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## United States poultry flocks remain unvaccinated against H5 influenza—but why?

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### Abstract

Vaccination is commonly used to minimize disease impacts on birds and promote sustainable poultry production. Vaccination against highly pathogenic avian influenza (HPAI) differs because HPAI is classified as a foreign animal disease in the US and disease control falls under federal jurisdiction. Vaccination for HPAI could negatively affect the nation's ability to export poultry and poultry products, representing the largest barrier to implementation. However, the continued burden of global HPAI cases requires a reevaluation of the cost of ongoing outbreaks and the need for new mitigation strategies, including HPAI vaccine use.

**Keywords:** H5 influenza, HPAI, poultry, strategy, vaccination program

Poultry populations are regularly vaccinated to protect them from a variety of diseases, but not for highly pathogenic avian influenza (HPAI), which is classified as a foreign animal disease. Vaccination against a foreign animal disease is under federal control and scrutinized by trading partners. Thus, all poultry sectors have a vested interest in H5-HPAI vaccination, even if a particular sector does not plan to use an H5-HPAI vaccine. We discuss opportunities to utilize and/or expand existing frameworks to address H5-HPAI vaccination programmatic needs and examine implementation barriers. Ultimately, to make vaccination available and reduce the ongoing HPAI outbreaks' impact on food security, business continuity, and public health, there is a need to understand and overcome these obstacles, acknowledging that there are remaining questions, including which regions or sectors may be vaccinated and for how long.

### Components of an H5-HPAI Vaccination Program Already Available in the US

#### *Fit-for-purpose vaccine*

Discussions of H5-HPAI vaccination often focus on the vaccines themselves. Although H5-HPAI vaccines could be improved, there are currently licensed vaccines produced in the US that protect poultry in experimental settings, could provide protection from current H5 strains, and can be differentiated from natural exposure and integrated into existing vaccination programs.<sup>1-3</sup> An effective vaccine is not a barrier to implementing an H5-HPAI vaccination program.

#### *Risk mitigation framework*

A concern with the use of an H5-HPAI vaccine is that infections, although rare, may go undetected since immunity reduces clinical signs of disease, thereby increasing the risk of viral spread.<sup>4-7</sup> However, there is already a framework in the US—the Secure Poultry Supply plan (SPS)<sup>8</sup>—that identifies and mitigates risks associated with movements of poultry not known to be infected (undetected) and their products from HPAI outbreak control areas.<sup>9,10</sup> The SPS risk assessment process has been used to guide

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poultry movements during HPAI outbreaks, explicitly supported by industry and implicitly accepted by trading partners. The accepted SPS risk assessment and mitigation system can be used to examine surveillance strategies for vaccinated populations with the use of processes that balance sensitivity, specificity, cost-effectiveness, and sustainability. Defining the undetected infection risk and subsequent viral spread is not a barrier to H5-HPAI vaccination.

### *Surveillance*

Communicating the surveillance plan for vaccinated flocks will be critical to assure trading partners that the virus is not circulating undetected. Leaning on existing partnerships between federal and state diagnostic laboratories and industry, surveillance strategies based on sensitivity, feasibility, and an agreed-upon acceptable risk level can be constructed.<sup>11</sup> Adjusting sample sizes, collection frequency, and timing from current surveillance strategies will be needed to assure adequate sensitivity for H5-HPAI vaccinated birds, but risk pathways in H5-HPAI vaccinated flocks will be largely unchanged. An acceptable probability of detection can be determined by incorporating variables such as vaccine efficacy, virus shedding levels, contact transmission rates, and immune status into mathematical models. Establishing a risk-based surveillance program is not a barrier to H5-HPAI vaccination.

## **Barriers to an H5-HPAI Vaccination Program in the US**

### *Trade*

In 2024, the US exported over \$6.25 billion in poultry and poultry products.<sup>12,13</sup> While the World Organization for Animal Health has indicated vaccination "... should not be a barrier to safe trade,..."<sup>14</sup> the US maintains its stance that vaccination will have a potential trade impact. Trade renegotiations require a written vaccination plan shareable with key partners such as Mexico, Canada, and China, which together account for approximately 43% of US exports.<sup>12</sup> However, no vaccination plan has been published as of March 2025. Meanwhile, H5 viral evolution continues, causing more frequent and protracted epizootics and epidemics, including an expansion into mammalian hosts. This global shift makes H5-HPAI poultry vaccinations more compelling for countries plagued with ongoing outbreaks and increases preparedness against future outbreaks caused by H5 or other hemagglutinin types of influenza virus.

