

# Interim HPAI Virus Biosafety Recommendations and Resources for Industry Laboratories and State Dairy & Dairy Product Laboratories

*Disclaimer: These recommendations were distributed via an email from FDA to the Association of Public Health Laboratories, but have not yet been officially published by the FDA.*

With the identification of Highly Pathogenic Avian Influenza (HPAI) virus in raw milk from dairy cattle, there is a need for biosafety recommendations for industry and state dairy laboratories whose functions do not include pathogen testing. The purpose of this email is to provide these laboratories with general information and resources on biosafety measures. Specific recommendations for laboratorians working in these settings may be updated as more is learned during this evolving situation. Safety of laboratory personnel working with milk and milk products that could contain infectious HPAI virus requires a site-specific and activity-specific risk assessment (henceforth, “risk assessment”). Laboratory personnel can also refer to the [CDC interim recommendations regarding clinical symptoms](#) and reporting of illnesses.

The risk assessment should consider that each laboratory has a differing physical facility set-up; internal processes for handling, testing, and disposing of samples; and routes of exposure, such as aerosols, droplets, and direct contact, for laboratory personnel. To provide information laboratories may consider in their risk assessment, an interagency group from the Centers for Disease Control and Prevention (CDC), United States Department of Agriculture (USDA), and Food and Drug Administration (FDA) developed the following considerations and references for industry and state dairy laboratories. This is not all-inclusive, and laboratories are encouraged to work with state officials, occupational health specialists, municipalities (waste disposal), biosafety professionals, and other relevant stakeholders to develop a comprehensive risk assessment appropriate to their specific laboratory environment. For guidance on conducting risk assessments for laboratory activities see [Biological Risk Assessment: General Considerations for Laboratories](#).

## Novel Influenza A Viruses Including HPAI Virus and Select Agent Status

HPAI virus is a Biological Select Agent or Toxin (BSAT), and its possession, use, and transfer are regulated by the Federal Select Agent Program (FSAP) which is a joint regulatory responsibility of the CDC Division of Regulatory Science and Compliance (DRSC) and the USDA Division of Agricultural Select Agents and Toxins (DASAT). HPAI virus is an agricultural-only agent, so primary regulatory authority comes from DASAT.

On June 6, 2024, DASAT, through its exemption authority, exempted H5 Avian Influenza Virus, which includes the strain currently involved in the outbreak in U.S. dairy cattle, from the requirements of the select agent regulations for a period of three years. You can find more details on the FSAP website at [www.selectagents.gov](http://www.selectagents.gov), including the select agent group contact information.

However, this will not change the programmatic requirements associated in the United States. Non-negative test results for influenza A virus from avian and livestock species detected at member laboratories of the National Animal Health Laboratory Network (NAHLN) will be forwarded to the National Veterinary Services Laboratory (NVSL) for confirmatory testing, with the exception of expected H1 or H3 subtypes in swine with typical presentations guided under a separate APHIS program.

It also does not reduce the need to continue implementing appropriate biosafety and biosecurity measures when handling influenza A/H5N1 suspect samples.

# Biosafety Recommendations for Raw Milk Samples

Samples of raw milk should be treated as potentially infectious and handled with standard precautions and safe laboratory practices which include the following:

- Treat samples as potentially infectious;
- Refrain from touching your face while working with samples;
- Wear gloves when directly handling samples, where applicable;
- Wash hands after removing gloves and before leaving the laboratory;
- Clean and disinfect laboratory surfaces and equipment with [registered antimicrobials effective against Avian Influenza virus](#); and
- Decontaminate all contaminated or potentially contaminated waste via an approved mechanism [e.g., heat (autoclave), chemical] prior to disposal. Conduct appropriate waste management for disposal of contaminated and potentially contaminated waste by following all local, state, regional, and national waste requirements.

A biosafety risk assessment should be conducted prior to any sample handling or analysis of potentially infectious raw milk to identify appropriate control measures to protect employees, the public, and the environment.

**For Biosafety Level 2 (BSL-2) laboratories** with an established biological risk assessment process, follow that process to determine appropriate control measures for activities involving raw milk samples.

**For laboratories not routinely operating at a BSL-2 (for example, drug residue testing in a chemistry laboratory),** perform a risk assessment to evaluate the risks for all activities related to raw milk handling and testing. Control measures identified in the risk assessment should be used in addition to any existing safety measures for the analytical process.

**For Central Milk Testing Laboratories** performing the required National Conference on Interstate Milk Shipments (NCIMS) testing procedures on raw, unpasteurized milk samples in certain laboratory settings, the laboratories may choose to relocate this testing to areas within the laboratory where a certified Class II biosafety cabinet (BSC) can be utilized, or BSL-2 level areas which have not been observed during an evaluation by the FDA Center for Food Safety and Applied Nutrition (CFSAN) Laboratory Proficiency and Evaluation Team (LPET). We ask that laboratories reach out to the FDA Laboratory Proficiency and Evaluation Team at CFSAN [LEOReports](#) regarding relocation requests. The request should include: 1) BSL level, including the presence or absence of a BSC, 2) available personal protective equipment (PPE), and 3) any other biosafety measures to be implemented in the alternate laboratory location.

For laboratories that do not have established biosafety risk assessment protocols, advice is available from the Biosafety in Microbiological and Biomedical Laboratories (BMBL 6th edition).

Recommendations from CDC on worker protection and PPE is available from the [Reducing Risk for People Working with or Exposed to Animals](#).

## Online Resources for Novel Influenza A Viruses Including Highly Pathogenic Avian Influenza

### Federal Agency (CDC, USDA, FDA) HPAI Updates

- CDC: [Information on Bird Flu](#)
- USDA: [Highly Pathogenic Avian Influenza \(HPAI\) Detections in Livestock](#)
- FDA: [Updates on Highly Pathogenic Avian Influenza](#)

### Select Agents

- [Federal Select Agent Program \(FSAP\)](#)
- [FSAP: Select Agents and Toxins Exemption: H5 Avian Influenza Virus](#)

## Biosafety

- CDC: [Biological Risk Assessment: General Considerations for Laboratories](#)
- CDC: [Biosafety in Microbiological and Biomedical Laboratories 6th Edition, Section II – Biological Risk Assessment, pages 9-20 and Section IV -Laboratory Biosafety Level Criteria, pages 32-69](#)
- OSHA: [Avian Influenza - Control and Prevention](#)
- EPA: [Registered Antimicrobial Products Effective Against Avian Influenza \[List M\]](#)

## Worker Safety

- OSHA [Avian Flu | Laboratory Workers](#)
- OSHA: [Safety Management - A safe workplace is sound business](#)
- CDC: [Updated Interim Recommendations for Worker Protection and Use of Personal Protective Equipment \(PPE\) to Reduce Exposure to Novel Influenza A Viruses Associated with Disease in Humans](#)

## Waste Management

- EPA: [State Universal Waste Programs in the United States](#)
- EPA: [Resource Conservation and Recovery Act \(RCRA\) Regulations](#)
- DOT: [Planning Guidance for Handling Category A Solid Waste | PHMSA](#)