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## **Quarterly Dairy Legal Webinar Series**

#### #18 in the series – covering the 4th quarter of 2024

- October 2024: Raw Milk—An Overview of State Raw Milk Regulations
- July 2024: U.S. State Milk Pricing & Supports, part 2
- April 2024: U.S. State Milk Pricing & Supports, part 1
- February 2024: Pennsylvania Milk Marketing Law (Beyond the OOP)
- October 2023: Risk Management/Income & Revenue Protection
- July 2023: Federal Milk Marketing Order Administrative Process
- April 2023: International Dairy Trade
- January 2023: Interstate Regulation of Milk Production and Processing
- October 2022: 2023 Farm Bill and the Potential Implications for the Dairy Industry
- July 2022: Labeling Standards
- April 2022: Animal Welfare
- February 2022: Dairy Industry Carbon Reduction Programs
- December 2021: USDA's Pandemic Assistance Programs
- July 2021: Geographical Indications
- April 2021: Federal Milk Marketing Order Reform
- January 2021: International Trade with Becky Rasdall
- October 2020: Federal Milk Marketing Order 51



Find upcoming topics at <a href="https://aglaw.psu.edu/quarterly-dairy-legal-webinar/">https://aglaw.psu.edu/quarterly-dairy-legal-webinar/</a>



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#### Snale Law Weekly Review

A WEEKLY UPDATE ON IMPORTANT SHALE LAW DEVELOPMENTS





#### Past Quarterly Dairy Legal Webinars and Materials

April 18, 2023 (1st Quarter of 2023) 12 noon ET. In addition to a round-up of quarterly legal developments, the focus topic will be the International Dairy Trade: Canada-U.S. USMCA Arbitration Round 2. Almost immediately upon entering the USMCA trade pact with Canada and Mexico in 2020, the U.S. trade relationship with Canada hit a rough patch over potential dairy exports to Canada, specifically the eligibility criteria for Canadian importers' potential use of a quota of favorable dairy tariff rates on U.S. dairy products. The U.S. took Canada to arbitration in 2021 and won. Nevertheless, Canada held steadfast to its dairy tariff rate quota system and made minimal changes. As a result, we are now headed to a second round of USMCA arbitration between the U.S. and Canada over the same, and some newly added, tariff rate eligibility issues. All will be explained as we examine the details of this dispute between international neighbors.

- PowerPoint April 2023 Quarterly Dairy Legal Webinar
- January-March 2023 Quarterly Dairy Legal Update
- Recording: April 2023 Quarterly Dairy Legal Webinar Industry Round Up
- Recording: April 2023 Quarterly Dairy Legal Webinar International Dairy Trade

January 17, 2023 (4th Quarter of 2022) 12 noon ET. In addition to a round-up of quarterly legal developments, the focus topic will be the Interstate Regulation of Milk Production and Processing: An Overview of the Pasteurized Milk Ordinance and Interstate Milk Shippers Program. The federal government's current role in the creation and maintenance of a federal milk pricing system is recognized. The historical state-by-state regulation of milk production and processing as a food safety function of government is sometimes said to be historically "left to the states." However, the reality is much more complex. Learn the nuts and bolts of how this most perishable of agricultural commodities has been freely flowing across state lines through a combination of federal and state regulatory authority and a large amount of voluntary industry contribution and compliance.

- 2022 Annual Dairy Legal Update 📙
- October-December 2022 Quarterly Dairy Legal Update
- PowerPoint January 2023 Quarterly Dairy Legal Webinar 📙
- · Recording: January 2023 Quarterly Dairy Legal Webinar

https://aglaw.psu.edu/quarterly-dairy-legal-webinar/



## More upcoming programs from the Ag Law Center.

## **Understanding Agricultural Law Series**

Understanding the Basics of--

Feb. 28, 2025—Pesticide Drift

Mar. 28, 2025—Clean Water Act & Ag: Impaired Waters & TMDL Process

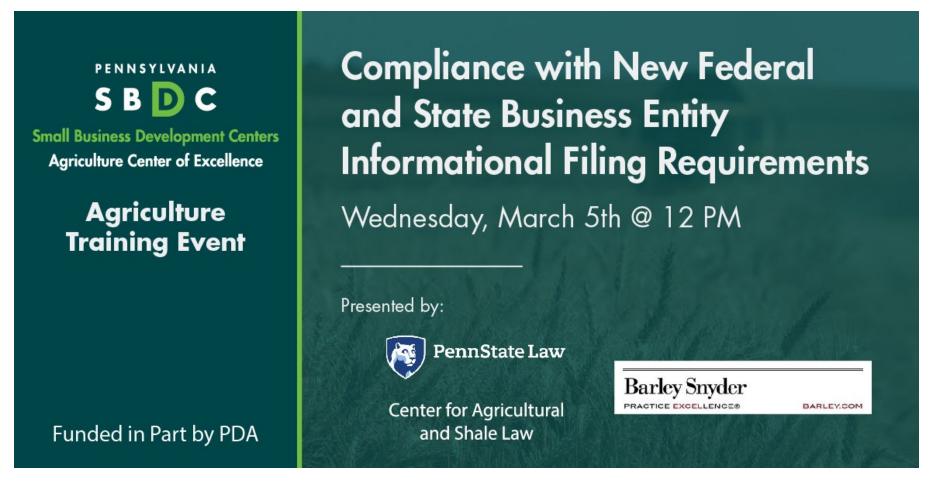
Apr. 25, 2025—PA Ag Exemptions for Inheritance Tax and Real Estate Transfers

## **Quarterly Dairy Legal Webinar Series:**

April 15, 2025—1st Quarter of 2025: Bovine Disease Controls: Federal and PA Laws & Regulations



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- This webinar will be recorded.
- Use the Q&A feature for questions.
- CLE credits:
- Link will be posted in the chat
  - Please fill out form
  - Listen for code word
  - Questions?
    - Email: aet17@psu.edu



## Center for Agricultural and Shale Law

## Industry Round-up – 4<sup>th</sup> Quarter 2024

- U.S. Department of Agriculture (USDA) Actions
  - USDA announced funding for dairy initiatives
  - USDA released final decision on FMMO pricing changes
  - USDA issued raw milk testing order and national strategy
- U.S. Food and Drug Administration (FDA) Actions
  - FDA published final rule on "healthy" food claim
  - FDA announced human foods program FY 2025 priorities
- Regional Dairy Actions & Issues
  - Federal court dismissed suit alleging milk marketing protections rules violate student speech
  - PDA issued new bulk milk testing order

### **USDA** Announced Funding for Dairy Initiatives

- The USDA granted \$11.04 million in funding for the Dairy Business Innovation (DBI) Initiatives
- The fund will be awarded "noncompetitively" to DBI programs at California State University Fresno, the University of Tennessee, Vermont Agency of Agriculture, Food & Markets, and the University of Wisconsin.
- "To date, the Initiatives have invested over \$64 million into more than 600 projects that are increasing dairy supply chain resiliency, creating new markets, and expanding economic growth in rural economies ... The initiatives will use the funding to provide valuable technical assistance and subaward funds to dairy farmers and businesses across their regions, supporting them with business plan development, marketing, and branding, as well as increasing access to innovative production and processing techniques to support the development of value-added products."

