address this novel issue:

- Distribute messaging to the public about the health risks of consuming raw milk and raw milk products. Health risks include illness, miscarriages, stillbirths, kidney failure and death. (source: Food Safety and Raw Milk | FDA)
- Monitor dairy cattle herds for signs of illness that would indicate infection with the HPAI H5N1 virus.
  - o Producers should continue to discard milk, with suitable protocols, from symptomatic cows.
  - o Any raw milk or raw milk products from exposed cattle that are fed to calves or any other animals should be heat-treated or pasteurized. Exposed cattle are those located on a premises

<sup>&</sup>lt;sup>1</sup> 21 CFR 1240.61.

with cattle with suspected or confirmed infections with HPAI H5N1 viruses. Many State Cooperative Extension Service programs have published detailed information on how to pasteurize or otherwise effectively treat waste milk before using it to feed calves (for example, Penn State - Pasteurization of Non-Saleable Milk<sup>2</sup>).

- Implement a surveillance testing program in your state to identify the presence of HPAI H5N1 virus
  in dairy herds that might be engaged in producing raw milk for intrastate sale. For states that
  implement such a surveillance testing program, sharing data and testing results with their dairy
  regulatory partners (state, FDA, and USDA) will allow for coordinated management of this novel
  virus. Upon request, FDA will provide technical assistance and methodologies for sampling or
  testing.
- For states that permit the sale of raw milk within their state, use regulatory authorities or implement other measures, as appropriate, to stop the sale of raw milk that may present a risk to consumers. This may include restricting the introduction of raw milk that may contain viable HPAI H5N1, for human or animal consumption, within a defined geographic area, or within your state. If HPAI H5N1 virus is identified within a herd, there is a risk that viable HPAI H5N1 virus could be present in raw milk from the herd, even when clinically ill cows are segregated.

We are committed to continuing to work with our partners to minimize the risks of HPAI H5N1 virus in raw milk and raw milk products. Last month, CDC provided guidance to healthcare professionals on communicating with the public about the risks of consuming raw milk<sup>3</sup>. In addition, USDA announced a voluntary dairy herd status program along with potential resources on May 30, 2024<sup>4</sup>.

The FDA is responsible for protecting the public health by ensuring the safety of our nation's food supply. Sharing the agency's recommendations on raw milk and raw milk products with our regulatory partners is part of that responsibility. We intend to share new research and data on both HPAI H5N1 virus in raw milk and raw milk products. We appreciate your attention and continued support and welcome the opportunity to work with you on any of these recommendations.

Sincerely,

Donald A. Prater, DVM Agency Incident Coordinator Acting Director, Center for Food Safety and Applied Nutrition

<sup>&</sup>lt;sup>2</sup> Pasteurization of Non-Saleable Milk (psu.edu)

<sup>&</sup>lt;sup>3</sup> https://www.cdc.gov/flu/avianflu/unpasteurized-raw-milk.htm; https://www.cdc.gov/food-safety/foods/raw-milk.html

<sup>&</sup>lt;sup>4</sup> https://www.usda.gov/media/press-releases/<u>2024/05/30/usda-announces-824-million-new-funding-protect-livestock-health</u>