

APHIS' Evaluation of the Status of High Pathogenicity Avian Influenza H5N1 (HPAI H5N1) in Germany

Animal and Plant Health Inspection Service

Veterinary Services

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ABBREVIATIONS

ADNS	Animal Disease Notification System
AI	avian influenza
APHIS	Animal and Plant Health Inspection Service
AU	Administrative Units
BfR	Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung)
BMVEL	Federal Ministry of Consumer Protection, Food and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft)
BVL	Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit)
CFR	Code of Federal Regulations
CRL	Community Reference Laboratory
CSF	Classical Swine Fever
EC	European Commission
END	Exotic Newcastle Disease
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FLI	Federal Research Institute for animal health (Friedrich-Loeffler-Institut)
FVO	Food and Veterinary Office
H5N1	hemagglutinin 5 neuraminidase 1
HPAI	highly pathogenic avian influenza
LPAI	low pathogenicity avian influenza
MS	Member State
NAI	notifiable avian influenza
NRL	National Reference Lab
OIE	World Organization for Animal Health
PCR	polymerase chain reaction
TRACES	Trade Control and Expert System
TSN	National Disease-Information-System; within the Friedrich-Loeffler Institute
SCFCAH	Standing Committee on the Food Chain and Animal Health

USDA United States Department of Agriculture

EXECUTIVE SUMMARY

On April 6, 2006, the German Federal Ministry of Consumer Protection, Food and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, BMVEL) reported their first outbreak of High Pathogenicity Avian Influenza subtype H5N1 (HPAI H5N1) in domestic poultry to the World Organization for Animal Health (OIE). The outbreak occurred in a turkey flock in the kreis (district) of Muldental in the Federal State of Saxony. This was the only outbreak to occur in domestic poultry in Germany during 2006. In 2007, Germany reported six outbreaks of HPAI H5N1 in domestic poultry; four in small hobby farms and two outbreaks on large duck farms with 170,000 ducks on each farm. No further findings of HPAI H5N1 in Germany in either domestic poultry or wild birds occurred until October 9, 2008, when a small outbreak in a single mixed species flock occurred in landkreis of Görlitz in the Federal State of Saxony following the identification of HPAI H5N1 in a wild bird on a nearby lake.

APHIS proposes to lift the restrictions established for the 2006 and 2007 outbreaks and maintain the restrictions established during the October 2008 outbreak until the European Commission lifts the restrictions. APHIS will review the status of the outbreak at that time.

In this document, APHIS presents the results of its evaluation of the HPAI H5N1 status of Germany based on the evaluation of documentation submitted by the BMVEL, European Commission (EC) Food and Veterinary Office (FVO) reports, EC legislation, and reports to OIE. APHIS has maintained contact with German veterinary authorities who kept APHIS advised of animal disease conditions in their country and concludes that a document review is sufficient to meet the needs of this evaluation. In addition, because of the long history of trade between the United States and Germany, APHIS did not require a site visit to complete this evaluation.

The documentation reviewed was consistent with the OIE Terrestrial Animal Health Code recommendation for reinstatement of trade with a region that has experienced an outbreak of notifiable high pathogenicity avian influenza. In brief, APHIS based this evaluation on the following critical factors: the specified regions in Germany have been free of HPAI H5N1 for at least 3 months as the result of effective control measures undertaken by the veterinary authorities; that HPAI H5N1 was a notifiable disease in Germany; an ongoing disease awareness program was implemented; all notified or suspect occurrences are investigated; an effective surveillance program for HPAI H5N1 existed that supported the detection and investigation of outbreaks; diagnostic and laboratory capabilities are adequate and effective; eradication and control measures and movement restrictions are appropriate to prevent further spread of disease; and appropriate procedures are used for repopulation of affected premises include monitoring to demonstrate that HPAI H5N1 had been eradicated.

APHIS considers that the presence of HPAI H5N1 in wild birds presents the highest risk for the reintroduction of HPAI H5N1 into Germany. Eradication of the disease should mitigate the immediate risk from resulting outbreaks but the reintroduction of disease into

domestic poultry remains a concern whenever HPAI H5N1 is present in wild or migratory bird populations. In that regard, BMVEL recognizes wild birds as the major pathway of introduction of HPAI and continues to adequately monitor with an appropriate surveillance system for HPAI in wild birds. Extensive surveillance in wild birds and domestic poultry for HPAI H5N1 in Germany continues. APHIS considers that if HPAI H5N1 were reintroduced into Germany it will be rapidly detected, and appropriate control and eradication measures would be applied to eliminate the disease.

As a result of this evaluation, APHIS concludes that BMVEL has the means to effectively control and eradicate HPAI H5N1 in its domestic poultry population and that the German authorities have adequate control measures in place to rapidly identify, control and eradicate the disease when it be reintroduced into Germany in either wild birds or domestic poultry. The effectiveness of the eradication program was attributed to prompt actions taken by BMVEL with cooperation from backyard and commercial flock owners.

Based on the results of the assessment, APHIS could not identify additional risk factors that would indicate that domestic poultry in the restricted kreis (district) of Muldenthal in the Federal State of Saxony, and several kreis in the Federal States of Thuringia, Bavaria, Brandenburg, Mecklenburg-Western Pomerania and Saxony-Anhalt, Germany, continue to be affected with HPAI H5N1. Therefore, APHIS concludes that the likelihood of introducing HPAI H5N1 into the United States through the import of live birds, poultry carcasses, parts or products of poultry carcasses, and eggs of poultry, game birds or other birds from these regions in Germany to be low. Restrictions placed on the Federal State of Saxony in October 2008 will remain in place until further notice.

INTRODUCTION

On April 6, 2006, the Federal Ministry of Consumer Protection, Food and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, BMVEL) reported an outbreak of high pathogenicity avian influenza virus subtype H5N1 (HPAI H5N1) in domestic poultry to the World Organization for Animal Health (OIE). The outbreak occurred in a turkey (*Melgeagris gallopavo*) flock near the town of Mutschen, in the kreis (district) of Muldentalkreis in Federal State of Saxony (Sachsen).

This followed the initial finding of HPAI H5N1 in wild birds in February, 2006, along the Baltic coast on Rügen Island, in the state of Mecklenburg-Vorpommern (Mecklenburg-Western Pomerania). HPAI H5N1 was confirmed in swans (*Cygnus olor* and *Cygnus cygnus*) and a northern goshawk (*Accipiter gentilis*) that were found dead on the Island. By September 2006, HPAI H5N1 had been found in 123 wild birds in many parts of the country. HPAI H5N1 was again reported in six groups of wild birds (swans and ducks) in June 2007, in the southern state of Bayern.

In 2007, six outbreaks of HPAI H5N1 were reported in domestic poultry, primarily in small hobby farms and also on two duck farms in Bavaria. During 2007, 326 cases of HPAI H5N1 were confirmed in wild birds. The affected species were predominantly black necked grebes (*Podiceps nigricollis*) and great crested grebes (*Podiceps cristatus*) (295) as well as mute swans (*Cygnus olor*) (22). Between December 25, 2007, and October 9, 2008, Germany did not report the presence of HPAI H5N1 in domestic poultry or wild birds.

On October 9, 2008, Germany announced the presence of HPAI subtype H5 in a flock of mixed species of domestic poultry which was confirmed on October 10 to be HPAI H5N1. This outbreak was limited to a single flock and extensive surveillance and epidemiologic investigations have not revealed additional affected flocks. In Council Directive 2008/812/EC, the European Commission has announced its intention to have these restrictions remain in place until November 13, 2008.

In this document, APHIS presents the results of its evaluation of the HPAI H5N1 status of Germany. APHIS is basing this review on the evaluation of documentation submitted by the Federal Ministry of Consumer Protection, Food and Agriculture (BMVEL) [1], information available on BMVEL's website [2], reports to the European Commission (EC) [3, 4, 7], EC legislation [Appendix I], and reports to OIE [5].