USDA Press Release, <u>USDA Invests more than \$11 Million to Support Resiliency in U.S. Dairy Industry</u> (October 4, 2024)



#### **USDA** Released Final Decision on FMMO Pricing Changes

- USDA Agricultural Marketing Service (AMS) <u>published</u> **final recommendations** on milk pricing formulas for all 11 Federal Milk Marketing Orders (FMMOs)
- Five key recommendations:
  - **Updating milk composition standards**—adjusting composition percentages: 3.3% protein, 6% other solids, and 9.3% nonfat solids.
  - Changing cheese price calculations—using only 40-lb cheddar blocks to determine the monthly average cheese price.
  - **Revising "make allowances"**—updating processing cost estimates and adjusting the butterfat recovery rate to 91%.
  - Returning to the "higher of" pricing method—revert to using the "higher of" Class III or Class IV prices
    for setting the base price for Class I skim milk and adding an adjustment for Extended Shelf Life (ESL)
    milk.
  - Adjusting location-based price differences—maintaining the base adjustment at \$1.60 while refining regional price values.



#### **USDA** Released Final Decision on FMMO Pricing Changes

- Final decision highlights:
  - Faster implementation of revised skim milk composition factors (6 months instead of 12 months)
  - Inclusion of a \$0.0015 per unit cost adjustment in "make allowances"
  - Adjusted calculation method for nonfat dry milk costs
  - Minor revisions to Class I (fluid milk) county-specific price differences
- Dairy producers voted on changes by January 15, 2025, with at least two-thirds in favor.
  - USDA AMS <u>published</u> a final rule on January 17, 2025 (further discussion scheduled for the next webinar session).



#### **USDA** Issued Raw Milk Testing Order and National Strategy

- USDA Animal and Plant Health Inspection Service (APHIS) <u>issued</u> a federal order, along with <u>guidance</u>, requiring nationwide raw milk collection and submission for HPAI testing.
  - Raw milk testing requirements
    - Dairy farms, transporters, transfer stations, and processors must allow USDA testing when requested.
    - Laboratories and state veterinarians must report any positive HPAI results in livestock, including raw milk
    - Herd owners with HPAI-positive milk must submit movement and epidemiological data to USDA.
  - Implementation timeline
    - First testing round began December 16, 2024.
  - Existing April 24, 2024, order still applies
    - Interstate cattle movement still requires HPAI testing and positive result reporting
  - National milk testing strategy launched—<u>five-stage plan</u> to protect U.S. dairy cattle from HPAI.



### FDA Published Final Rule on "Healthy" Food Claim

- FDA <u>published</u> a final rule revising the definition of the implied nutrient content claim "healthy."
  - Food group requirement
    - Must contain a specified amount from at least one of the six main food groups
    - e.g., dairy = 2/3 cup equivalent
  - Nutrient limits (for dairy products)
    - Added sugars: ≤ 5% DV
    - Sodium: ≤ 10% DV
    - Saturated fat: ≤ 10% DV
  - Automatic qualification
    - Fat-free and low-fat dairy qualify without meeting nutrient limits, as long as they contain no added ingredients other than water.



#### FDA Announced Human Foods Program FY 2025 Priorities

- FDA <u>announced</u> Human Foods Program FY 2025 Priority
  - Key deliverable: Combatting HPAI in dairy
    - Monitor and ensure the safety of dairy and milk products amid HPAI concerns in collaboration with USDA, CDC, NCIMS, and state agencies.
    - Advance the HPAI silo study to assess potential risks to human health via milk.

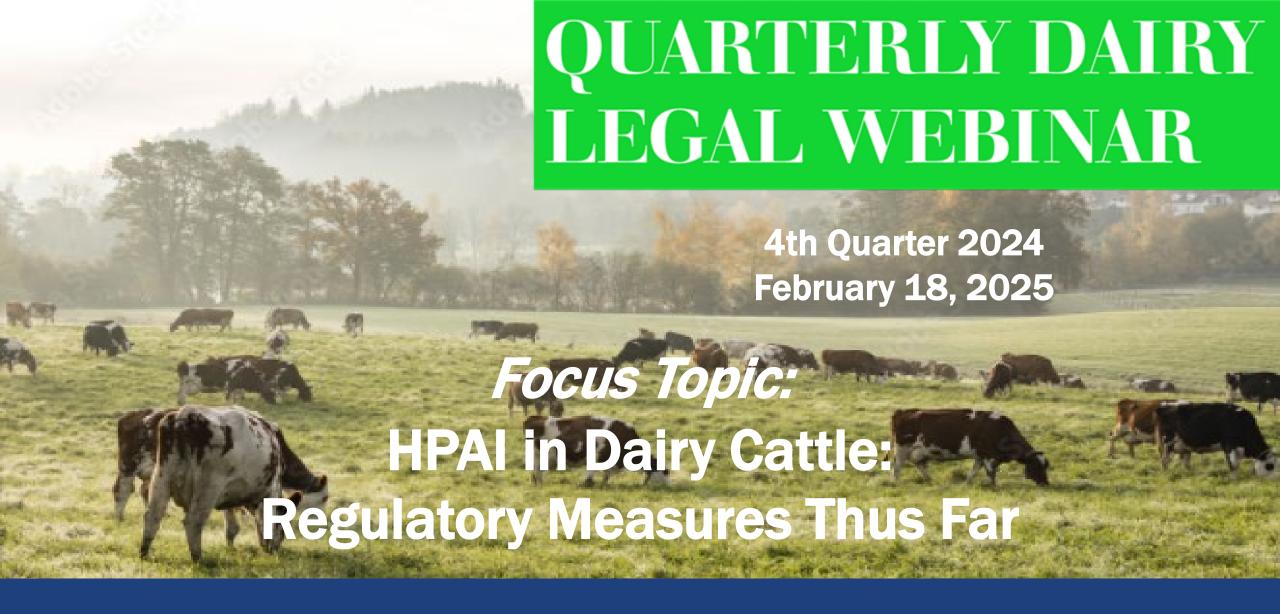


# Federal Court Dismissed Suit Alleging Milk Marketing Protections Rules Violate Student Speech

- Marielle Williamson, et al. v. USDA, et al., USDC C.D. California, No. 2:23-cv-3307
- A high-school student <u>challenged</u> the USDA Milk Marketing Protections rules, alleging they violated her First Amendment rights by restricting anti-dairy speech.
  - Milk Marketing Protection Rules, 7 C.F.R. § 210.10(d)(4)—"Restrictions on the sale of fluid milk. A
    school food authority participating in the [National School Lunch] Program, or a person approved by a
    school food authority participating in the Program, must not directly or indirectly restrict the sale or
    marketing of fluid milk ... at any time or in any place on school premises or at any school-sponsored
    event."
  - School required pro-dairy materials alongside due to USDA regulations tied to the National School Lunch Program (NSLP).
- The court ruled Marielle's case was moot since she had graduated.

#### PDA Issued New Bulk Milk Testing Order

- On November 20, 2024, PDA <u>issued</u> new bulk milk testing order for HPAI.
- Main requirements:
  - All milk from Pennsylvania farms must be tested for HPAI
  - Milk processors and out-of-state dairy farms must submit samples by November 26, 2024.
  - Samples from each tanker must be collected at least once every two weeks from all farms.
  - Samples can be spread over the first 14 days following November 26.
  - Samples must be sent within 48 hours to a nearby Pennsylvania Animal Diagnostic Lab (by hand delivery or mail).
  - Response to positive test:
    - Infected farms will be quarantined.
    - A zone around the farm will be marked as infected.
      - Regular testing required for dairy herds in the affected areas.
    - PDA will monitor and test the zone until the quarantine is lifted.





# Prior HPAI Outbreak in Poultry 2014-2015

The hardest hit states were Minnesota (over 100 affected premises) and Iowa (over 70 affected premises); South Dakota, Wisconsin, Nebraska, California, Missouri, North Dakota, and Arkansas also had one or more detections of HPAI in commercial flocks.

