



OCT 24 2006

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary
Services

Washington, DC
20250

Dr. Preben Willeberg
Chief Veterinary Officer
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg
DENMARK

Dear Dr. Willeberg:

Thank you for sending the King of Denmark's statement of August 26, 2006, regarding the highly pathogenic notifiable avian influenza (HPNAI) status of Denmark. As you know, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) had imposed restrictions on the importation of poultry and poultry products from Funen County after an outbreak of the H5N1 subtype there. It is our understanding that you are asking the United States to remove these restrictions because Denmark is now an HPNAI-free country, according to the standards of the World Organization for Animal Health (OIE).

We acknowledge your statement and congratulate you on your achievement. However, U.S. regulations require APHIS to follow a regulatory process for removal of countries or zones from APHIS' list of H5N1-affected regions. This process involves conducting a risk analysis, which will be used to support rulemaking if the results warrant. The risk analysis will be released to the public, and comments will be solicited. If comments are favorable, APHIS will publish a rule to remove Funen County from the list of H5N1-affected regions.

The risk analysis will be based on information provided by your veterinary authorities relevant to the 11 factors described in Title 9 of the *Code of Federal Regulations* (CFR) section 92.2. We already have a significant amount of general information on file from our exotic Newcastle disease evaluation. Please submit information that focuses particularly on the epidemiology of the HPAI outbreak in Funen County and the procedures implemented to contain and control the outbreak.

The information should document the following:

- Funen County has been HPNAI-free for 3 months.
- HPAI was notifiable in Denmark; there was an ongoing awareness program in place for veterinary officials and the public; and all notified or suspect occurrences of HPAI were subjected to field and laboratory investigations.
- A surveillance program existed which addressed the specific needs in Denmark. This program supported detection and investigation of the outbreaks and included clinical inspection, active and passive surveillance (serological and agent detection), and serological and virological testing in high-risk areas and of high-risk flocks sufficient to detect disease effectively and quickly, even in the absence of clinical signs.



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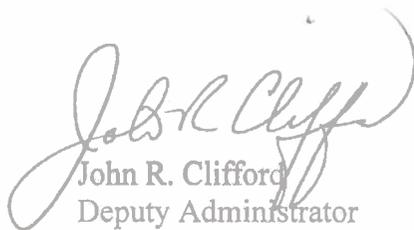
- Under the surveillance program, all notified and/or suspect AI cases were investigated and appropriate actions taken; samples were collected and transported in a manner that ensured integrity of the sample for testing purposes; and laboratory results were documented.
- The system for recording, managing, and analyzing diagnostic and surveillance data was sufficient to demonstrate effectiveness of disease control measures.
- Laboratory confirmation capabilities were effective. Laboratory testing procedures were documented and standardized.
- The eradication program included the definition of appropriate quarantine and surveillance zones, monitoring of those zones, and implementation of movement restrictions. Measures were capable of containing and controlling disease spread from these zones. Procedures for lifting quarantines were followed and were sufficient to prevent further spread of disease.
- Standard operating procedures for depopulation, cleaning and disinfection, and other applicable measures (such as carcass disposal) were documented, familiar to relevant personnel, and followed during the outbreak. These measures were effective in controlling the disease.
- Premises were repopulated (if applicable) according to documented procedures and there was no disease recurrence. Monitoring conducted after repopulation demonstrated that the disease has been eradicated.

The information we are requesting is consistent with that outlined in Article 2.7.12.2 of the OIE Terrestrial Animal Health Code (2006) as necessary to regain NAI-free status for a country, zone, or compartment after an infection has been reported.

Please submit the information for our evaluation. The results of the evaluation will be documented in the risk analysis, which will be released for public comment. If the results warrant, we will remove Funen County from the list of H5N1-affected regions through rulemaking.

We look forward to working with you on this issue.

Sincerely,



John R. Clifford
Deputy Administrator
Veterinary Services