Previously, APHIS has conducted reviews of the animal health control system of the European Union and has concluded that Germany has in place an effective system to identify, control and eradicate animal diseases [8]. In the 2004 risk assessment for Classical Swine Fever (CSF), APHIS evaluated the veterinary infrastructure of 15 Member States of the European Union (EU) [9], including Germany, with regard to the ability to apply the harmonized and binding animal health regulations imposed by the EC on all Member States. Important animal health requirements include compulsory notification of specific animal diseases to both the EC and OIE. END, CSF and HPAI, including HPAI H5N1; are all notifiable diseases in the EU.

In 2005, APHIS identified and presented for public comment what it would consider to be the smallest sub-national jurisdictions or Administrative Units (AUs) in the 15 EU Member States (MS). The AU was considered to have “effective oversight of normal animal movements into, out of, and within that jurisdiction, and that, in association with national authorities, if necessary, has effective control over animal movements and animal diseases locally”. APHIS recognized that local authorities in these EU-MS have effective oversight and control of animal diseases locally within their respective AUs and in the event of future animal disease outbreaks in the EU, APHIS would regionalize the EU-MS to the level of one or more of the identified AUs. Although the document specifically addressed CSF, the concept of regionalization to the AU level was considered to be more broadly applicable and not disease-specific. In the case of Germany the AU was considered to be the kreis (district) [9].

These evaluations of the veterinary infrastructure, including laboratory capability and the ability to implement appropriate control measures, movement controls, and emergency measures, apply equally to HPAI H5N1. The information provided by Germany regarding HPAI H5N1, in addition to the information from previous evaluations of poultry, swine, and ruminant diseases provide a background that is consistent with the 11 factor approach in 9 CFR 92.2. APHIS has maintained contact with German veterinary authorities who kept APHIS advised of animal disease conditions in their country and concludes that a document review is sufficient to meet the needs of this risk analysis. In addition, because of the long history of trade between the United States and Germany, APHIS did not require a site visit to complete this evaluation.

Germany provided the information requested by APHIS to support their request for being removed from the APHIS list of H5N1 affected countries. The documentation provided was consistent with recommendations outlined in Chapter 10.4 of the World Organization for Animal Health (OIE) Terrestrial Animal Health Code (OIE 2008) for information recommended for reinstatement of trade and HPAI H5N1 free status from a region that has experienced an HPAI H5N1 outbreak.

APHIS conducted a risk analysis that is consistent with these recommendations, specifically:

- The specified regions in Germany have been HPAI H5N1 free for 3 months because of control measures undertaken by an effective veterinary infrastructure. Restrictions will remain in place for the most recent outbreak and will be reconsidered after the EC lifts those restrictions.
- HPAI (as defined in 9 CFR) was a notifiable disease in Germany. An ongoing awareness program was in place for veterinary officials and the public, and all notified or suspect occurrences of HPAI H5N1 were subjected to field and laboratory investigations.
- A surveillance program for HPAI H5N1 already existed that addressed Germany's needs. This program supported the detection and investigation of outbreaks, including clinical inspection, active and passive surveillance (both serological and agent

detection), and serological and virological testing in high-risk areas and of high-risk flocks. These actions were sufficient to detect disease effectively and quickly, even in the absence of clinical signs.

- Under the surveillance program, all notified and/or suspected avian influenza cases were investigated, and officials took appropriate actions including collecting and transporting these samples in a manner that ensured their integrity for testing purposes, and documenting subsequent laboratory results.
- The system for recording, managing, and analyzing diagnostic and surveillance data was sufficient to demonstrate the effectiveness of Germany's disease control measures.
- Laboratory capabilities were effective, and 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 taken by officials were sufficient to contain and control the spread of disease from these zones. Procedures for lifting quarantines were followed and were sufficient to prevent further spread of disease.
- Documented standard operating procedures described procedures for depopulation, cleaning, disinfecting, and other applicable measures, such as carcass disposal. All relevant personnel were familiar with these standard procedures and followed them during the outbreak. These measures were effective in controlling the disease.
- Premises repopulation, when applicable, was carried out according to documented procedures, including evidence that the disease did not recur and monitoring after repopulation to demonstrate that the disease was eradicated.

As a result of this evaluation, APHIS concludes that Germany is able to effectively control and to eradicate HPAI H5N1 in its domestic poultry population. The effectiveness of the eradication program is attributed to prompt actions taken by BMVEL and the cooperation of backyard and commercial flock owners. Since the initial 2006 outbreak, Germany has conducted extensive surveillance for HPAI H5N1. Germany had not identified any new HPAI H5N1 outbreaks in domestic poultry since December 25, 2007, and on March 26, 2008, declared to OIE to be free of HPAI. On October 10, 2008, a small outbreak was identified in the landkreis of Görlitz, in the Federal State of Saxony. Those restrictions remain in place and will be evaluated at a later date by APHIS.

OBJECTIVE

The objective of this report is to evaluate the HPAI H5N1 status of several regions of Germany following outbreaks in domestic poultry in 2006 and 2007, in order to serve characterize the risk associated with importing live birds, poultry carcasses, parts or products of poultry carcasses, and eggs of poultry, game birds, or other birds from the restriction areas in Germany.

BACKGROUND

Germany, as an EU-MS, is obligated to comply with all EC regulations including those for animal health and disease eradication. Council Directive 2005/94/EC describes the

measures for control of avian influenza (AI), and Commission Decision 2004/402/EC requires that all MS develop and implement AI contingency plans to ensure that the most appropriate measures are immediately implemented. In the case of Germany, each Länder (state) maintains its own contingency plan, and each plan is reviewed and approved at both the national and EC levels. These measures are harmonized and binding throughout the EU serving as an important means to prevent the spread of HPAI H5N1 within the EU as well as other countries through its export market. The EC has the authority to conduct periodic evaluations to verify compliance by the EU-MS [3, 4]. The EU system for animal disease control for CSF has been extensively evaluated by APHIS and provides a basis for understanding the EU system for control of HPAI [8, 9].

APHIS has concluded that BMVEL is able to effectively control and to eradicate HPAI in its domestic poultry population and that the EU system for animal disease control provides a basis for detecting, controlling and eradicating the disease. Based on the results of the assessment, APHIS could not identify additional risk factors that would indicate that 2006 and 2007 restricted areas in Germany are currently affected with HPAI H5N1. The restriction areas for the landkreis of Görlitz and Bautzen in the Federal State of Saxony remain in place.

HISTORY OF HPAI H5N1 IN GERMANY

After the recognition of the spread of HPAI H5N1 from Asia into Western Europe, the EU increased surveillance for the virus in wild and migratory birds. In 2005, Romania was the first European country to report to the OIE the presence of HPAI H5N1 in wild birds and domestic poultry. In 2006, HPAI H5N1 was reported in Austria, Bulgaria, Czech Republic, Denmark, France, Greece, Germany, Hungary, Italy, Poland, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom. In 2007, HPAI H5N1 was again reported in Czech Republic, France, Germany, Hungary, Slovenia, and the United Kingdom [5]. In reviewing the HPAI H5N1 situation in the EU during the 2006 – 2007 H5N1 outbreaks it was found that swans, especially mute swans (*Cygnus olor*) were most frequently involved. The exceptions was Germany in 2007 where grebes were the most frequently affected species and there was an incident with high mortality in which swans in the same area were not affected. In 2006, HPAI H5N1 was also isolated from grebes in Spain, Denmark and Sweden [7].

In mid-February 2006, HPAI H5N1 was found in dead wild birds along the Baltic Coast on Rügen Island, in the state of Mecklenburg-Vorpommern (Mecklenburg-Western Pomerania). HPAI H5N1 was found in swans (*Cygnus olor* and *Cygnus cygnus*) and a northern goshawk (*Accipiter gentilis*) that were found dead on the island. HPAI H5N1 was also isolated from four mammals in this outbreak; three cats and a stone martin (*Martes foina*, a weasel like animal) [7]. Increased surveillance of wild birds throughout Germany was subsequently undertaken, with special emphasis on waterfowl in coastal regions and other regions where migratory wild birds are normally dense in winter and early spring. Between March and April of 2006, HPAI H5N1 was found in wild birds in eight Länders, primarily in swans and ducks; however, no additional cases of HPAI H5N1 were detected in wild birds for the rest of 2006.