 In total, 21 States have had HPAI detections in commercial premises, backyard flocks, captive wild birds and/or wild birds.

Approximately 50.5 million commercial birds were depopulated or succumbed to the virus (primarily layers and turkeys).



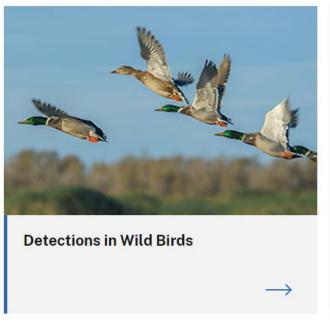




## Current U.S. HPAI Outbreak - 1st detection Feb. 2022

• USDA APHIS' Detections of Highly Pathogenic Avian Influenza









#### Detections in Livestock

The U.S. Department of Agriculture, Food and Drug Administration, Centers for Disease Control and Prevention, and State veterinary and public health officials are investigating cases of highly pathogenic avian influenza (HPAI) in dairy cows.



# H5N1 subtype of Influenza A (as opposed to B, C and D)

#### **About Avian Influenza**

Avian influenza is caused by influenza Type A virus (influenza A). Avian-origin influenza viruses are broadly categorized based on a combination of two groups of proteins on the surface of the influenza A virus: hemagglutinin or "H" proteins, of which there are 16 (H1-H16), and neuraminidase or "N" proteins, of which there are 9 (N1-N9). Many different combinations of "H" and "N" proteins are possible. Each combination is considered a different subtype, and related viruses within a subtype may be referred to as a lineage. Avian influenza viruses are classified as either "low pathogenic" or "highly pathogenic" based on their genetic features and the severity of the disease they cause in poultry. Most viruses are of low pathogenicity, meaning they cause no signs or only minor clinical signs of infection in poultry.

Six main hemagglutinin (HA) subtypes of bird flu viruses have infected people to cause acute respiratory illness (H3, H5, H6, H7, H9, and H10 viruses). Among these, H5N1 and H7N9 viruses have caused the majority of infections in people.

Source: CDC



## Current animal totals since 2022: cdc

- 11,966 wild birds detected as of 2/11/2025 | Full Report
- **51** jurisdictions with bird flu in wild birds
- 159,307,978 poultry affected as of 2/14/2025 | Full Report
- 51 jurisdictions with outbreaks in poultry
- 968 indiv. dairy cow cases confirmed as of 2/12/2025 | Full Report
- 16 states with outbreaks in dairy cows

## Confirmed Human Cases since ~March 2024 CDC

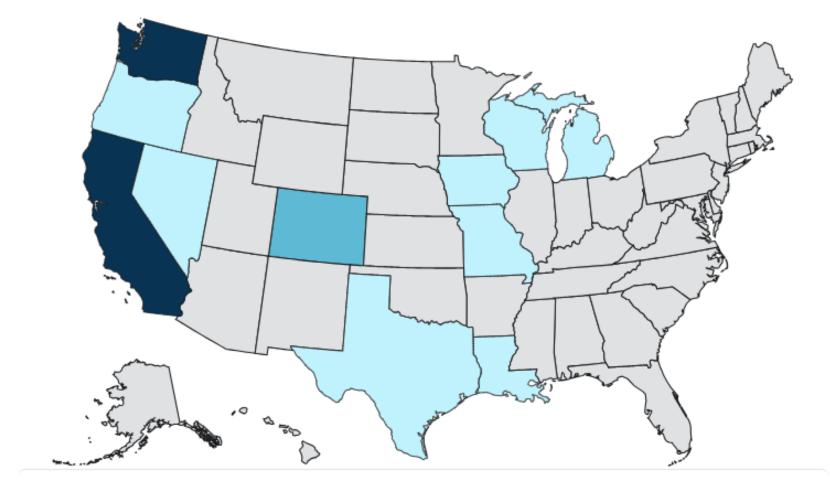
Traced to dairy exposure: CA-36, NV-1, CO-1, TX-1, MI-2.

National Total Cases: 68

Cases	Exposure Source
41	Dairy Herds (Cattle)*
23	Poultry Farms and Culling Operations*
1	Other Animal Exposure†
3	Exposure Source Unknown‡

NOTE: One additional case was previously detected in a poultry worker in Colorado in 2022. Louisiana reported the first H5 bird flu death in the U.S.

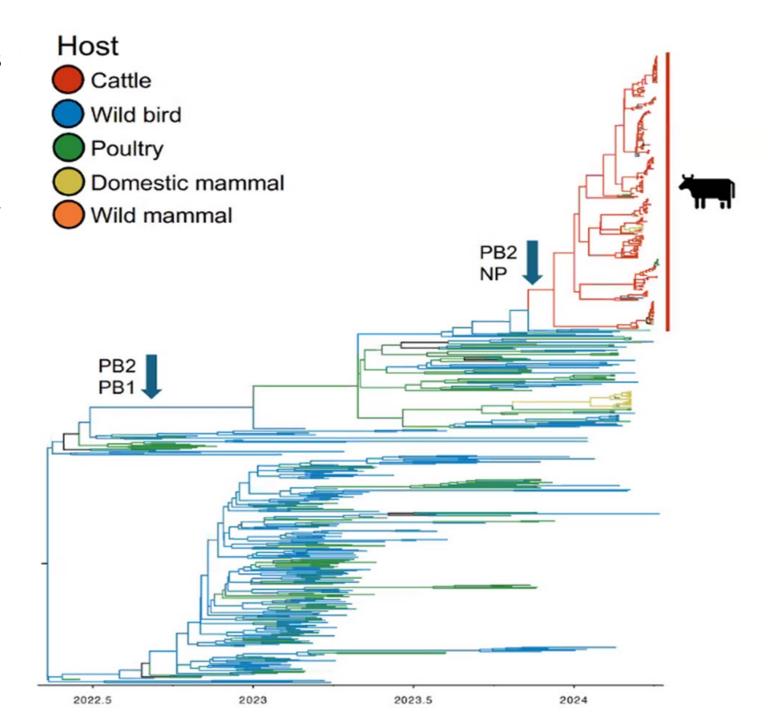
\*Exposure Associated with Commercial Agriculture and Related Operations <sup>†</sup>Exposure was related to other animals such as backyard flocks, wild birds, or other mammals <sup>‡</sup>Exposure source was not able to be identified



#### Total cases

On July 12, 2024, Pennsylvania's State Veterinarian supplied this graphic compiled by USDA/CDC research from the entire outbreak. It charts the outbreak by species, time, organized by genotype of the virus in each detection.

The "cross-over" of a mutated genotype of the H5N1 virus in wild birds to dairy cattle was a one-time event and is not a continually recurring event as some might expect. So far, there has been comparatively little transmission back from cattle to other species.



# Host Cattle Wild bird Poultry Domestic mammal Wild mammal PB2 NP



## **Bovine Outbreak Features**

- Not as virulent as in birds; mild symptoms; full recovery (?)
- High \$ value domestic animal, incl. value of milk production
- Carries/transmits via lactation = inherent limitation on spread
- Milk production inherently less "bio secure."



