

CVB Policy Regarding Regulations for the Licensure and Distribution of Avian Influenza (AI) Vaccines



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Center for Veterinary Biologics Mission

The USDA, APHIS, Veterinary Services, Center for Veterinary Biologics implements the provisions of the Virus-Serum-Toxin Act (VSTA) to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective.



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Avian Influenza Overview

- Avian influenza (AI) - identified in the early 1900s
- Natural Host – Avian Species, particularly aquatic birds
- AI – Influenza A Virus of family Orthomyxoviridae

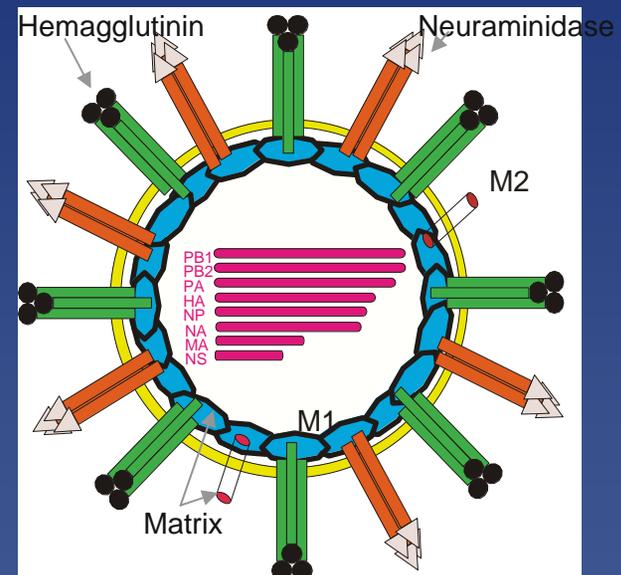


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Avian Influenza Overview (cont.)

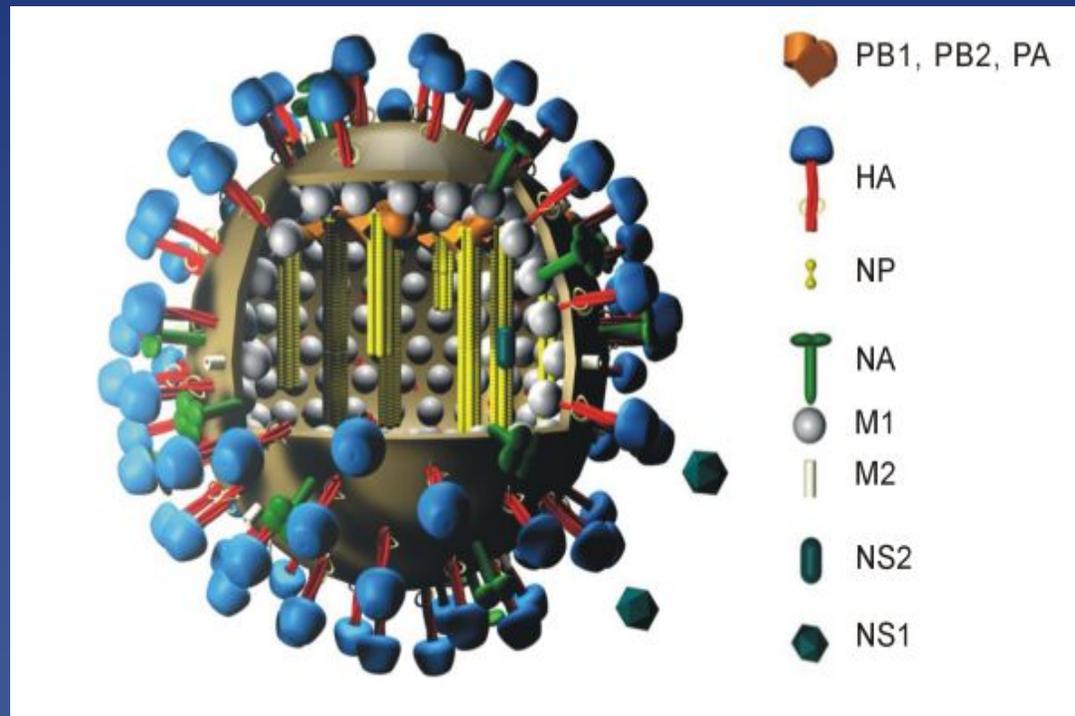
- **Virion – enveloped, segmented, single stranded, negative sense RNA**
- **Characterization based on the surface glycoprotein - Hemagglutinin (16) and Neuraminidase (9)**