On April 6, 2006, an outbreak of HPAI H5N1 was reported on a turkey farm (*Melgeagris gallopavo*) in the Länder of Sachsen (Saxony) near the town of Mutschen, in the kreis (district) of Muldentäl. In August 2006, the presence of HPAI H5N1 in a black swan in a zoo in Saxony Dresden was reported; however, all other birds at the zoo were tested and found to be negative. In total, HPAI H5N1 was found in 344 wild birds, one domestic turkey farm and one zoo in Germany during 2006.

No further identification of HPAI H5N1 was made until June of 2007, when it was reported again in wild birds, starting with six wild swans in the German state of Bavaria. Between June 24 and August 18, 2007, HPAI H5N1 was confirmed in 326 wild birds, primarily in swans, geese, and grebes. In the area of the Kelbra Dam water reservoir bordering the Länders of Thuringia and Saxony-Anhalt, there was an outbreak with high mortality in black necked grebes (*Podiceps nigricollis*) in which there were more than 200 dead birds recorded out of a population of 500 grebes. The outbreak occurred between July 3 and 24, 2007, and epidemiological investigation indicated it to be a recent introduction of the virus. No other species in the area were affected, including swans which have normally been considered the most susceptible species. Since August 16, 2007, HPAI there have been no additional detections of HPAI in wild birds in Germany. The 2007 wild bird HPAI H5N1 outbreaks in Germany were strongly associated with water ways and occurred in the following Länders (see Appendix II and Appendix III):

- Bavaria: 16 cases on two adjacent lakes in the city of Nuremberg,
- Saxony and Thuringia: six cases on a lake in the kreis' of Frohburg and Leipziger in Saxony and Windischleuba and Altenburger in Thuringia,
- Thuringia and Saxony-Anhalt: 287 cases on a water reservoir at the Kelbra Dam in Badra, Kyffhäuser kreis (Federal State of Thuringia) and Kelbra, Mansfeld-Südharz kreis (Federal State of Saxony-Anhalt), as described above,
- Thuringia: 12 cases in Ebeleben, Kyffhäuser kreis (three cases) and Auleben, Nordhausen kreis (nine cases),
- Saxony: one case in Torgau, Torgau-Oschatz kreis and 1 case in Machern, Muldentalkreis kreis, and
- Bavaria: three cases on a reservoir near Munich.

In the year 2007, there were also six outbreaks of HPAI in domestic poultry in Germany (see table 1 and figure 2). Since December 25, 2007, there have been no HPAI detections in either domestic or wild birds in Germany.

TABLE 1. SUMMARY OF HPAI H5N1 OUTBREAKS IN GERMANY DOMESTIC POULTRY FOR 2007 [1, 7].

No.	Date of Detection	State	Kreis (district)	Type of Farm	Population
1	7/6/07	Thuringia	Saalfeld-Rudolstadt / Saalfelder Höhe	hobby farm	5 ducks, 5 geese
2	8/25/07	Bavaria	Erlangen-Höchstadt / Wachenroth	poultry fattening farm	169,857 ducks
3	9/10/07	Bavaria	Schwandorf / Bruck i.d. Oberpfalz	poultry fattening farm	170,856 ducks
4	12/15/07	Brandenburg	Oberhavel /	hobby farm	11 chickens

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			Großwoltersdorf		
5	12/21/07	Brandenburg	Potsdam-Mittelmark / Bensdorf	hobby farm	hobby farm 30 chickens
6	12/25/07	Brandenburg	Ostprignitz-Ruppin / Heiligengrabe	hobby farm	15 chickens

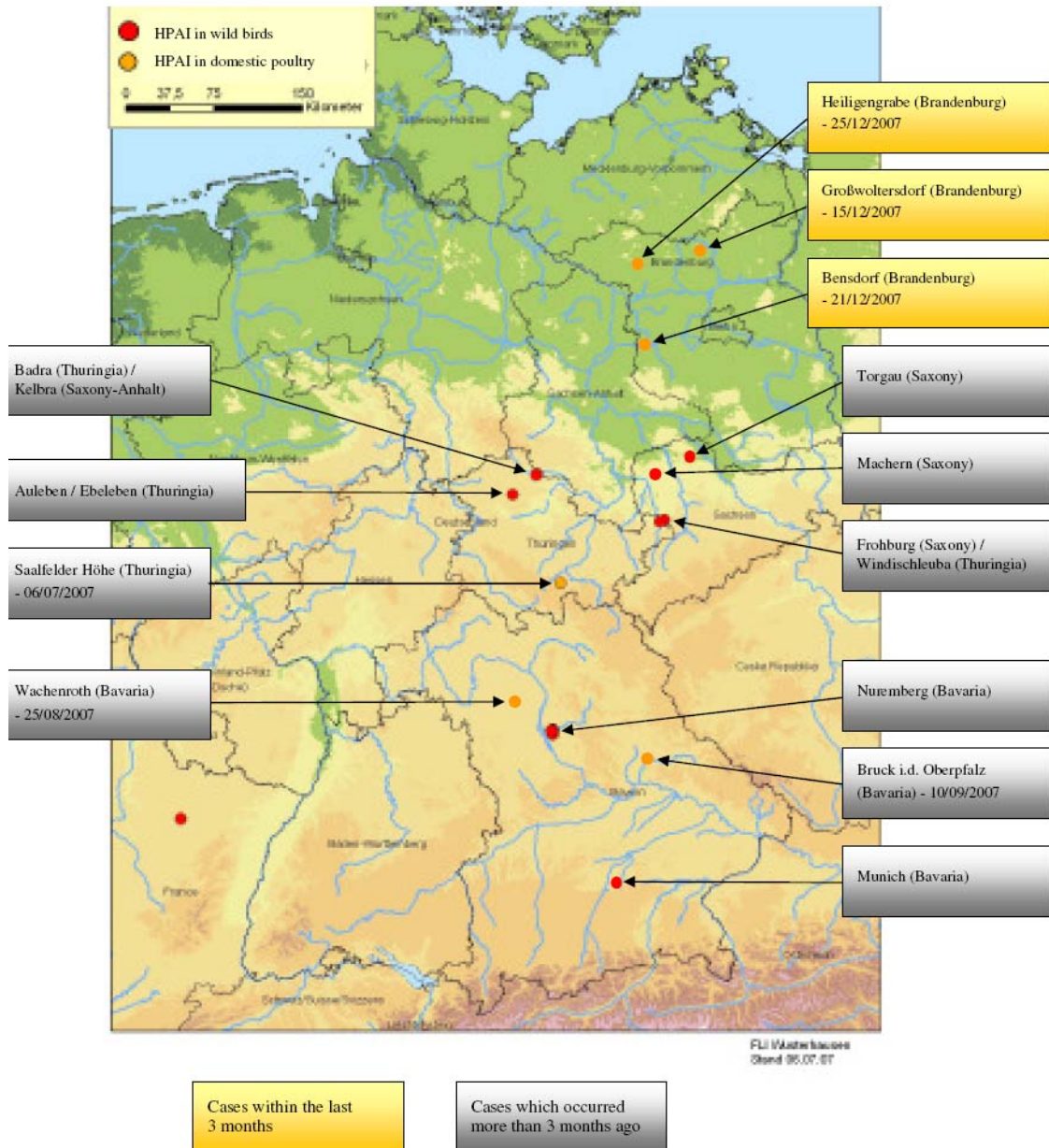
On October 10, 2008, the presence of HPAI H5N1 was identified in the municipality of Markersdorf in the district (landkreis) of Görlitz, in the Federal State of Saxony (see Figure 2). The outbreak was limited to a single farm of mixed species. The farm had an avian population of 800 geese, 550 ducks, 60 chickens and 245 turkeys. All birds except the turkeys were free range. The ducks were the only affected species; further testing of the ducks found 24 positive samples and an additional 150 samples to be negative. Samples from the turkeys were found to be negative. In addition, the farm also had 106 cattle, 4 sheep, 8 pigs and 1 pony. Investigation of epidemiologic links, surveillance of the surrounding area and investigation of three potential contact holdings have not indicated the presence of additional HPAI H5N1 affected poultry. At this point, the most likely source for the introduction of the virus is through contact with wild birds. The restrictions remain in place and will be evaluated at a later date by APHIS.