# **Federal Legal Authority**

for Animal Disease Control



## **USDA Org Chart** – Where is Animal Disease Control?

Under Secretary for Under Secretary for Under Secretary Under Secretary for Under Secretary for Under Secretary for Under Secretary Under Secretary for Farm Production Food, Nutrition and for Marketing and Natural Resources Research, Education Trade and Foreign for Food Safety Rural Development and Conservation Agricultural Affairs Consumer Services Regulatory Programs and Environment and Economics FPAC Business Food and Nutrition Service Food Safety and Agricultural Marketing Forest Service Rural Housing Service · Office of the Chief Foreign Agricultural Service Inspection Service Service Scientist Center Rural Utility Service · Animal and Plant Health Agricultural Research Farm Service Agency Rural Business U.S. Codex Office Inspection Service Service Cooperative Service Risk Management National Agricultural Agency Statistical Service U.S. DEPARTMENT OF AGRICULTURE Natural Resources ANIMAL AND PLANT HEALTH INSPECTION SERVICE National Institute of Food Conservation Service and Agriculture The mission of the Animal and Plant Health Inspection Service is to protect the Economic Research health and value of American agriculture and natural resources. Service Marketing and Regulatory **Animal Care** Biotechnology Regulatory Legislative and Public International Services **Programs Business** Services Affairs Services 34 80 34 60 34 20 34 07 34 10 Plant Protection and Policy and Program Veterinary Services Wildlife Services Quarantine Development 34 50 34 30 34 03 34 70



## Animal Health Protection Act (7 U.S.C. § 8301 - 8322)

- Re-enacted wholesale as part of 2002 Farm Bill from provisions of various dates and statutes.
- "To prevent and eliminate burdens on interstate commerce and foreign commerce" among other findings in the preamble.
- Concurrent with states' "intra-state" authority.
- States depend upon USDA for technical assistance, research and resources/\$\$\$ (indirect mostly).
- 2014-2015 HPAI outbreak = created opportunities to fine tune processes.
- COVID illustrated some analogous working relationships that are rarely seen in action.
- Authority granted is extremely broad see following slides.

#### CHAPTER 109—ANIMAL HEALTH PROTECTION

Sec.	
8301.	Findings.
8302.	Definitions.
8303.	Restriction on importation or entry.
8304.	Exportation.
8305.	Interstate movement.
8306.	Seizure, quarantine, and disposal.
8307.	Inspections, seizures, and warrants.
8308.	Detection, control, and eradication of dis-
	eases and pests.
8308a.	Animal disease prevention and management.
8309.	Veterinary accreditation program.
8310.	Cooperation.
8311.	Reimbursable agreements.
8312.	Administration and claims.
8313.	Penalties.
8314.	Enforcement.
8315.	Regulations and orders.
8316.	Authorization of appropriations.
8317.	Effect on regulations.
8318.	Veterinary training.
8319.	Surveillance of zoonotic diseases.
8320.	Expansion of Animal and Plant Health In-
	spection Service activities.
8321.	Pest and Disease Response Fund.
8322.	National aquatic animal health plan.



## Powers Granted to USDA-APHIS (§8301 - 8305)

- Grants Import, Export and Interstate movement authority
- What regulated? Pests and Diseases of Livestock.

Livestock: "all farm-raised animals."

<u>Disease</u> – "the meaning given that term by the Secretary."

<u>Pest</u> - "any of the following that can directly or indirectly injure, cause damage to, or cause disease in livestock: protozoan, plant, bacteria, fungus, virus or viroid, infectious agent or other pathogen, arthropod, parasite, prion, vector, any organism similar to or allied with any" of the foregoing.

- **How?** Issue **orders** and promulgate **regulations** . . .
  - prohibiting or restricting **importation**, entry, or movement, or
  - order the destruction, removal or disinfection,
  - "of any animal, article or means of conveyance;"
  - "necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock."

## Center for Agricultural and Shale Law

- Contains identical grants of authority re: <a href="exportation"><u>exportation</u></a> "necessary to prevent the **dissemination from** or within the United States of any pest or disease of livestock."
- Contains identical grants of authority re: <a href="introduction">introduction</a> or dissemination within the United States of any pest or disease of livestock."
- Export certification: "The Secretary may certify the classification, quality, quantity, condition, processing, handling, or storage of any animal or article intended for export."
- Enforcement If **failure to comply with order**, "take remedial action, destroy, or remove from the United States the animal or progeny of any animal, article, or means of conveyance" and "and recover from the owner the costs of any care, handling, disposal, or other action." [includes "equitable" measures]



## Seizure, Quarantine, and Disposal - §8306(b)

- May "seize, quarantine, treat, destroy, dispose of, take other remedial action re: animal or progeny of any animal, article, or means of conveyance" "moving or has been moved in interstate commerce or has been imported or entered" and
- "the Secretary has reason to believe may carry, may have carried, or may have been affected with or exposed to any pest or disease of livestock" or otherwise is in violation of the statute, regs or orders.



#### HPAI Animal Health Emergency Alert

A form of highly pathogenic avian influenza (HPAI) has been causing widespread disruption and illness in birds since first being detected in 2022. Learn more about <u>Detections of HPAI</u> and <u>HPAI Emergency Response</u>.

HPAI has also been detected in domestic livestock. For the latest information, visit Detections of HPAI in Livestock.

## Extraordinary Emergencies - §8306 (b)

- "if the Secretary determines
  - that an extraordinary emergency exists because of the presence in the United States of a pest or disease of livestock and
  - that the presence of the pest or disease threatens the livestock of the United States,
- hold, seize, treat, apply other remedial actions to, destroy (including preventative slaughter), or otherwise dispose of, any animal, article, facility, or means of conveyance if the Secretary determines the action is necessary to prevent the dissemination of the pest or disease.
- "The Secretary may <u>take action in a State</u> under this subsection only on finding that measures being taken by the State are inadequate to control or eradicate the pest or disease, after review and consultation," with the Governor or tribal head.
  - Also contains public notice and Federal Register publication requirements.



## Compensation - §8306 (d)

- "The Secretary shall compensate the owner of any animal, article, facility, or means of conveyance that the Secretary requires to be destroyed under this section."
- Fair market value, as determined by the Secretary (minus "any compensation received by the owner from the State or other source.")
- "The determination by the Secretary of the amount to be paid . . . shall be final and not subject to judicial review."
- Exceptions No payment shall be made if
  - moved or handled by the owner in violation of an agreement for the control and eradication of diseases or pests or in violation of this chapter;
  - any animal, article, or means of conveyance that is refused entry under this chapter [i.e. rejected at the border];
  - becomes affected with or exposed to any pest or disease of livestock because of a violation of an agreement for the control and eradication of diseases or pests or a violation of this chapter by the owner.



## Other powers granted

#### 8307(b) Warrantless inspections:

The Secretary may stop and inspect, without a warrant, any person or means of conveyance moving—

- (1) **into the United States**, to determine whether the person or means of conveyance is carrying any animal or article regulated under this chapter;
- (2) in interstate commerce, on probable cause to believe that the person or means of conveyance is carrying any animal or article regulated under this chapter; or
- (3) in intrastate commerce from any State, or any portion of a State, quarantined under section 8306(b) of this title, on probable cause to believe that the person or means of conveyance is carrying any animal or article quarantined under section 8306(b) of this title.



# Warrantless investigatory powers granted

#### §8308 Detection, Control, and eradication of diseases and pests

- "The Secretary may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals), including animals at a slaughterhouse, stockyard, or other point of concentration."
- "The Secretary may pay a claim arising out of the destruction of any animal, article, or means of conveyance consistent with the purposes of this chapter."
- The Secretary shall **compensate industry participants and State agencies** that cooperate with the Secretary in carrying out operations and measures under subsection (a) for 100 percent of eligible costs relating to cooperative programs involving Federal, State, and industry participants to control diseases of *low pathogenicity* in accordance with regulations issued by the Secretary.

# Animal Health Protection Act Regs 9 CFR §

Where are the applicable regulations for HPAI?