There are 2 main trade concerns. The most substantial argument is based in economics, as renegotiation may require the US to open its own markets to poultry imports. The US poultry meat and egg trade surplus in 2024 was approximately \$5 billion, yet the US also imported \$1 billion in poultry meat and eggs in 2024.<sup>12,13</sup> Exporting countries adopting H5-HPAI vaccination sometimes face import restrictions from trading partners that do not vaccinate, effectively creating nontariff trade barriers.<sup>14,15</sup>

The second concern is the perceived risk of introducing undetected virus via importation of products

from vaccinated flocks that are silently infected.<sup>4,6,15</sup> This risk has not been documented; however, it is the primary reason robust surveillance and traceability programs must be included in a national H5-HPAI vaccination program.<sup>11</sup>

### *Traceability*

Requirements associated with administering an H5-HPAI vaccine will likely include documenting vaccine administration (what, when, and how many) as well as the flocks' movements after vaccination to track their products through the supply chain. Although this tracking would be new to government agencies, systems to track vaccine distribution, flock movements, and finished products already exist in the poultry industry. For example, companies producing No Antibiotics Ever (NAE) products track when a flock is treated with antibiotics and no longer qualifies for NAE label claims in a USDA-verified process. While traceability itself is possible and might not be a barrier, the repurposing of existing systems to a centralized, auditable, and validated traceability process<sup>16</sup> that is acceptable to trading partners remains a barrier.

## **Weighing the Impact of Vaccination and the Burden of Ongoing Epizootics and Epidemics**

The costs of an H5-HPAI vaccination program and potential export market disruptions are clearly the main barriers to implementation, but those costs need to be compared to the expense of ongoing H5-HPAI outbreaks. While the economic cost of H5-HPAI to the poultry industry is relatively easy to measure and frequently the only perspective presented, that cost does not account for the ongoing burden that can be attributed to leaving flocks unvaccinated. Therefore, the true impact of choosing to not implement an H5-HPAI vaccination program is not represented.

The true H5-HPAI economic burden should reflect the impact that ongoing infections have on the following: (1) all poultry sectors, including those without substantial exports; (2) communities, especially rural, where sustainable poultry production is a cornerstone of local economies; (3) US taxpayers' money spent on state and federal response efforts; (4) consumers experiencing food choice limitations and higher costs; and (5) hunger relief centers being unable to procure economical, nutritionally dense protein for people experiencing food insecurity. While economics are critical to sustainability, the direct, nonmonetary costs should also be included when calculating an outbreak's toll. The repercussions of ongoing response efforts on the health and well-being of people involved in disease control and the increasing human pandemic threat from increased virus circulation should also be counted as burdens of H5-HPAI outbreaks. The environmental impact of controlling H5-HPAI is not usually considered a "cost," but every infected flock that is depopulated has an environmental footprint. For example, the depopulated flock will have consumed large amounts of resources (water, feedstuffs) that

were not translated into a subsequent societal value (food, wages for workers). Focusing only on industry economics obfuscates the true burden of H5-HPAI epizootics and epidemics, creating a barrier for implementing H5-HPAI vaccination.

The use of vaccination in poultry as an additional mitigation strategy for H5-HPAI outbreaks seems, at first glance, a simple prospect. After all, US poultry are already vaccinated for many diseases. However, there are known challenges that need to be addressed before a national H5-HPAI vaccination program would be deemed acceptable to the poultry industry, state and federal regulators, and trade partners. We have outlined the aspects of a vaccination program that, while occasionally perceived as barriers, are in fact already in place and could facilitate vaccination program implementation; for example, utilizing the SPS framework to develop surveillance programs. We have also outlined known barriers and discussed how they could be addressed and overcome. Considering these potential solutions, as well as the need to approach H5-HPAI in a new way, the vaccination of poultry against H5-HPAI is not a simple matter but is achievable and warranted.

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