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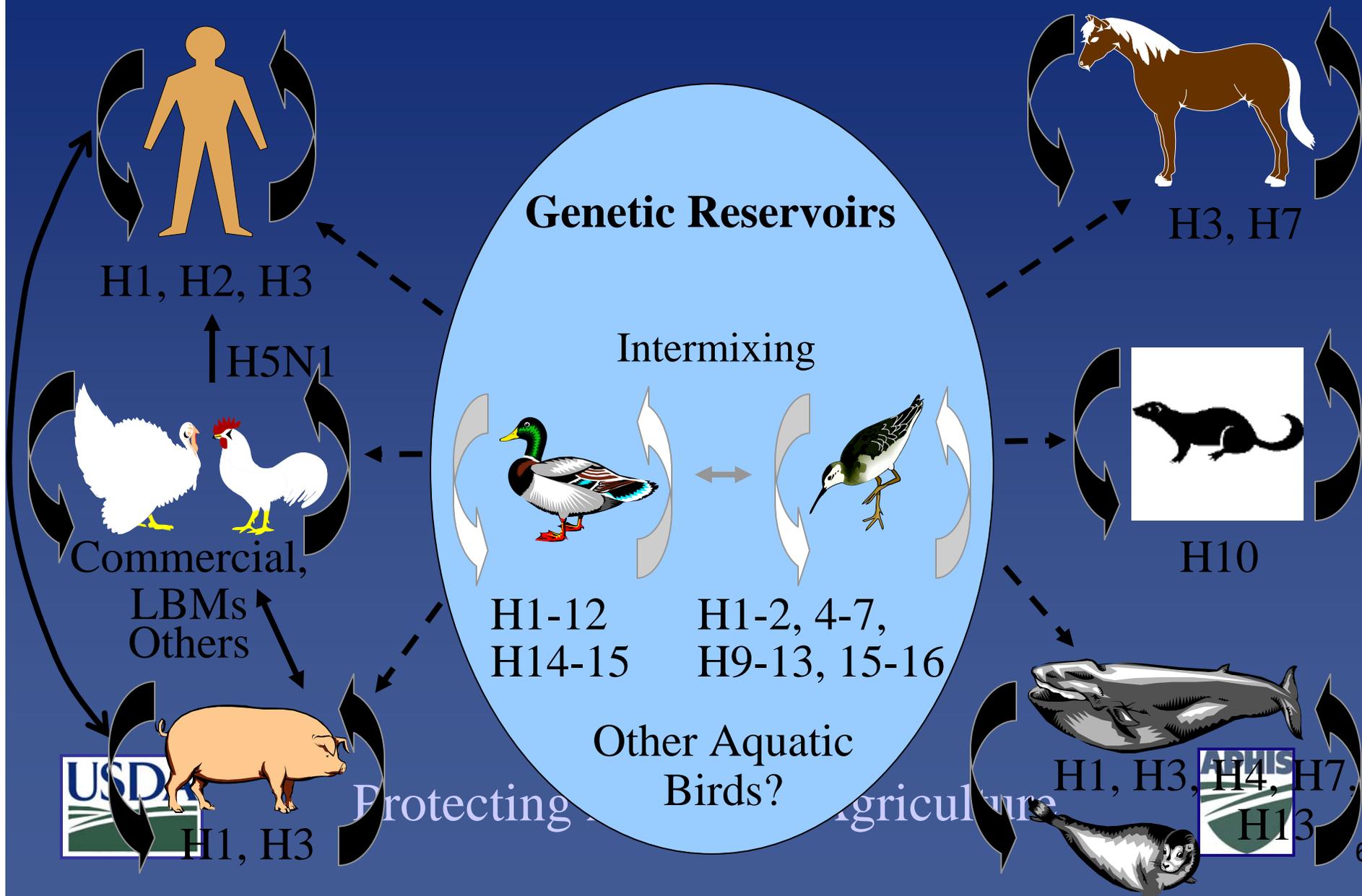
Avian Influenza Overview (cont.)