Titl	e 9 Animals and	Animal Products	Part / Section
▼ (	Chapter I Animal Agricult	and Plant Health Inspection Service, Department of ure	1 – 199
		Cooperative Control and Eradication of Livestock or Poultry Diseases	49 – 56
	▼ Part 49 Rule	es of Practice Governing Proceedings Under Certain Acts	49.1 - 49.10
	Subpart A	General	49.1
	Subpart B	Supplemental Rules of Practice	49.10
	▼ Part 50 Anir	nals Destroyed Because of Tuberculosis	50.1 - 50.22
	§ 50.1	Definitions.	
	Subpart A	General Indemnity	50.2 - 50.16
	Subpart B	Dairy Cattle and Facilities in the El Paso, Texas, Region	50.17 - 50.22
	▼ Part 51 Anir	mals Destroyed Because of Brucellosis	51.1 - 51.33
	Subpart A	Indemnity for Cattle, Bison, and Swine	51.1 - 51.10
	Subpart B	Indemnity for Sheep, Goats, and Horses	51.20 - 51.33
A	▶ Part 52 Swi	ne Destroyed Because of Pseudorabies	52.1 - 52.7
$\checkmark$	➤ Part 53 Foo	t-and-Mouth Disease, Pleuropneumonia, and Certain Other	53.1 - 53.11
	Con	nmunicable Diseases of Livestock or Poultry	
	▼ Part 54 Con	trol of Scrapie	54.1 - 54.22
	§ 54.1	Definitions.	
	§ 54.2	Cooperative agreements and memoranda of understanding	g with States.
	Subpart A	Scrapie Indemnification Program	54.3 - 54.11
	Subpart B	Scrapie Free Flock Certification Program	54.20 - 54.22
	▼ Part 55 Con	trol of Chronic Wasting Disease	55.1 - 55.25
	§ 55.1	Definitions.	
	-	Chronic Wasting Disease Indemnification Program	55.2 – 55.8
		Chronic Wasting Disease Herd Certification Program	55.21 – 55.25
	▶ Part 56 Con	trol of H5/H7 Low Pathogenic Avian Influenza	56.1 – 56.10



### HPAI Regs - 9 CFR § Part 53.11 (2016, rev. 2018)

[Extremely brief and do not address HPAI control issues in bovines in any way whatsoever. Strictly addresses domestic poultry for meat and eggs.]

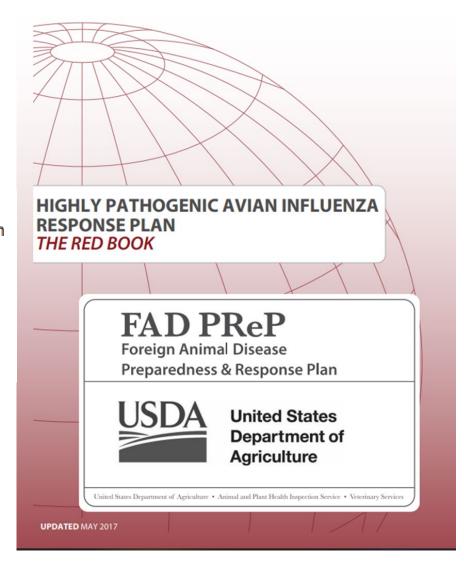
#### § 53.11 Highly pathogenic avian influenza; conditions for payment.

- (a) When poultry or eggs have been destroyed pursuant to this part, the Administrator may pay claims to any party with whom the owner of the poultry or eggs has entered into a contract for the growing or care of the poultry or eggs. The indemnity the Administrator may pay to such a party or parties shall be determined as by the following method:
- (1) Divide the value in dollars of the contract the owner entered into with the contractor by the duration in days of the contract as it was signed prior to the highly pathogenic avian influenza outbreak;
- (2) Multiply this figure by the time in days between the date the contractor began to provide services relating to the destroyed poultry or eggs under the contract and the date the poultry or eggs were destroyed due to highly pathogenic avian influenza.

### Foreign Animal Disease Preparedness and Response Plan - APHIS webpage

Between December 2014 and June 2015, the United States experienced its largest highly pathogenic avian influenza (HPAI) outbreak—and most serious animal health disease incident—in history. This plan was updated in August 2015 to reflect immediate changes required based on those events. Soon thereafter, in January 2016, there was an HPAI/low pathogenicity avian influenza (LPAI) outbreak in Indiana. This version of the USDA APHIS HPAI Response Plan: The Red Book (Updated May 2017) reflects the knowledge and lessons learned during both of these outbreaks, as well as in the recent HPAI/LPAI incident in 2017. Additionally, this version incorporates changes made in related Foreign Animal Disease Preparedness and Response Plan (FAD PReP) materials.

This guidance document represents the Agency's position on this topic and is intended solely as guidance. It does not have the force and effect of law, does not create or confer any rights for or on any person, and does not bind the U.S. Department of Agriculture (USDA) or the public. Language suggesting that this guidance is mandatory (e.g., "shall," "must," "required", or "requirement") should not be construed as binding unless the terms quote from a statutory or regulatory requirement. The information this document contains may be made available to the public. While this document provides guidance for users outside VS, VS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.



"THE RED BOOK"



### There are multiple "Red Books"

FAD	Primary type of animal affected	Highly contagious disease	Vector- borne disease	Zoonotic disease potential
Diseases with FAD PReP Response Plans (Red Books)				
Highly pathogenic avian influenza (HPAI)	Avian, others	Yes	No	Yes
Foot-and-mouth disease (FMD)	All cloven hoofed animals	Yes	No	No
Classical swine fever (CSF	Swine	Yes	No	No
Newcastle disease (ND) (virulent ND virus)	Avian	Yes	No	Yes Minor

Will there be a Red Book someday for HPAI in dairy cattle or the broader category of bovines?



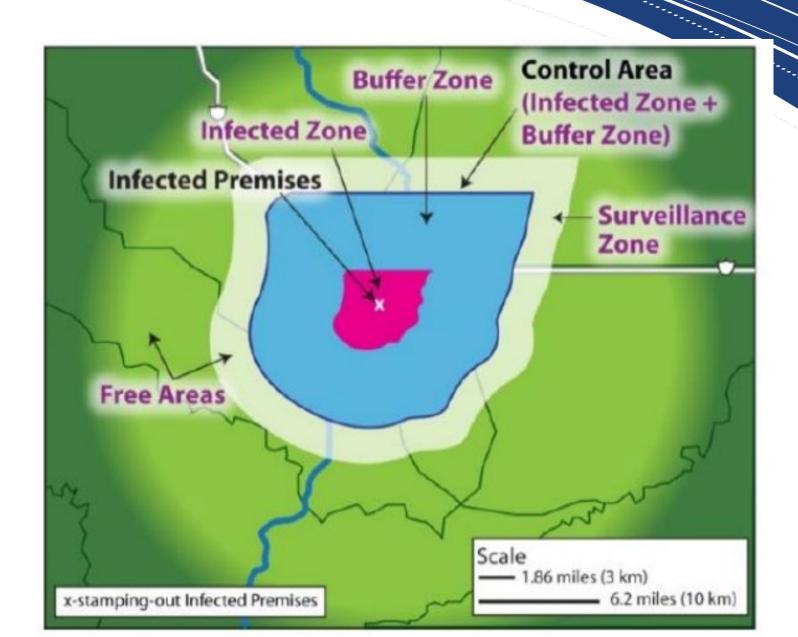
### **Poultry Approach**

(Depop = 90M+ birds)

### "Stamping Out Infected Premises"

The primary measure employed by USDA APHIS for HPAI in poultry is to immediately (w/in 48 hours) **depopulate** all poultry on the premises.