Figure 1. Map of Germany showing the Federal States [source Map from: http://www.geographic.org/maps/new2/germany_maps.html]

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FIGURE 2. MAP OF HPAI H5N1 OUTBREAKS IN GERMANY, 2007 [1, 7].



HAZARD IDENTIFICATION

APHIS has identified several animal diseases listed by OIE that pose primary hazards associated with initiating trade in animals and animal products from foreign regions. The listed foreign animal diseases of primary concern are addressed specifically in APHIS regulations. One of these diseases, High Pathogenicity Avian Influenza H5N1 (HPAI H5N1) is recognized by APHIS as a hazard of primary concern. In this regard, prior to

resumption of trade in poultry and poultry products with a region or country considered by APHIS to have been affected with HPAI H5N1, APHIS must conduct an import risk analysis in support of this action.

Avian influenza (AI) is caused by an orthomyxovirus virus that infects wild birds (such as ducks, gulls, and shorebirds) and domestic poultry (such as chickens, turkeys, ducks, and geese). AI viruses are classified by a combination of two groups of proteins: the hemagglutinin or H proteins, of which there are 16 (H1-H16), and neuraminidase or N proteins, of which there are 9 (N1-N9). AI strains also are divided into two groups based upon the ability of the virus to produce disease (pathogenicity): low pathogenic (LP) and highly pathogenic (HP).

HPAI H5N1, often referred to as "Asian" H5N1", is the type causing worldwide concern. HPAI H5N1 spreads rapidly and is often fatal to chickens and turkeys. Millions of birds have died in countries where HPAI H5N1 has been detected. This virus has also infected people, most of whom have had direct contact with infected birds. "Asian" HPAI H5N1 has not been detected in the United States.

Low pathogenicity (LPAI) H5N1, often referred to as the "North American" H5N1, is of less concern. LPAI H5N1 has been detected in wild birds in the US, as recently as 2007. Other strains, specifically H5N2, of HPAI have been detected and eradicated three times in the United States: in 1924, 1983 and 2004. The 2004 H5N2 isolate did not result in clinical disease and inoculation studies showed it to be a low pathogenic strain; however, genetic sequencing was consistent with one of the OIE definitions for HPAI. No significant human illness resulted from these outbreaks.

EVALUATION OF THE STATUS OF HPAI H5N1 IN GERMANY

APHIS conducted this evaluation based on the information outlined in the OIE Terrestrial Code Chapter 10.4 for reinstatement of HPAI free status and trade from a region that has experienced an HPAI outbreak. For the purpose of this report, risk refers to the likelihood that HPAI H5N1 exists in Germany and, if so, how likely it would be for the disease to be introduced into the United States through imports of live birds, poultry carcasses, parts or products of poultry carcasses, and eggs of poultry, game birds, or other birds from Germany. The likelihood will depend on the effectiveness of the eradication and control measures undertaken by Germany in response to the 2006-2007 outbreaks and the ongoing 2008 outbreak of HPAI H5N1 and the ability to detect the presence of HPAI H5N1 if it were to be re-introduced.

Evidence that Germany has been HPAI-free for 3 months because of control measures undertaken by an effective veterinary infrastructure.

Germany has the legal authority to respond to HPAI through a comprehensive set of regulations, directives and decisions that are harmonized and regularly updated for all EU MS [Appendix I]. The major German national legislations for animal health and avian influenza include: The Animal Diseases Act of 22 June 2004 (Federal Law Gazette I, p. 1260), The Ordinance on Preventing AI and ND (Avian Influenza Ordinance, as

announced in the Federal Law Gazette I, p. 3538, December 20, 2005) and the Ordinance on Notifiable Animal Disease (Federal Law Gazette I, p. 2764, dated November 3, 2004). In Germany, the central veterinary authority is the Federal Ministry of Consumer Protection, Food and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft; BMVEL). Under the BMVEL are the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit; BVL), Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung; BfR) and the Federal Research Institute for Animal Health (Friedrich-Loeffler-Institute;). FLI also serves as the National Reference Laboratory (NRL).

In addition to the fixed body of legislation laid down for AI, the EC has adopted additional or emergency measures under the AI Directive, with other pieces of primary animal health legislation as their legal basis. The EC, with backing of the Member States, puts forward legislative measures through the Standing Committee on the Food Chain and Animal Health (SCFCAH). Measures implemented include import bans, prevention and control measures, domestic and wild bird surveillance programs and defining risk areas around protection and surveillance zones. APHIS also found that the contingency plans, as required by EC regulations, adequately provided emergency funds, laboratory staff, equipment and infrastructure for animal disease outbreak control and eradication.

Comprehensive AI specific measures are provided in Council Directive 2005/94/EC (updating Council Directive 92/40/EEC). This Directive established comprehensive provisions for the early detection of infection in poultry aimed at a quick response and adoption of appropriate and proportionate control and eradication measures and is frequently updated by Commission Decisions. This requires that a system of active surveillance is carried out by EU-MS and control measures are applied in the event of an outbreak of AI in poultry or other captive birds. This directive also details the measures for the compulsory notification of suspected cases of HPAI, depopulation of poultry on holdings where HPAI is confirmed, cleaning and disinfection of affected premises, repopulation, establishment of protection (3 kilometer radius) and surveillance (10 kilometer radius) zones around affected holdings to enforce movement controls, epidemiological investigations of all cases, and the requirement that a national laboratory be maintained in each Member State and a Community reference laboratory for HPAI diagnosis.

Immediate notification of the competent authority is compulsory under Council Directive 82/894/EEC for suspected or confirmed presence of AI. Notification of outbreaks of animal diseases to the Commission is required by Council Directive 92/40/EC. Commission Decision 2004/402/EC requires that all MS have approved AI contingency plans and Commission Decision 2006/563/EC requires that all EU-MS establish the legal powers necessary for the implementation of the contingency plans. Commissions Decision 2004/450/EC established standard requirements for Community financing for programs for the eradication, monitoring and control of animal disease.

AI surveillance in both domestic poultry and wild birds has been in place for many years

in the EU and the programs have been regularly updated. Following the recognition of risks associated with the presence of HPAI H5N1 in wild birds, a number of specific measures related to surveillance and control measures following detection of HPAI H5N1 in wild birds were implemented and are updated frequently (for example see: Commission Decisions 2002/649, 2002/673, 2004/111, 2004/464, 2004/615, 2004/630, 2005/646, 2005/726, 2005/731, 2005/732, 2006/101, 2006/314, 2007/268). These measures established control and monitoring areas for wild and domestic bird population where HPAI H5N1 subtype is detected in wild birds to help prevent virus introduction into commercial and non-commercial poultry flocks. For example, Commission Decision 2006/563/EC specifies surveillance programs, notification and describes the necessary epidemiological investigation to be done in all cases where the presence of HPAI H5N1 in wild birds is confirmed. This decision requires the establishment of protection, surveillance and restricted zones for domestic birds around the areas HPAI H5N1 was identified in wild birds.

Biosecurity measures for HPAI H5N1 are established by the EC (Commission Decisions 2005/734/EC, 2005/745/EC, 2005/855/EC, 2006/405/EC and 2006/574/EC) to reduce the risk of transmission from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk. Epidemiological investigation of all contact holding was done, including tracing the origins of the animals, contact holdings and human contacts. One of the outbreaks in Germany involved contacts from other countries within the EU (Czech Republic).