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Species Affected



How is the virus spread among birds?

- Direct contact between healthy and infected birds
- Infected fecal matter
- Can be found on surface of unwashed egg shells from infected birds



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Avian Influenza Classification

- **Classification – pathogenicity and genetic sequencing**
- **Low-pathogenicity avian influenza (LPAI), any H type**
- **High-pathogenicity avian influenza (HPAI), only H5 & H7**
- **AI viruses mutate easily; only H5 and H7 viruses have the potential to mutate from an LPAI to an HPAI form**



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Three HPAI Findings in U.S.

- 1924 – “Fowl Plague” affected live bird markets in the Northeastern U.S.
- 1983 – destruction of 17 million birds in PA and VA
- 2004 – quickly contained and eradicated in TX



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Control of Avian Influenza in US

- Exotic Disease
- Trade Restrictions
- Surveillance
 - NPIP, State, Universities
- Vaccine



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Licensed Avian Influenza Biologics

Avian Influenza Vaccines: (Full or Conditionally licensed)

- Killed Virus Vaccines (Chickens)
- Killed Virus Vaccines (Turkeys)
- Autogenous (Turkeys)
- Recombinant vaccines (Chickens, export and Vaccine Bank only)



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Licensed Avian Influenza Biologics

Avian Influenza Diagnostics Products:

- Antibody Test Kit
- Antigen Test Kit



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Conditional Licensure

- Conditional licensure of AI products is in accordance with 9 CFR 102.6
- Progress towards full licensure is required for all conditionally licensed products



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USDA Guidelines for AI Vaccine Licensure

- AI vaccines prepared from any serotype subject to restrictions in VS Memorandum 800.85
- H5 and H7 vaccines used as a tool to combat any potential outbreak of HPAI in US
- Master Seed Virus prepared per 9CFR 113.200 and 113.300



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USDA Guidelines for AI Vaccine Licensure (Cont)

- Conventional modified live virus vaccines
- Live/inactivated recombinant, subunit, or biotechnology derived vaccines



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USDA Guidelines for AI Vaccine Licensure (Cont)

- **Autogenous vaccines –**
 - **inactivated cultures**
 - **distribution restriction**
- **Licensure for conventional killed vaccine**



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Restrictions Associated With Inactivated Vaccine Production

- LPAI viruses obtained from Diagnostic Virology Laboratory of National Veterinary Services Laboratories must be used for MSV for these vaccines
- AI virus isolate must be obtained under US permit
- Permit Issuance may require facility inspection prior to the issue
- Receipt of such isolate must also be authorized by State officials



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Vaccine Efficacy

- Application for Licensure
- Protocol Review
- Facility Inspection
- HPAI challenge restrictions



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Labeling Restrictions

- Limited species recommendation –
- Distribution Statement – “.... may only be distributed and used as part of an official USDA animal disease control program”
- Indication of H and N type



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Distribution Restrictions

- Distribution of Non H5 and H7 Vaccines in turkeys
- Domestic distribution and use of licensed H5 and H7 vaccines in turkeys
- Distribution and use of AI vaccines in chickens
- Export Distribution of all AI vaccines



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Questions?



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