Coupled with a **Control Zone** to attempt to stop transmission beyond the infected premise.





## "Agreement for the control and eradication of diseases or pests"

- Recall the phrase used in Animal Health Protection Act.
- USDA APHIS strives to conduct its animal disease emergency activities through disease control agreements with producers to authorize activities.
- The incentive to agree is indemnity and compensation.
- So far, rarely is court enforcement of special quarantine orders (applicable to a single premise) necessary.

### **Understanding USDA Indemnity/Compensation**

#### **Procedures for Indemnity / Compensation**

- <u>VS Guidance 8603.2 Procedures for Indemnity and Compensation Claims in Cases of H5/H7 Low Pathogenicity Avian Influenza Infection in Poultry.</u>
- Within this document are mentioned forms to be used. Those forms are either found: (a) directly within VS Guidance 8603.2 discussed above; or (b) found on the APHIS webpage titled, <u>Highly Pathogenic Avian Influenza Emergency Response</u>, under the blue drop-down menu titled "Finance and Administration Processes."

#### Rates of Indemnity (payment for birds and eggs)

- <u>HPAI Response: Poultry Indemnity Valuation</u> (Apr. 2022) explains the process and how valuations are set
- <u>USDA Indemnity Values for 2022: Commercial Table</u> (Mar. 2022) the actual published amounts for 2022
- <u>VS Indemnity Values for 2022: Specialty Table</u> (Mar. 2022) the actual published amounts for 2022

#### Rates of Compensation (payment for depopulation, disposal and disinfection, i.e., "virus elimination")

- HPAI Virus Elimination: Per-Square-Foot Rates for Floor-Raised Poultry— explains the process, how amounts are set and contains the actual published amounts.
- HPAI Virus Elimination: Per-Cubic-Yard Flat Rates for Table Egg-Laying Bird Barns and Table Egg
   Storage and Processing Facilities explains the process, how amounts are set and contains the actual published amounts.



### **USDA Disease Control Tools Available**

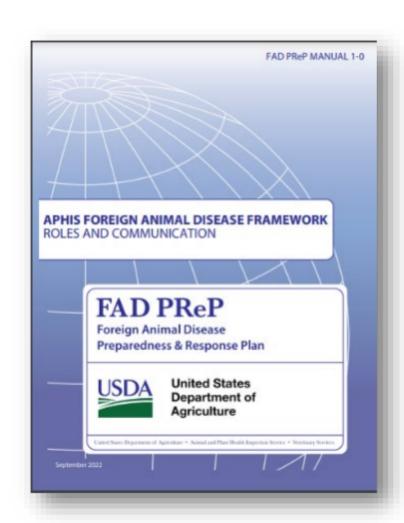
#### Measures to Control and Eradicate HPAI

- Surveillance and diagnostics
- Quarantine and movement control
- Biosecurity measures
- Epidemiological investigations
- \*Appraisal and compensation
- Depopulation (euthanasia) of affected poultry
- **Carcass disposal**
- Cleaning and disinfection (virus elimination)
- **Emergency vaccination (if appropriate)**

# Roles and Coordination

APHIS Foreign Animal Disease Framework

FAD PReP Manual 1-0
September 2022



#### **USDA APHIS Authorities for an FAD Incident**

The AHPA authorizes the Secretary of Agriculture to perform the following in pursuit of FAD preparedness and response:

- Prohibit or restrict imports, exports, and/or interstate commerce;
- Implement remedial measures (i.e., destruction or removal activities, movement restrictions);
- Disinfect articles, conveyances, individuals and personal articles involved in the importation or exportation of animals;
- Declare an extraordinary emergency;
- Compensate the owner of animals, articles, facilities, or conveyances destroyed in the process of FAD eradication;
- Inspect, without warrant, persons or conveyances moving regulated animals or articles into the United States, in interstate commerce, or in intrastate commerce;
- Obtain warrants, for the purpose of entering, inspecting and seizing (if

- necessary) premises in the United States;
- Establish a veterinary accreditation program as well as standards of conduct for accredited veterinarians;
- Cooperate with both domestic and international government and nongovernment actors;
- Pay overtime for employees performing import/export services;
- Levy civil and criminal penalties against violators of the AHPA;
- Conduct investigations and administer subpoenas necessary for the administration of the AHPA; and
- Transfer funds from other USDA agencies and corporations for the arrest, control, eradication, and prevention of an FAD.



### **Dairy Cattle Approach Continues to Evolve**

- 4/24/24 MANDATORY <u>Federal Order Requiring Testing and Reporting of HPAI in Livestock</u> mandatory testing for interstate movement of only <u>lactating dairy cattle</u>; mandatory report by states and laboratories of Influenza A in <u>all livestock</u>.
- 5/14/24 VOLUNTARY (& clarification of above mandatory measure) <u>APHIS Requirements and Recommendations for Highly Pathogenic Avian Influenza (HPAI) H5N1 Virus in Livestock For State Animal Health Officials, Accredited Veterinarians and Producers "This document outlines both the interstate movement requirements, as well as APHIS recommendations to limit the spread. Updated laboratory guidance, including details on required reporting, are located on the APHIS website."</u>
- 5/23/24 & 7/1/24 VOLUNTARY USDA Support for Diary Herd Producers, <u>Summary Part 1</u>; <u>Summary Part 2</u>; <u>ELAP details</u>.
- 5/30/24 VOLUNTARY <u>Dairy Herd Status Program</u> established, creating an option for freer movement of lactating dairy cattle through alternative testing schedule to the Federal Quarantine Order and creating a "monitored herd" status. Enrollment so far is 8 herds in 7 states.



### USDA Issued Order Requiring Testing, Reporting for Interstate Dairy Cattle Movement

- <u>Federal Order Requiring Testing for and Reporting of Highly Pathogenic Avian Influenza (HPAI) in Livestock</u> (effective April 29, 2024)
  - Prior to interstate movement, all dairy cattle must receive a negative HPAI test at a laboratory accredited by the National Animal Health Laboratory Network (NAHLN).
  - Owners of dairy cattle testing positive for HPAI are required to submit epidemiological information, including animal movement records.
  - Interstate movement of dairy cattle must comply with all relevant requirements and recommendations established by the USDA Animal and Plant Health Inspection Service (APHIS).
  - Laboratories and state veterinarians must report all positive diagnostic results for HPAI in livestock to the USDA APHIS.
- APHIS will cover the costs of testing including for (1) dairy cattle showing clinical signs of disease; (2) premovement testing; (3) producers who want to know the disease status of their animals; and (4) testing conducted on livestock animals other than dairy cattle.
- <u>Technical Notes: Clarification to Inquiries Received on April 24 Federal Order (May 7, 2024)</u>

#### **USDA Announced Additional Funding to Address HPAI Spread**

- Media Release; USDA, HHS Announce New Actions to Reduce Impact and Spread of H5N1 (May 10, 2024)
  - ... up to \$2,000 per affected premises per month ... for producers who supply PPE to employees and/or provide outwear uniform laundering, for producers of affected herds who faciliate the participation of their workers in USDA/CDC workplace and farmworker study.
  - ... up to \$5,000 per affected premises ... to develop biosecurity plans based on existing secure milk supply plans."
  - If a producer establishes a system to heat treat all waste milk before disposal, USDA will pay the producer up to \$2,000 per affected premises per month.
  - Veterinary costs are eligible to be covered from the initial date of positive confirmation at NVSL for that farm, up to \$10,000 per affected premises.
  - Additionally, the USDA will allocate \$98 million to the APHIS to assist states in implementing movement restrictions within their borders; will compensate producers for lost milk production through the Emergency Assistance for Livestock, Honey Bees, and Farm-Raised Fish (ELAP) program.