On December 26, 2007, cleaning and disinfection was finished for the last outbreak in domestic poultry. No additional cases of HPAI H5N1 were reported in Germany in either domestic poultry or wild birds although heightened levels of surveillance remain in place. On March 26, 2008, Germany declared itself as free from HPAI H5N1 in poultry to the OIE, reflecting the three month time period specified for return to a notifiable avian influenza (NAI) free status [6].

On October 10, 2008, the presence of HPAI H5N1 was identified in free range ducks on a single farm of mixed species in the Landkreis of Görlitz, in the Federal State of Saxony. The outbreak was limited to a single farm of mixed species. Further investigation has not found additional HPAI H5N1 affected poultry. At this point, the most likely source for the introduction of the virus is through contact with wild birds.

Additional control measures were put in place on October 13 that included the mandatory housing of all domestic poultry within 50 km of the outbreak for at least 21 days. Commission Decision 2008/795/EC indicates the intention of the EC is to lift restrictions on November 8, 2008, if no further outbreaks are found. The APHIS restrictions imposed for the October 2008 outbreak remain in place and will be evaluated at a later date.

Conclusion: APHIS concludes Germany has an effective veterinary infrastructure that was able to carry out the appropriate control measures to eradicate HPAI H5N1 in domestic poultry. APHIS has previously evaluated the German veterinary infrastructure and found it to be effective and able to implement adequate and timely control and

eradication measures [8, 9]. Regarding the regions in Germany reporting outbreaks in 2006 and 2007, there have been no additional reports of HPAI H5N1 in domestic poultry or wild birds in these regions since it made its final report to OIE on March 26, 2008. In regards to the single outbreak reported on October 10, 2008, APHIS intends to leave the current restrictions in place and apply the OIE standard for lifting restrictions in the near future.

Documentation that HPAI (as defined in 9 CFR) was a notifiable disease in Germany and an ongoing awareness program was in place for veterinary officials and the public, and all notified or suspect occurrences of HPAI were subjected to field and laboratory investigations.

In Germany, HPAI H5N1 is a notifiable disease. Council Directive 2005/94/EC requires that all EU-MS notify the EC within 24 hours of the confirmation of any primary outbreak or detection of AI and of all suspected or confirmed incidents. All forms of AI confirmed by the competent authority in slaughterhouses, means of transport, border inspection posts and other places at Community borders and quarantine facilities or centers operating in accordance with Community legislation on imports of poultry or other captive birds are considered to be notifiable under Council Directive 92/40/EC. Commission Decision 2004/402/EC requires that all EU-MS have AI contingency plans, reviewed and approved by EC, in place to ensure that the most appropriate measures are immediately implemented.

Outreach to the public and bird owners was made through announcements and information campaigns in the national and local press related to all findings of infected wild birds.

Conclusion: HPAI H5N1 was and continues to be a notifiable disease in Germany, and all notified or suspect occurrences of HPAI H5N1 are subject to immediate field and laboratory investigation. Awareness and educational outreach programs were in place and efforts were increased following the identification of the presence of HPAI H5N1 in wild birds. These efforts were further enhanced to specifically include hobby and backyard flocks in areas where HPAI H5N1 had been identified in wild birds.

A surveillance program for HPAI already existed that addressed Germany's needs. This program supported the detection and investigation of outbreaks, including clinical inspection, active and passive surveillance (both serological and agent detection), and serological and virological testing in high-risk areas and of high-risk flocks. These actions were sufficient to detect disease effectively and quickly, even in the absence of clinical signs.

Since 2002, all EU-MS have implemented mandatory surveys for AI in domestic poultry and wild birds by submitting yearly surveillance programs to the Commission for review and approval (Commission Decisions 2002/649/EC, 2004/111/EC, 2005/464/EC and 2006/101/EC, 2007/268/EC). However, prior to 2002, Germany had already been doing wild bird surveillance. Commission Decision 2002/673/EC provided for the EC's financial contribution to cover 50% of the costs of the testing. These programs continue

to be supported by Community funding and are updated annually. Guidelines for sampling were provided to the MS for poultry, turkey, duck and goose holdings as well as guidance for wild bird sampling.

Wild bird sampling plans were designed to include different species of free living birds with a primary emphasis on waterfowl and shorebirds. The 2002 EU-wide baseline HPAI survey in wild birds was designed so that the sample is comprised of 70% waterfowl, 20% shorebirds and 10% other free-living birds (Commission decision 2002/649/EC). HPAI surveillance sampling of wild birds included birds trapped, hunted and found freshly dead. Testing of samples was carried out at or under the control of the MS's national reference laboratory. Test antigens were supplied by the Community Reference Laboratory (CRL) to ensure uniformity of testing and all results were reported to the CRL for collation.

By 2004 wild bird surveillance was done in sixteen EU-MS and a total of 7,482 samples were tested, of these 15 were positive for the H5 subtypes and 7 for the H7 subtypes, including one H5 positive in Germany [7]. In 2005, due to emergence of the H5N1 epidemic in Asia, it was decided to intensify the planned wild bird surveillance (Commission Decisions 2005/726/EC and 2005/464/EC) and focus sampling on birds migrating in autumn and early winter. The intensified surveillance included separate recommendations for risk-based active and passive surveillance and targeted higher risk species based on their origin, migratory flyways, numbers and their likelihood of contact with poultry. Sampling was done in locations where mixing of migratory birds could occur, in proximity to poultry farms and along known flyways. A targeted list of 15 wild bird species presenting a higher risk was included and was updated as new scientific evidence became available [7].

In 2005, 47,232 wild birds were tested in the EU, nearly six times the number tested in 2004. All 25 MS participated and 165 samples were positive for subtypes H5 or H7. The H5 subtype was found in Germany and nine other EU-MS (Denmark, France, Greece, Italy, Latvia, The Netherlands, Spain, Sweden and the UK) [7]. In February 2006, wild bird surveillance throughout the EU became compulsory (Commission Decision 2006/101/EC) with three types of wild bird surveillance:

- Active surveillance of live birds targeting higher risk species and/or risk areas;
- Passive surveillance monitoring for indication of increased morbidity and mortality; and
- Sentinel surveillance, primarily by regular testing of ducks kept in high-risk areas.

In 2006, the European Epidemiology Working Group for Surveillance of Avian Influenza in Wild Birds was established to optimize wild bird surveillance and evaluate the results of wild bird surveillance for HPAI and improve analysis of HPAI epidemiology. The main objectives of wild bird surveillance in the EU are:

- To ensure early detection of HPAI H5N1 by investigating all increased incidences of mortality in wild birds, especially in higher risk species.
- To provide a baseline surveillance of different species of free-living migratory birds as part of a continuous monitoring of LPAI viruses especially in species

considered to be highest risk for carriage of LPAI H5/H7 viruses; such as waterfowl (Anseriformes) and shorebirds (Charadriiformes).

During 2006, 149,908 wild birds were sampled in the EU including samples from Bulgaria and Romania. In Germany, more than 27,000 wild birds were sampled in 2006, making up 18.62% of all wild birds samples in the EU. In 2006 in the EU, HPAI H5N1 positive samples originated from 41 different wild bird species although the majority of those were taken from swans (*Cygnus* spp. 137 birds, 51%). Other bird species with significant numbers of positive isolations included; buzzards (*Buteo* spp.), ducks (*Aythya* and *Anas* spp.) and gulls (*Larus* spp.). In addition to the wild birds sampled, Germany also detected HPAI H5N1 mammals including several feral cats and a stone marten (*Martes foina*).

