Highly Pathogenic Avian Influenza (HPAI)

HPAI and Vaccine Use

The outbreak of highly pathogenic avian influenza (HPAI) H5 in spring 2015 was the worst animal disease outbreak in U.S. history. This disease is extremely deadly to chickens and turkeys and caused significant losses earlier this year. More than 200 premises were affected in 15 States, with more than 48 million birds depopulated.

The U.S. Department of Agriculture (USDA), along with State and industry partners, is planning and preparing for the possibility that the disease will reemerge this fall and beyond. This includes considering whether to use vaccine to help prevent illness in birds and stop or slow the spread of the disease.

There are many opinions on whether USDA should use vaccine, because doing so would potentially impact the ability of our American producers to export poultry overseas, an ability that is crucial to the profitability of the entire industry. Some trading partners may decide to suspend imports from those areas where vaccination is used, impacted States, or even the entire country. Also, there has been no widely available and effective vaccine.

Decision To Use Vaccination

USDA's Animal and Plant Health Inspection Service (APHIS) has <u>not</u> approved the use of vaccine at this time. Before doing so, USDA would take into consideration the:

- extent and rate of spread of the outbreak (including the effectiveness of response activities),
- type of poultry operations affected,
- potential impact on domestic and international supplies and markets,
- potential impact on the ability of our American producers to export poultry overseas, and
- effectiveness and availability of vaccine.

However, APHIS is taking steps necessary in order to be ready to make this decision. This includes reviewing new potential vaccines for licensing, stockpiling doses of approved vaccines so they would be readily available, and completing any required environmental assessments. If APHIS approves vaccine use, it would not be used alone. Instead, it would be part of a larger, overall strategy to contain and eliminate the HPAI virus from the United States. While vaccinating, APHIS still would focus on enhanced biosecurity and biosurveillance, rapid depopulation, and other virus elimination methods to help end the outbreak. Ultimately, only these actions can achieve total eradication and restore the poultry industry to full production and exports.

Available Vaccines

To work well, vaccines need to match the genetics of the virus. Because avian influenza (AI) viruses are adaptable, the genetics can change over time. The closer the genetics match to the virus, the more effective the vaccine is.

There are AI vaccines currently available, but they are not a specific match to the genetics of the current outbreak's virus. Therefore, these vaccines would not be sufficient to ensure eradication.

Researchers and vaccine companies are developing vaccines that use the genetics from the current HPAI virus that caused disease in spring 2015. They are studying how much protection the vaccine will provide for immunized birds.

APHIS regularly reviews new vaccine options as they are developed and submitted for licensing. As required by the Virus-Serum-Toxin Act—a law in place for over a century—APHIS ensures every licensed vaccine is safe, potent, pure, and effective. To receive a license, a company must test the vaccine on the species for which it is seeking licensure.

APHIS would only stockpile and use licensed HPAI vaccines that show potential to reduce the spread of the virus and death loss. APHIS would then decide which vaccines to use, based on the overall needs of the disease response.

Vaccine Administration

Vaccines can be administered to poultry in three ways by injection, by aerosol mist (breathing in the vaccine), or through drinking water. The vaccines currently approved or being researched are all injectable-type vaccines.

Vaccine could be administered to hatching eggs or to day-old chicks. Immunity to the virus develops in about 21 days. Depending on the bird's lifespan, a booster dose may be necessary. Turkeys would likely receive at least one booster dose, while layer chickens may need two or more booster doses. Broiler chickens have much shorter lifespans—around 40 days—so vaccinating them would not be as useful.

Limits of Vaccine

It is important to understand what HPAI vaccine would and would not do.

HPAI vaccines reduce sickness, clinical signs, and death in domestic poultry. They <u>would not</u> prevent birds from becoming infected with the AI virus or from producing and shedding virus into the environment. Vaccine <u>would</u>, however, reduce the amount of virus an infected bird sheds into the environment, which in turn helps prevent spread to new locations.

USDA would carefully target where to use vaccines; they would not be used on a widespread basis. Limiting vaccination to some areas and some species would offer the best chance of limiting crippling export sanctions. Producers <u>would not</u> be able to obtain vaccine from their veterinarian and proactively vaccinate their birds. Only USDA and State veterinarians <u>would</u> authorize vaccine use and monitor its administration.

After Vaccination

Producers would not be allowed to move vaccinated birds outside of the vaccination area, unless the shipment was sent directly to slaughter under a permit from State or Federal animal health officials. Products from vaccinated birds could only be moved and used within the United States.

Animal health officials would regularly monitor and test vaccinated flocks for HPAI infection. If they find infection, APHIS would depopulate the flock and provide indemnity to the producer. APHIS would also work with producers to closely track all vaccinated birds through their normal lifespans to confirm when they are removed from the U.S. poultry population.

If there are indications that the vaccine strategy is not working to help contain the disease, APHIS would re-evaluate the use of vaccine. Finally, APHIS would stop vaccination after the outbreak is contained and HPAI eradicated. Once all vaccinated birds were removed from the U.S. poultry population, APHIS could re-declare the United States HPAI-free without vaccination.

FOR MORE INFORMATION

To learn more about HPAI and emergency response and find helpful resources on these topics, go to:

- www.usda.gov/avian_influenza.html
- www.aphis.usda.gov/fadprep

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