## APHIS Requirements and Recommendations for Highly Pathogenic Avian Influenza (HPAI) H5N1 Virus in Livestock For State Animal Health Officials, Accredited Veterinarians and Producers May 14, 2024

"This document outlines both the interstate movement requirements, as well as APHIS recommendations to limit the spread. Updated laboratory guidance, including details on required reporting, are located on the APHIS website."

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#### **USDA Announced New Voluntary Bulk Milk Testing Pilot Program**

<u>Press Release</u>; <u>USDA Announces</u> \$824 <u>Million in New Funding to Protect Livestock Health</u>; <u>Launches</u>
 Voluntary H5N1 Dairy Herd Status Pilot Program (May 30, 2024)

#### Emergency Funding

 "To help ensure the Animal and Plant Health Inspection Service (APHIS) can continue to provide critical rapid response activities, Secretary Vilsack approved the transfer of \$824 million ... to APHIS to directly support the response efforts. This funding allows APHIS to continue its critical work with state and local partners to quickly identify and address cases of HPAI/H5N1 in poultry and livestock."

#### • Voluntary Dairy Herd Status Pilot Program

• "The main benefit for farmers who choose to enroll in the Voluntary H5N1 Dairy Herd Status Pilot Program is that once they can demonstrate their herds are free of H5N1 with results from a National Animal Health Laboratory Network (NAHLN) facility, they will then need to conduct weekly tests on bulk milk from that herd to confirm that status and will be able to ship their cows at the time they prefer and without testing individual animals."

#### **USDA Allows ELAP Payments for Milk Losses from Avian Influenza**

On July 1, 2024, the U.S. Department of Agriculture (USDA) Commodity Credit Corporation (CCC) published in the Federal Register a final rule (89 FR 54331) amending the Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program (ELAP) to "provide financial assistance to dairy producers who face milk losses due to H5N1 infection of their dairy herds." Also announced by USDA, the program allows for a "per cow milk loss payment . . . based on an expected 21-day period of no milk production when a cow is removed from the milking herd, followed by seven days when the cow has returned to milking but produces 50% of the normal amount of production." According to the rule, the payment calculation will be 90% of the "per head payment rate," multiplied by the product of the "number of eligible adult dairy cows," and the "producer's share in milk production." USDA states that "the final date to file a notice of loss and application for payment for eligible losses is 30 days after the end of the prior calendar year, which is January 30." The final rule became effective and the program opened for application upon publication of the rule.



### **National Milk Testing Strategy (NMTS)**

### The U.S. Department of Agriculture (USDA) Issued Raw Milk Testing Order, Announced National Milk Testing Strategy

On December 6, 2024, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) issued a federal order along with accompanying guidance requiring the nationwide collection and submission of raw milk samples to the USDA for HPAI testing. The federal order requires (1) any dairy farm, bulk milk transporter, bulk milk transfer station, or dairy processing facility to allow APHIS to collect raw milk samples for HPAI testing when requested; (2) laboratories and state veterinarians to report any positive HPAI test results in livestock, including raw milk, to USDA APHIS; and (3) owners of herds with HPAI-positive milk to submit epidemiological and animal movement information to the USDA. This federal order does not replace or cancel the April 24, 2024, Federal Order, which still requires mandatory testing of all dairy cattle moving between states and the reporting of any positive results. The first round of testing began on December 16, 2024. Additionally, the USDA announced the beginning of the National Milk Testing Strategy, a comprehensive five stage-plan designed to ensure U.S. dairy cattle are free from HPAI.

#### Stage 1: Standing Up Mandatory USDA National Plant Silo Monitoring

USDA will immediately begin testing of milk silos at dairy processing facilities. This national sample will allow USDA to identify where the disease is present, monitor trends, and help states identify potentially affected herds.

#### Stage 2: Determining a State's H5N1 Dairy Cattle Status

Building on the results of silo monitoring, in collaboration with states, USDA will also stand up bulk tank sampling programs that will enable us to identify herds in the state that are affected with H5N1.

#### Stage 3: Detecting and Responding to the Virus in Affected States

For states with H5N1 detections, APHIS will work quickly to identify specific cases and implement rapid response measures, including enhanced biosecurity using USDA's existing incentives programs, movement controls and contact tracing.

#### Stage 4: Demonstrating Ongoing Absence of H5 in Dairy Cattle in Unaffected States

Once all dairy herds in a given state are considered to be unaffected, APHIS will continue regular sampling of farms' bulk tanks to ensure the disease does not re-emerge. Bulk tank sampling frequency will progressively decline as the state demonstrates continual silo negativity (e.g., weekly, monthly, quarterly if continually negative). If a state becomes affected, USDA will re-engage detection and response activities, and the state will return to Stage 3.

#### Stage 5: Demonstrating Freedom from H5 in U.S. Dairy Cattle

After all states move through Stage Four, APHIS will work with the states to begin periodic sampling and testing to illustrate long-term absence from the national herd.

### 42 States Enrolled in the NMTS and Performing Active Surveillance

3 States are Unaffected

41 States are Provisionally Unaffected

#### Choose Map Type

- NMTS State Status
- NMTS State Enrollment

#### **NMTS State Status**

Hover over States for more information

#### Map Legend

Provisional Unaffected

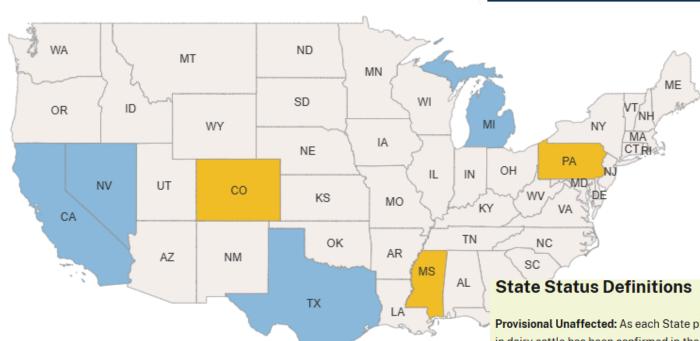
Affected

Unaffected



Surveillance of H5 Avian Influenza in Dairy Cattle State Statuses based on Testing/Surveillance Activities, as part of the National Milk Testing Strategy (NMTS)

Report Date: February 16, 2025 Data updated every Friday



**Provisional Unaffected:** As each State phases into the NMTS, the State's status will be Provisional Unaffected, unless a new case of HPAI in dairy cattle has been confirmed in the State within the last 30 days or testing and surveillance activities demonstrating disease absence of H5 in dairy cattle herds in the State have not yet been completed.

Unaffected: Ongoing testing and surveillance activities demonstrate absence of disease in dairy cattle in the State.

Affected: Ongoing testing and surveillance activities demonstrate presence of disease in dairy cattle in the State.



