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Chairman Rouzer, Ranking Member Costa and Members of the Subcommittee, I am Dr. David Swayne, Laboratory Director and Supervisory Veterinary Medical Officer, at the Southeast Poultry Research Laboratory (SEPRL) which is part of the Agricultural Research Service's (ARS) U.S. National Poultry Research Center in Athens, Georgia.

I am sure you are aware of the great hardships that the U.S. poultry industry and producers have suffered because of Highly Pathogenic Avian Influenza (HPAI). It goes without saying that ARS, and particularly the research staff at SEPRL, are committed to eradicating the H5N8 or H5N2 viruses at the center of the current North American outbreak through cutting edge research in diagnostics, epidemiology, pathology, molecular biology, and vaccinology. ARS is determined to aid our sister agency, the Animal and Plant Health Inspection Service (APHIS), and the poultry industry to ensure that this strain of avian influenza is understood and can be scientifically managed to protect animal agriculture and the food supply.

Background

ARS's Exotic and Emerging Avian Viral Diseases Research Unit at SEPRL has been conducting research on avian influenza since the mid-1970s. Our research has helped U.S. poultry farmers increase exports, led to the eradication of low pathogenic avian influenza (LPAI) in U.S. poultry, and contributed to the overall global efforts to combat LPAI and HPAI. Today, SEPRL is USDA's national research laboratory for avian influenza and an international reference laboratory recognized by both the World Organization for Animal Health (OIE) and the Food and Agriculture Organization (FAO) of the United Nations. We also work within the OIE/FAO Animal Influenza Expert Laboratory Network (OFFLU) that cooperatively works internationally to control influenza in all agricultural species.

Initial Research Response

In response to the first detections of H5N8 and H5N2 in wild waterfowl and captive raptors in the United States in December of 2014, ARS refocused its HPAI research

direction to the most imminent research needs to address the U.S. outbreak. Within weeks, scientists at SEPRL developed a rapid molecular test to detect the Asian H5 HPAI, which would quickly differentiate it from the North American LPAI viruses. The test was quickly validated by researcher at SEPRL for sensitivity and specificity, and transferred to the National Veterinary Services Laboratory (NVSL) of APHIS. In addition, SEPRL developed a rapid test for the identification of the N8 gene of the Asian HPAI viruses and helped NVSL optimize its neuraminidase sequence test.

Infectivity and Transmission

Representative H5N8 and H5N2 HPAI virus strains from the United States were tested in terrestrial poultry, domestic ducks, and captive mallards to determine how easy it was to infect birds and produce disease. The initial HPAI viruses required high intranasal doses of virus to infect chickens and turkeys, and contact transmission to birds was inefficient. However, all infected chickens and turkeys became ill and died. By contrast, the domestic ducks and mallards became infected with lower doses of virus and had more efficient contact transmission. They did not become ill or die, but shed virus into the environment through the feces and oral secretions for up to 14 days.

These studies suggest the early H5 HPAI viruses were best adapted to waterfowl and difficult to transmit from wild waterfowl to poultry. The HPAI virus detections in wild birds from the Pacific Flyway corroborate this observation as detections were observed at an unexpectedly high rate in several duck species, with more limited detection in backyard flocks and only two commercial poultry flocks.

However, the later outbreak of the H5N2 virus in the Midwest required less virus to infect chickens, and contact transmission occurred more easily than with the initial HPAI viruses. This demonstrated that the wild bird viruses had changed and were more easily transmitted to and among chickens and turkeys, potentially allowing for farm-to-farm spread of the virus.

Molecular Analysis of Virus Spread

It is critical in developing control and eradication strategies to understand how the viruses are introduced onto farms and how they spread. SEPRL researchers have been working with APHIS virologists and epidemiologists as well as field and university poultry veterinarians to provide molecular network analysis of the HPAI viruses. The data produced by this analysis supports the idea that the early outbreak viruses were likely introduced by wild birds. However, the analysis of later viruses showed molecular sequence evidence of clustering, which is a sign of farm-to-farm spread.

