



Executive Summary

DRAFT Interagency Risk Assessment for the Public Health Impact of Highly Pathogenic Avian Influenza Virus in Poultry, Shell Eggs, and Egg Products

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Background

The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) developed a quantitative risk assessment for the highly pathogenic avian influenza virus(es) (HPAIV) in food in collaboration with the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA) and USDA's Animal and Plant Health Inspection Service (APHIS). The risk assessment was developed by an Interagency Workgroup formed from representatives of each of these three agencies. The purpose of this risk assessment was to 1) estimate the exposure and potential human illness from consumption of HPAIV-contaminated poultry, shell eggs, and egg products from the index flock, and 2) examine the effectiveness of mitigation strategies to control HPAIV if detected in the United States.

Public Health Context

Avian influenza viruses are typically species-specific, causing disease in birds. However, H5N1 and other H5 and H7 HPAI subtypes have recently become a zoonotic concern. In June 2008, the World Health Organization reported that worldwide from 2003-2008, there have been 385 confirmed HPAIV human illnesses, resulting in 243 deaths. Retrospective studies have determined that the majority of these cases are associated with close contact with live or dead HPAIV-infected birds likely caused by respiratory inhalation of infective droplets or self-inoculation (*e.g.*, by a human handler touching mucous membranes or conjunctiva after contact with avian fecal contamination, avian respiratory secretions, or avian body fluids), rather than consumption of poultry or shell eggs or egg products. Currently, there is no compelling epidemiological evidence linking the consumption of cooked poultry meat, shell eggs, or egg products to human illness caused by HPAIV. HPAIV is not considered to be a foodborne pathogen although the virus has been isolated from poultry muscle and the interior of eggs. Two HPAIV-confirmed human illnesses may have been related to the consumption of infected raw duck blood products, although contact with live or dead HPAIV-infected poultry could not be epidemiologically excluded. Despite this lack of evidence, the possibility of poultry and egg consumption as an exposure route to HPAIV remains a concern to food safety experts. In light of this and the recent HPAIV poultry and human illnesses in Asia, Africa, Europe, and the Middle East, the Interagency Workgroup developed this food safety risk assessment for HPAIV exposure and illnesses in humans from consumption of poultry meat, shell eggs, and egg products.

Model Approach

The risk assessment model simulates human exposure and potential illness from consumption of H5 and H7 HPAI strains that can make humans ill and lead to death. Exposure from HPAIV is modeled separately for poultry meat and for shell eggs. Each model consists of three modules representing production, processing, and consumer preparation. The production module assumes introduction of HPAIV into the index flock of a single U.S. meat or egg poultry house following HPAIV entry into the U.S. A bird-to-bird transmission model simulates HPAIV spread to estimate within-flock prevalence of HPAIV at the farm and for poultry meat production, during transportation. For an infected flock destined for meat production the transmission model simulates an increase in the prevalence of HPAIV in the flock until substantial bird mortality would allow the disease to be detected or the undetected flock is sent to slaughter. In the processing module, it was assumed birds sent to slaughter are subject to federal inspection, which could result in the removal of infected birds. The likelihood an infected bird is identified due to visible pathology was dependent on how long the bird was infected before slaughter. The amount of HPAIV in each serving of poultry is related to the time between infection and slaughter. For the shell egg model, egg production continues to be simulated until substantial bird mortality would allow the disease to be detected. Routine inspection of shell eggs sent to processing prior to flock detection would not detect HPAIV within shell eggs, but may identify non-specific markers of HPAI. Therefore, for the purpose of the model, shell eggs with visible pathology (*e.g.*, thin-shelled, soft-shelled, or abnormally small) are removed from commerce and are not included in the risk estimates. The consumer preparation module examines the impact of cooking and cross-contamination on levels of HPAIV, thereby resulting in estimates of the level of HPAIV ingested by the consumer. The predicted amount of contaminated poultry meat or number of infected eggs available for human consumption is used along with a dose-response function to estimate the number of potential human illnesses. Other routes of exposure such as inhalation, mucosal contact, and wound exposures by food preparers and consumer contact with contaminated raw poultry and shell eggs, as well as farm and processing occupational exposures, are not addressed in this risk assessment.

Results

This risk assessment has been developed as a tool to evaluate mitigation scenarios should HPAIV be identified in the U.S. The number of human illnesses predicted serves as a basis to assess the magnitude and effectiveness of mitigation strategies. Given the uncertainty regarding the dose-response relationship and the uncertainty regarding the likelihood of human illness from consumption of poultry and eggs, the model-predicted number of human illnesses should not be considered an absolute value, and it should not be used outside of the context of the scenario analysis described below. Using scenario analysis, the following outputs were identified:

1. Poultry Model

- If a flock is exposed to HPAIV, the model predicts a 94 and 98% probability that a chicken and turkey flock, respectively, would be identified as HPAIV-positive before

slaughter and not enter commerce. This is because flocks infected early in the grow-out period will have enough time to demonstrate significant mortality ($\geq 2\%$ flock mortality over a single day) on the farm, resulting in identification of the flock as HPAIV-positive.