In 2007, Germany continued very aggressive surveillance testing of wild birds. Germany tested more than 18,000 samples and provided the highest number of samples in most quarters and more than one third of all samples done in the EU for the year. During the time of heightened surveillance, between June 24 and August 15, 2007, Germany confirmed the presence of HPAI H5N1 in a number of wild birds in sampling done throughout the country. This surveillance effort also detected the presence of seven cases of LPAI [7]. [see table 2 below]

TABLE 1. SUMMARY OF HPAI H5N1 WILD BIRD SURIVELLANCE IN GERMANY AND EU, 2006 AND 2007 [1, 7]

Type of Surveillance Samples	Feb-May 2006	June-Aug 2006	Sep – Dec 2006	Total 2006	2nd Quarter 2007	3rd Quarter 2007	4th Quarter 2007	Total 2007
Active surveillance	114	1078	5613	6805	4150			
Passive surveillance	16427	2660	1148	20232	978			
Germany Total	16603²	3925²	7385³	>27,000	4738	7446	6365	18549⁴
EU ¹	10552	9959	32213	52724				
EU ¹	53789	6264	3716	63769				
EU¹ Total	83515	17197	36837	116493				55523

¹ EU includes the 25 MS comprising the EU in 2006 plus Romania and Bulgaria

² the highest number of samples submitted by an EU-MS

³ the second highest number of samples submitted by an EU-MS

⁴ represents more than 33% of the total number of EU samples

In the face of the recognized risk of HPAI H5N1 introduction from wild birds, Commission Decisions required that all EU-MS heighten their surveillance and identify domestic poultry holdings located in areas where the risk for disease introduction from wild birds to poultry is considered to be higher. Specific risk factors for virus introduction into domestic poultry were identified including location of the holding along migratory flight paths of birds from areas where HPAI had been identified; proximity to wet areas, ponds, swamps, lakes or rivers where migratory water fowl may gather; location of the poultry holdings in areas with a high density of migratory birds, particularly waterfowl; and open air holdings of poultry or other captive birds or in any

other premises in which contact between wild birds and poultry or other captive birds cannot be sufficiently prevented.

Extensive surveillance for HPAI in domestic poultry was also done throughout the EU during this same time period (2005/732/EC, 2006/101/EC, 2006/314/EC, 2007/268/EC). In Germany, surveillance samples were taken on a much higher number of holdings than the EU surveillance plan called for and the testing was done for a number of AI subtypes with positive identification of H5N3, H6N1 and H7 as well as H5N1. For example, in 2006, samples were taken from 1,024 domestic poultry holdings with chickens, turkeys, ducks, geese and ratites from 12 regions and in 2007, Germany sampled 796 domestic poultry holdings [7]. In 2008 extensive routine surveillance continues. Additional surveillance was done in response to the October finding of H5N1 in western Saxony. On October 9, H5 specific RNA was found in a northern shoveler (*Anas clypeata*) in the Leipzig zoo in eastern Saxony. The avian population at the zoo was depopulated (21 geese, 58 ducks, 25 chickens and 7 quail). The NRL at FLI confirmed the presence of low pathogenic AI on October 14 [7].

Conclusion: APHIS concludes that the existing surveillance program for HPAI H5N1 was appropriate for the detection the presence of HPAI effectively and quickly, even in the absence of clinical signs. Extensive surveillance continues at a level adequate to find additional outbreaks of HPAI H5N1 that may occur in domestic poultry in the future.

Under the surveillance program, all notified and/or suspected avian influenza cases were investigated, and officials took appropriate actions including collecting samples, transporting these samples in a manner that ensured their integrity for testing purposes, and documenting subsequent laboratory results.

Council Directive 2005/94/EC requires that a protection zone is to be established following the identification of HPAI (H5 or H7) in domestic poultry and a census of all the holdings in the zone made as soon as possible. Visits by the official veterinarian to all commercial holdings must be carried out as soon as possible to conduct a clinical examination of poultry and other captive birds with collection of samples for laboratory tests, as necessary. Non-commercial holdings in the protection zone are also visited by an official veterinarian before lifting of the protection zone. Additional surveillance is immediately implemented to identify any further spread of avian influenza in the holdings located in the protection zone.

Commission Decisions 2006/115/EC and 2006/135/EC updated Community level measures following the finding of HPAI H5N1 in wild birds, replacing the interim protection measures applied after HPAI H5N1 first entered the EU to prevent that disease from spreading from wild birds to domestic poultry. Commission Decision 2006/115/EC requires that protection (3 km) and surveillance zones (10 km) are established around the place where the disease was detected in wild birds to prevent virus introduction into commercial and non-commercial poultry flocks. These zones are based on geographical, administrative, ecological and epidemiological factors and may include the territory of adjacent EU-MS. The housing or confinement of poultry in these zones is required to

prevent direct and indirect contact of wild birds with other poultry and captive birds.

In the case of the October 2008 outbreak, infection was first identified on October 9 and by October 14 surveillance and protection zones had been established and a census of all holding within these zones and extensive surveillance testing had been conducted.

Conclusion: APHIS concludes that German officials were able to investigate all notified and/or suspected avian influenza cases and provide the necessary diagnostic support to verify the eradication of HPAI H5N1 in domestic poultry in Germany. The effectiveness of the eradication program was mainly due to the prompt actions taken by BMVEL and the cooperation of backyard and commercial flock owners.

The system for recording, managing, and analyzing diagnostic and surveillance data was sufficient to demonstrate the effectiveness of Germany's disease control measures.

Germany and the EU have several mechanisms to record and manage surveillance data, including Animal Disease Notification System (ADNS) and Trade Control and Expert System (TRACES). ADNS was established by Council Directive 82/894/EC and updated by Commission Decision 2005/176/EC, to record and report outbreaks of notifiable animal diseases in the EU-MS and other participating countries including Turkey, Iceland and the Faroe Islands, Andorra, and Switzerland. ADNS reports and documents individual outbreaks of notifiable animal diseases and automatically forwards information on primary outbreaks to the EC within 24 hours of initial identification and updates secondary outbreaks on a weekly basis. The information is posted on the internet with maps showing the location of the outbreaks and summary data. In 2006, ADNS registered a total of 3,787 notifications, 1,005 in 2005, and 1,850 notifications in 2004, covering all reportable animal diseases and species.

TRACES is a centralized database to ensure the control and traceability of animals and animal products moving within the EU. The system provides electronic certification, data retrieval and central statistical information for imports of animals and animal products and allows for the issuance of central risk assessments and warnings. The TRACES provides a platform for updated information on disease alerts to be instantly available.

EC measures in place for the control of avian influenza in Council Directive 2005/94/EC requires maintaining records of all visits by the official veterinarians in protection zones which are specifically supported in several Commission Decisions. Germany maintains an extensive system for recording, managing, and analyzing diagnostic and surveillance data at both the national and state levels. The system in place was sufficient to demonstrate the effectiveness of Germany's disease control measures.

Conclusion: APHIS concludes that the system in place in both Germany and the EU for recording, managing, and analyzing diagnostic and surveillance data is sufficient to demonstrate the effectiveness of Germany's HPAI H5N1 disease control measures.

Laboratory confirmation capabilities were effective, and testing procedures were

documented and standardized.

The EU has in place comprehensive requirements for the laboratory confirmation procedures for HPAI H5N1. These measures were put in place by Council Directive 92/40/EEC and updated in great detail in Council Directive 2005/94/EC. In Germany, the Friedrich-Loeffler-Institut (FLI) serves as the National Reference Laboratory (NRL) and performs virological diagnostic analyses for AI, including HPAI H5N1, in compliance with Council Directive 2005/94/EC. The EU central reference laboratory is the Weybridge laboratory in the UK, which also serves as an OIE reference laboratory for HPAI.

FLI primarily uses RT-PCR diagnostic methods for screening followed by virus isolation for confirmation. The RT-PCR diagnostic methods in use were validated as a part of a European Commission project (AVIFLU) coordinated by the EU-reference laboratory in conformity to the methods required by Council Directive 2005/94/EC. Serum may also be screened using hemagglutination inhibition test (HI test) in accordance with Council Directive 92/40/EC using antigens and control sera provided by the Community Reference Laboratory. Samples that are serologically positive are further examined for confirmation. Virus isolation is also performed and the virus further characterized by conventional neuraminidase test (N-typing). An N-1 specific RT-PCR method may be applied to samples of the virus collected either directly from sick or dead birds or harvested from inoculated SPF embryonated eggs.