Vaccine Issues

In the United States, there is no vaccine approved or currently in use in commercial poultry for H5N8 or H5N2 HPAI. While some nations have attempted to utilize vaccine to protect poultry against the H5N1 HPAI virus, a primary focus on vaccines has not led

to immediate eradicate of HPAI. Ninety-nine percent of the vaccine use to this point has been in China, Egypt, Vietnam and Indonesia were H5N1 HPAI is endemic.

Issues associated with vaccine use, including vaccine failure and vaccine resistance, have been identified in countries using the vaccine long-term. In addition, vaccine efficacy is limited over time. Similar to human influenza, avian influenza viruses change over time, and vaccine efficacy decreases as the outbreak viruses change. This has necessitated continued surveillance for vaccine-resistant field strains within vaccinated poultry populations of these countries, and periodic change of the vaccine seed strain to more closely match the circulating field HPAI virus for optimal protection. In countries vaccinating against HPAI, virological surveillance in vaccinated flocks is crucial to collect viruses for genetic and antigenic analysis to assess field protection between vaccine seed strains and current circulating field viruses.

ARS plays a critical role with APHIS and other public health authorities in providing scientific information and countermeasures to significantly and measurably mitigate the impact of HPAI disease outbreaks. When addressing the need for vaccination, SEPRL first evaluates new avian influenza outbreak viruses by sequence analysis and serologic characteristics, which provides a good estimation of how close the new viruses are to other influenza viruses and existing vaccines. Then we select the most representative challenge viruses to use in vaccine efficacy and challenge studies. Because these are HPAI viruses, the studies must be conducted in high biocontainment facilities.

Vaccine and Testing

SEPRL conducts vaccine seed strain development and testing as well as routine research activity, but it does not manufacture vaccines nor decide when or if vaccines should be used in the field. The licensing and use of a vaccine is determined by APHIS. Currently, SEPRL is evaluating registered HPAI vaccines and has developed a H5 vaccine seed strain for protection in chickens and turkeys against the current H5 HPAI outbreak viruses. If viable, the appropriate vaccine seed strain will be transferred to a commercial vaccine manufacturer.

Measuring Efficacy

Vaccine protection or efficacy is measured primarily by two means in vaccinated poultry: (1) prevention of clinical disease and death; and (2) a reduction in virus shedding, which reflects the growth of the challenge virus and release of the virus in body secretions (oral secretions and feces). Decreased virus shedding is important in reducing environmental contamination, and thus reducing virus transmission and infection. Low quality vaccines or vaccines with antigenic mismatches do not prevent infection. Thus birds challenged with a high dose of HPAI virus will become infected and excrete a great deal of virus into the environment.

Vaccination can play a helpful role in disease eradication if properly implemented, but historically vaccination negatively affects poultry exports, which is a crucial part of the

U.S. poultry industry. Efforts to mitigate the effect of vaccination on exports include the use of testing that can identify infected birds within a vaccinated poultry population using reliable and cost effective serological and virological testing; i.e so termed DIVA strategy. This differentiation approach has been shown to work experimentally, but with only limited field experience for HPAI vaccine. SEPRL is evaluating all the vaccines being tested for the ability to identify infected birds within vaccinated poultry. Because of the many types of vaccines proposed for use, some strategies need more research work for development and validation. The validation of this approach is a priority for SEPRL and its collaborators.

Conclusion

The current HPAI outbreak presents unique and unprecedented challenges to the U.S. poultry industry. The widespread presence of HPAI in wild birds provides an ongoing threat to the U.S. poultry industry. That is why SEPRL immediately began to work to identify specific strains of the virus, and develop a test to detect the HPAI virus in affected poultry. In addition, SEPRL continues to work, develop and test an effective vaccine for the specific strains of the virus impacting the U.S. As mentioned before, we are in the initial testing phase for the H5 HPAI strain. While testing looks promising, much more work is needed before a registered vaccine is found to be a viable option.

We will continue to develop new and improved tools for containment of the virus, and work to make these tools commercially available, where possible, as a means to prevent the widespread losses the poultry industry and producers have sustained during this outbreak. The Agricultural Research Service, along with Animal and Plant Health Inspection Service, will continue to work hard to address this complex problem. Thank you again for the opportunity to testify and for Congressional support as we continue to fight this virus.