- There is a 6 and 2% probability that an HPAIV-infected chicken or turkey flock, respectively, may go to slaughter without detection of the disease. This would happen when HPAIV infects a flock that is approaching market weight with not enough time for the flock to demonstrate significant mortality on the farm. In these instances, some fraction of HPAIV-contaminated poultry meat may enter commerce.
- On-farm HPAIV testing as a potential mitigation strategy has the greatest impact of lowering predicted illnesses. Approximately 95% of illnesses are mitigated if flocks are tested immediately before being sent for slaughter.
- Increased on-farm surveillance of daily flock mortality is predicted to reduce human exposure and illness. However, the model predicts that relying on a single day of flock mortality to detect all HPAIV-infected, but undetected flocks is impractical. This is because a flock may have few dead birds if infected late in its grow-out period as about 36 to 42 hours are required before infected birds die from HPAI.
- Increased surveillance at processing during FSIS' antemortem inspection is predicted to reduce human exposure and illness. However, the model predicts that using the number of dead birds following transportation to trigger detection of all HPAIV-positive flocks is impractical given that a flock may have few dead birds if infected late in its grow-out period.
- Cooking poultry to the FSIS recommendation of 165°F is predicted to inactivate the virus and result in negligible risk to public health from HPAIV-contaminated poultry meat.
- Cross-contamination of HPAIV from contaminated poultry to foods not likely to be cooked resulting in oral uptake increased the number of predicted illnesses by approximately 2.5%. Consumer messages should continue to emphasize measures to prevent the potential cross-contamination of HPAIV and other microbiological hazards.

2. *Shell Egg and Egg Products Model*

- If a 100,000 hen flock becomes infected with HPAIV, the baseline scenario predicts that 11,293 HPAIV-contaminated eggs are produced before the flock is discovered as HPAIV-positive. However, the baseline model predicts no human illnesses because $> 99.99\%$ of HPAIV-positive eggs would still be in the distribution chain at the time of diagnosis and not yet be available for consumers to purchase. This assumes that all HPAIV-positive eggs can be removed from distribution.

- If the risk assessment model baseline assumptions are changed using scenario analysis, HPAIV-positive shell eggs may enter commerce. Thorough cooking of eggs (150 °F) results in inactivation of the virus; however, if eggs are not cooked completely, the model predicts a few illnesses are possible. For example, the model predicts two illnesses may occur before a flock is identified as HPAIV-positive in a scenario where eggs reach market within 24-hours.
- As a mitigation strategy, removing HPAIV-positive shell eggs from commerce will reduce potential exposure. Effectiveness is dependent on how many days of eggs production are removed. The model predicts that greater than 97% of potentially contaminated shell eggs can be removed from commerce given a 2 day market withdrawal.
- In-shell pasteurization of HPAIV-positive eggs is predicted to inactivate the virus and result in negligible risk to public health.
- Data from USDA's Agricultural Research Service show that FSIS time and temperature recommendations for egg product processing are sufficient to inactivate HPAIV, therefore this risk assessment model does not quantitatively assess the risk of illness from HPAIV-contaminated egg products. Only dried egg white processing may not completely inactivate HPAIV; however, the process of preparing dried egg whites requires a minimum of 7 days. It is likely that the hen flock that produced the contaminated eggs would have been identified as HPAIV-positive before the process is completed, and egg products processors would be alerted to the problem. APHIS is currently developing a separate risk assessment to assess the risk of illness from HPAIV-contaminated egg products.

Summary

This quantitative risk assessment provides a science-based, analytical approach to collate and incorporate available data into a mathematical model, and it provides risk managers a decision-support tool to evaluate the effectiveness of interventions to reduce or prevent foodborne illness from HPAIV in the U.S. This risk assessment can also be used to target risk communication messages, identify and prioritize research needs, and provide a framework for coordinating efforts with stakeholders. The risk assessment is being used to help guide APHIS's HPAI emergency response planning and FDA's HPAI preparedness.

Although unlikely, the risk assessment demonstrates that some amount of HPAIV-contaminated poultry and shell eggs could enter commerce. The data indicate that there is a 3.5- or 6-day window during which potentially HPAIV-positive poultry or shell eggs, respectively, could escape detection. The model predicts that consumption of HPAIV-contaminated poultry and shell eggs poses a negligible risk if properly cooked. At the same time, data suggest that some people will undercook these products and could become exposed and possibly ill.

The model shows that preventive measures, such as HPAIV-flock testing and increased inspection, would result in increased detection of HPAIV-contaminated flocks and reduce the risk of HPAIV illnesses by preventing the consumption of contaminated poultry. In addition, effectively recalling shell eggs would substantially reduce the risk to consumers from HPAIV-contaminated shell eggs.