Conclusion: APHIS concludes that Germany has the laboratory capabilities to diagnose AI as part of an effective local, national and EC laboratory system that can conduct appropriately standardized testing and documentation procedures.

Emergency control, biosecurity procedures and eradication program: The eradication program included the definition of appropriate quarantine and surveillance zones, monitoring of those zones, and implementation of movement restrictions. Measures taken by officials were able to contain and control the spread of disease from these zones due to effective program measures. Procedures for lifting quarantines were followed and were sufficient to prevent further spread of disease.

Commission Decision 2004/402/EC requires that all MS develop and maintain an approved contingency plan for the control of avian influenza and Newcastle disease. Council Directive 2005/94/EC requires each that each Contingency Plan which is periodically reviewed by the EC and be updated at least every five years. In the case of Germany, each Länder (state) develops and maintains its own contingency plan which are each approved by the EC. The Contingency Plan must specify the national measures to be implemented in the event of an outbreak including the establishment of a crisis centre at the national level to coordinate all control measures in the MS.

Additional components of the Contingency Plan include establishment of local disease control centers with adequate staff, facilities and resources to coordinate local disease control measures; assuring that available equipment and materials to effectively carry out the disease control measures are in place; training programs for field and administrative

personnel; ensuring that diagnostic laboratories have the necessary testing capacity and sample handling to ensure rapid diagnosis; maintain registration of commercial poultry holdings with identification of areas with a high density of poultry. The Contingency Plan must also provide for diagnostic laboratory support and cooperation with the OIE and Food and Agriculture Organization of the United Nations (FAO) reference laboratories for avian influenza. The Commission reviews and approves all Contingency Plans to determine that they are adequate and has the authority to require any necessary amendments to ensure that they are compatible with those of the other EU-MSs.

Protection and surveillance zones were established around areas where HPAI H5N1 was found in wild birds in compliance with Commission Decision 2006/115/EC. The protection zone established due to findings of HP H5N1 in wild birds can be lifted 21 days after the bird was received at the laboratory for analysis. Under EC regulation the earliest that protection zones can be lifted is 21 days after completing the cleaning and disinfection of the infected flock. All poultry flocks within the zone, including backyard and hobby flocks, must be visited before lifting the protection zone. A surveillance zone can be lifted 30 days after the cleaning and disinfection of the infected flocks has been completed.

In Germany, there are crisis centers in place in the 436 rural and urban kreis (districts) lowest veterinary administrative level. The 16 Länder (state) governments also have crisis centers responsible for veterinary affairs as well as at the national level in BMELV. The rural or urban kreis notify the Länder and BMELV immediately upon the suspicion or official recording of an outbreak of infectious diseases via computerized data transmission, using the national online system " National Disease-Information-System located within the Friedrich-Loeffler Institute (TSN)". The notification includes the individual case reports with geographic information transmitted immediately after the initial identification of an occurrence of a notifiable disease, as well as follow-up reports about the disease and reports of the lifting of restriction measures.

In Germany, local HPAI disease control includes immediate implementation of movement controls, daily inspection of flocks and collection of clinically ill and dead wild birds around lakes and ponds. At the local level they have the responsibility to implement measures, such as: providing information campaigns, post warning signs, establish bans on hunting, require all dogs to be leashed and require all cats to be kept indoors. In the established protection and surveillance zones all households with poultry were identified and visited. The monitoring plans and procedures in place were regularly reviewed and updated by epidemiological experts from state and federal authorities and measures were based on risk analysis of the specific area and prevailing conditions. Extensive surveillance was done in each of the surveillance and protection zones established around all findings of HPAI and included intensive surveillance of wildlife within in these zones.[7]

The last detection of HPAI H5N1 in domestic poultry was made on December 25, 2007. The last protection and surveillances zones put in place surrounding this identification were lifted in January 2008. Despite continued enhanced surveillance for HPAI in both

domestic poultry and wild birds, no further detections have been made.

Conclusion: APHIS concludes that the emergency controls, biosecurity procedures, and eradication procedures are adequate to contain and control the spread of disease.

Germany put in place appropriate quarantine and surveillance zones, with monitoring adequate to detect the presence of HPAI H5N1 if it were present. The measures taken by German officials before lifting quarantines are in compliance with EC standards and are sufficient to prevent further spread of disease.

Documented standard operating procedures described procedures for depopulation, cleaning, disinfecting, and other applicable measures, such as carcass disposal. All relevant personnel were familiar with these standard procedures and followed them during the outbreak. These measures were effective in controlling the disease. Premises repopulation, if applicable, was carried out according to documented procedures, including evidence that the disease did not recur and monitoring after repopulation to demonstrate that the disease was eradicated.

Measures for cleaning and disinfection of the HPAI H5N1 infected holdings are carried out under official supervision in compliance with Council Directives 92/40/EC and 2006/563/EC. Council Directive 2005/94/EC provides a comprehensive set of criteria under which repopulation of holdings can occur. Repopulation can not take place for a period of 21 days following the date of completion of the final cleaning and disinfection. Poultry on the repopulated premises undergo at least one clinical examination by an official veterinarian with routine laboratory testing and mandatory testing of all poultry that die during the repopulation phase. The owner is required to keep records of production data, including morbidity and mortality data, immediately reporting any significant change or abnormalities to the competent authority. The newly repopulated facility is monitored for compliance with appropriate biosecurity measures. No commercial poultry can leave the holding without the authorization of the competent authority.

Conclusion: Standard operating procedures for depopulation, cleaning, disinfecting, carcass disposal and repopulation were in place and conducted under official supervision during the outbreak. APHIS concludes that these measures are effective in controlling the disease.

RISK FACTORS APPLICABLE TO GERMANY, OCCURRENCE OF OUTBREAKS

The occurrence of the HPAI H5N1 in Germany posed a risk of introducing HPAI H5N1 into the United States through exports of live birds, poultry, parts or products of poultry carcasses, and eggs of poultry, game birds or other birds from affected regions in Germany. While eradication of disease should mitigate immediate risk from the outbreaks that occurred, reintroduction of disease into domestic poultry remains a concern when HPAI H5N1 is present in wild or migratory bird populations. However, the response to the 2006-2007 HPAI H5N1 outbreaks demonstrates that the German authorities have adequate measures in place to rapidly identify, control and eradicate the disease should it be reintroduced into Germany in either wild birds or domestic poultry.

In response to the October 2008 outbreak on a single farm, the measures in place appear to be adequate to identify, control and appropriately eradicate the presence of HPAI H5N1.

APHIS cites the following factors as relevant to the situation in Germany:

- The presence of HPAI H5N1 in wild birds represents a high risk for reintroducing the disease in domestic poultry. Ongoing surveillance programs in the EU for wild birds are in place to detect the presence of the disease in these populations.
- BMVEL was able to effectively control and eradicate the HPAI H5N1 outbreaks in domestic poultry as a result of an effective eradication program and prompt actions taken by BMVEL with the cooperation of backyard and commercial flock owners.
- BMVEL recognized wild birds as the major pathway of introduction of HPAI and has in place an adequate and appropriate surveillance system for the detection of the presence of HPAI in wild birds if it were to be reintroduced.
- Even before time the presence of HPAI H5N1 was first confirmed in wild birds in February 2006, Germany has conducted an extensive surveillance program in wild birds and domestic poultry. However, no other flocks of poultry were found to be infected with HPAI H5N1 and no restriction zones have been put in place for the presence of HPAI H5N1 since Germany declared itself NAI-free to OIE at the end of March 2008.
- In October 2008, Germany identified the reintroduction of HPAI H5N1 in the Federal State of Saxony. Appropriate eradication and control measures were implemented and restrictions put in place. The EC has announced the intention to lift these restrictions, barring further occurrence, in mid-November 2008.