### **State Legal Authority**

for Animal Disease Control





### PA's Domestic Animal Law - 3 Pa.C.S. 2301 - 2390

#### Definitions

- "Quarantine." Restrictions upon the use, movement or other disposition of domestic animals, domestic animal products, equipment, facilities, vehicles, buildings and other articles required to eradicate, contain or otherwise control a dangerous transmissible disease or to control or prevent contamination by hazardous substances.
- **General quarantine."** A quarantine order published in at least one newspaper that restricts the movement of animals and materials, including conveyance into, within or from a designated area or locality.
- "Special quarantine." An order of quarantine issued by the Department of Agriculture covering a single premises or a single domestic animal or any number of domestic animals when confined or contained in or on the same premises and any conveyances, goods, products, materials, containers or articles which may carry disease or contamination by a hazardous substance.
- §2305 "The department shall have authority to regulate the keeping and handling of domestic animals to exclude or contain dangerous transmissible diseases and hazardous substances and to protect the environment . . ."
- "Dangerous transmissible disease" designation = The department may establish regulations addressing the specific discovery, prevention, reporting, testing, control and eradication measures which it determines are necessary



### PA's Domestic Animal Law (cont.)

#### Subchapter C. Detection, Containment or Eradication of Certain Diseases

§	2321.	Dangerous Transmissible Diseases
§	2322.	Neoplastic Diseases, Metabolic Diseases and Heritable Diseases
§	2323.	Health Requirements
§	2324.	Safety of Domestic Animal Feed
§	2325.	Use of Biologicals, Antibiotics, Genetic Material, Chemicals, Diagnostic Agents and Other Substances
§	2326.	Sanitation
§	2327.	Disease Surveillance and Detection
§	2328.	Entry on Premises
§	2329.	Quarantine
8	2330.	<u>Condemnation</u>
8	2331.	<u>Indemnification</u>
§	2332.	Depopulation Incentive
§	2333.	Restriction on Payment of Indemnification and Depopulation Incentive
§	2334.	Report on Insurance or Cost-Sharing Program
8	2335.	Contract Growers
§	2336.	Posted Notice with Information on Dangerous Transmissible Diseases



### 3 Pa.C.S. § 2329 Quarantine

(a) Power to establish and enforce.--Whenever a dangerous transmissible disease or contamination by hazardous substances exists anywhere within or outside of this Commonwealth,

or whenever it is deemed advisable to test or treat any domestic animal upon the reasonable suspicion that it has contracted or been exposed to a dangerous transmissible disease or is contaminated with a hazardous substance,

or whenever the testing or treatment of a domestic animal indicates that the domestic animal has been exposed to a dangerous transmissible disease or contaminated with a hazardous substance so as to render future accurate testing for recent exposure of that domestic animal to that dangerous transmissible disease or hazardous substance impractical or impossible,

the department shall have the power to establish and enforce quarantines of any such infected, exposed, contaminated, suspected or susceptible domestic animal.

In addition to the aforedescribed domestic animals, a quarantine may apply to any goods, products, facilities, containers, vehicles or materials that may carry dangerous transmissible disease or that may be contaminated with a hazardous substance and may be applied on or in or against any premises, area or locality as defined in this chapter.



### Pennsylvania Issued HPAI Quarantine Order for Dairy Cattle; Issued Quarantine Order for Dairy Cattle Exhibitions

- <u>Interstate and International Quarantine Order; Restriction of Movement and Pre-Movement Influenza Testing of Dairy Cattle,</u> 54 Pa. B. 2095 (effective April 20, 2024)
  - « ... dairy cattle from a State, Commonwealth, foreign nation, province or territory where [HPAI] has been confirmed in dairy cattle within the past 30 days may not be imported into, stopped off in, or unloaded in Pennsylvania ... » unless they meet certain testing requirements.
  - There are a few exceptions to the testing requirements for (1) calves under one year old; (2) dairy cattle brought in for immediate slaughter at a licensed meat establishment within 72 hours of arrival; and (3) dairy cattle with a « formalized commuter agreement « approved by PDA.
- General Quarantine Order; Influenza A Viruses in Ruminants Exhibition of Dairy Cattle (effective May 29, 2024)
  - Dairy cattle are prohibited from entering exhibition premises if (1) the cattle show clinical signs of HPAI infection; (2) have been on premises with confirmed HPAI cases in dairy cattle or domestic birds; or (3) have been on premises within a three-kimeter radius of a location with confirmed HPAI in domestic birds.
  - Dairy cattle over 18 months old must be tested within 7 days prior to their arrival on exhibition grounds
    - There is an exception to the testing requirement for dairy cattle less than 18 months prior to exhibition.



### PA Bulk Milk Testing

### The Pennsylvania Department of Agriculture (PDA) Issued New Order Requiring Bulk Milk Testing

On November 20, 2024, the Pennsylvania Department of Agriculture (PDA) issued a general quarantine order requiring bulk testing of milk from all Pennsylvania farms for highly pathogenic avian influenza (HPAI), effective immediately. The order requires that all instate milk processors receiving bulk raw milk directly from Pennsylvania dairy farms or milk cooperatives must submit samples from each milk tanker compartment for testing no later than November 26, 2024. The order also extends to any Pennsylvania dairy farm or cooperative that delivers bulk raw milk to an out-of-state processor. In an announcement, Agriculture Secretary Russell Redding stated, "[i]f the virus is detected, it will trigger further investigation to identify the source. Special quarantine measures will be established to contain and eliminate the virus at the source." The order will remain in effect for 12 months unless rescinded or modified.

#### Thanks for attending.

### **QUESTIONS?**



### Thank you for joining us!

#### **Understanding Agricultural Law Series**

Understanding the Basics of--

Feb. 28, 2025—Pesticide Drift

Mar. 28, 2025—Clean Water Act & Ag: Impaired Waters & TMDL Process

Apr. 25, 2025—PA Ag Exemptions for Inheritance Tax and Real Estate Transfers

#### **Quarterly Dairy Legal Webinar Series:**

April 15, 2025—1st Quarter of 2025: Bovine Disease Controls: Federal and PA Laws & Regulations

March 5, 2025—Compliance with new Federal and State Business Entity Informational Filing Requirements w/ SBDC Ag Center of Excellence

#### CENTER MISSION AND BACKGROUND

Center programs are funded in part by the Commonwealth of Pennsylvania through the Pennsylvania Department of Agriculture. The Center for Agricultural and Shale Law is a partner of the National Agricultural Law Center (NALC) at the University of Arkansas System Division of Agriculture, which serves as the nation's leading source of agricultural and food law research and information.

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### **BONUS SLIDES**

# Which disease control measures are chosen and why?

#### **Regulatory Intervention During an FAD Outbreak**

The scope of regulatory intervention and the selection of a response strategy or strategies in an FAD outbreak will depend on the following:

- Transmission characteristics of the FAD agent
  - Rate of contagious disease agent transmission
  - Potential for zoonotic transmission
  - Number and types of susceptible animal species.
- Consequences of the FAD outbreak
  - To national security, food security, public health, animal health, the environment, and the economy
  - Regulatory impacts for owners, growers, stakeholders, and the general public.

#### **Regulatory Intervention During an FAD Outbreak**

#### (continued)

- Acceptance
  - Social and political acceptance of the response policy by different communities.
    - Local, State, Tribal, U.S. regional, U.S. national, North American, and international.
- Scale of the outbreak
  - Number of animals, species, and premises infected
  - The susceptible animal population density for infected or high-risk areas.
- Rate of outbreak spread
  - Numbers and types of premises
  - Numbers and types of animals
  - Rate at which each Infected Premises (IP) leads to infection of one or more additional IP.
- Veterinary countermeasures available
  - Availability and efficacy of countermeasures, such as FAD vaccines.

#### Regulatory Intervention During an FAD Outbreak

#### (continued)

- Resources available to implement response strategies
  - Capabilities and resources available to:
    - eradicate an FAD in domestic animals and
    - to control and eradicate and FAD in potential wildlife reservoirs.
- Domestic animal disease management capabilities
  - Capability, feasibility, and resources available to:
    - eradicate an FAD in domestic animals as an emergency response control as an animal disease program
    - monitor as an endemic animal disease.
- Wildlife management capabilities
  - Capability, feasibility, and resources available to eradicate, control, or monitor an FAD in wildlife reservoirs.