RISK ESTIMATION AND CONCLUSION

With the successful eradication of HPAI H5N1 following the 2006-2007 HPAI H5N1 outbreaks in Germany and the subsequent measures implemented in response to those outbreaks, APHIS could identify no additional risk factors that would justify not removing the following regions of Germany from the APHIS' list of Countries/Regions Affected with Highly Pathogenic Avian Influenza subtype H5N1. Specifically, the following kreis (districts) in the Länders (states) of:

- Bavaria: Aisch (Aichach-Friedberg), Bamberg, Kitzingen, and Neustadt A.D. (Neustadt (Aisch)-Bad Windsheima);
- Brandenburg: Erlangen-Hochstadt, Havelland, Oberhavel, Ostprignitz-Ruppin, Prignitz, Potsdam-Mittelmark and Uckermark;
- Mecklenburg-Western Pomerania (Mecklenburg-Vorpommern): Mecklenburg-Strelitz;
- Saxony (Freistaat Sachsen): Döbeln, Muldentalkreis (Muldentalkreis) and Torgue-Oschatz;
- Saxony-Anhalt: Jerichower Land, and;
- Thuringia: Saalfeld-Rudolstadt.

However, the restrictions will remain in place for the October 2008 outbreak until APHIS is able to provide further analysis of the risk HPAI H5N1 in the context of the OIE standard for the return of a region to free status following an outbreak of HPAI. Specifically the kreis (districts) of Görlitz and Bautze in the Länders (states) of Saxony will remain under restriction until further evaluation.

Germany was able to rapidly identify, control and successfully eradicate HPAI H5N1 following the 2006-2007 outbreaks. In October 2008, Germany was able to rapidly identify, eradicate and control a reintroduction of HPAI H5N1 on a single farm by rapid application of comprehensive control measures. Germany has in place adequate surveillance measures to rapidly identify the presence of the disease in either wild or domestic bird population. In addition, APHIS considers that if there were further reintroductions, Germany would be able to rapidly identify, control and eradicate the disease.

APHIS concludes that a likelihood of reintroduction of HPAI H5N1 into Germany's poultry population will continue when HPAI H5N1 is present in the wild or migratory bird populations. However, in consideration of the quick and decisive actions undertaken by German authorities following the identification of HPAI H5N1 in wild birds in Germany and its neighboring countries, the measures implemented in Germany, and the high level of awareness and cooperation from German poultry keepers, APHIS concludes that, if reintroduced, spread of HPAI in Germany would be limited.

Based on the results from this evaluation, APHIS considers the risk of introducing HPAI H5N1 into the United States from the import of live birds, poultry carcasses, parts or products of poultry carcasses, and eggs of poultry, game birds or other birds from Germany to be low.

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APPENDIX I.

SUMMARY OF SELECTED EU COUNCIL DIRECTIVES, COUNCIL DECISIONS APPLICABLE TO AVIAN INFLUENZA CONTROL.

Council Directive	Full Title
Council Directive 2005/94/EC	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC
Council Directive 92/40/EEC	Council Directive 92/40/EEC of 19 May 1992 introducing Community measures for the control of avian influenza, as amended for the accession of Norway, Austria, Finland and Sweden, Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia
Council Directive 82/894/EEC	Council Directive of 21 December 1982 on the notification of animal diseases within the Community
Commission Decision	Full Title
Commission Decision 2008/812/EC	Commission Decision of 24 October 2008 amending Decision 2006/415/EC concerning certain protection measures in relation to an outbreak of highly pathogenic avian influenza of the subtype H5N1 in poultry in Germany
Commission Decision 2008/795/EC	Commission Decision of 10 October 2008 concerning certain interim protection measures in relation to highly pathogenic avian influenza of subtype H5N1 in poultry in German
Commission Decision 2007/878/EC	Commission Decision of 21 December 2007 amending Decision 2006/415/EC concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in Germany, Poland and the United Kingdom
Commission Decision 2007/598/EC	Commission Decision of 28 August 2007 concerning measures to prevent the spread of highly pathogenic avian influenza to other captive birds kept in zoos and approved bodies, institutes or centres in the Member States
Commission Decision 2007/591/EC	Commission Decision of 27 August 2007 amending Decision 2006/415/EC concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in Germany
Commission Decision 2007/556/EC	Commission Decision of 1 August 2007 amending Decision 2006/415/EC concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in the Community

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Commission Decision 2007/483/EC	Commission Decision of 9 July 2007 amending Decision 2006/415/EC concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in Germany
Commission Decision 2007/268/EC	Commission Decision of 13 April 2007 on the implementation of surveillance programs for avian influenza in poultry and wild birds to be carried out in the Member States and amending Decision 2004/450/EC
Commission Decision 2006/574/EC	Commission Decision of 18 August 2006 amending Decision 2005/734/EC as regards certain additional risk mitigating measures against the spread of avian influenza
Commission Decision 2006/563/EC	Commission Decision of 11 August 2006 concerning certain protection measures in relation to highly pathogenic avian influenza of subtype H5N1 in wild birds in the Community and repealing Decision 2006/115/EC
Commission Decision 2006/474/EC	Commission Decision of 6 July 2006 concerning measures to prevent the spread of highly pathogenic avian influenza caused by influenza A virus of subtype H5N1 to birds kept in zoos and approved bodies, institutes and centres in the Member States and repealing Decision 2005/744/EC
Commission Decision 2006/415/EC	Commission Decision of 14 June 2006 concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in the Community and repealing Decision 2006/135/EC
Commission Decision 2006/405/EC	Commission Decision of 7 June 2006 amending Decisions 2005/710/EC, 2005/734/EC, 2005/758/EC, 2005/759/EC, 2005/760/EC, 2006/247/EC and 2006/265/EC as regards certain protection measures in relation to highly pathogenic avian influenza
Commission Decision 2006/314/EC	Commission Decision 2006/314/EC of 16 March 2006 approving the Member States' survey programs for avian influenza in poultry and wild birds during 2006.
Commission Decision 2006/115/EC	Commission Decision of 17 February 2006 concerning certain protection measures in relation to highly pathogenic avian influenza in wild birds in the Community and repealing Decisions 2006/86/EC, 2006/90/EC, 2006/91/EC, 2006/94/EC, 2006/104/EC and 2006/105/EC
Commission Decision 2006/101/EC	Commission Decision of 6 February 2006 on the implementation of survey programs for avian influenza in poultry and wild birds to be carried out in the Member States in 2006

APHIS' Evaluation of the Status of High Pathogenicity Avian Influenza H5N1 (HPAI H5N1) in Germany

Commission Decision 2005/855/EC	Commission Decision of 30 November 2005 amending Decision 2005/734/EC laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk
Commission Decision 2005/745/EC	Commission Decision of 21 October 2005 amending Decision 2005/734/EC laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by influenza A virus of subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk
Commission Decision 2005/734/EC	Commission Decision of 19 October 2005 laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk
Commission Decision 2005/732/EC	Commission Decision 2005/732/EC of 17 October 2005 approving the programs for the implementation of Member States' surveys for avian influenza in poultry and wild birds during 2005 and laying down reporting and eligibility rules for the Community financial contribution to the implementation costs of those programs
Commission Decision 2005/731/EC	Commission Decision 2005/731/EC of 17 October 2005 laying down additional requirements for the surveillance of avian influenza in wild birds
Commission Decision 2005/726/EC	Commission Decision of 17 October 2005 amending Decision 2005/464/EC on the implementation of survey programmes for avian influenza in poultry and wild birds to be carried out in the Member States
Commission Decision 2005/464/EC	Commission Decision 2005/464/EC of 21 June 2005 on the implementation of survey programs for avian influenza in poultry and wild birds to be carried out in the Member States
Commission Decision of 2004/630/EC	Commission Decision of 2004/630/EC of 27 July 2004 approving the programs for the implementation of Member States' surveys for avian influenza in poultry and wild birds during 2004 and laying down reporting and eligibility rules for the financial contribution from the Community to the implementation costs of those programs. [amended by 2004/679/EC on 5 October 2004]

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Commission Decision 2004/615/EC	Commission Decision of 23 July 2004 amending Decision 2004/111/EC on the implementation of surveys for avian influenza in poultry and wild birds in the Member States to be carried out during 2004
Commission Decision 2004/464/EC	Commission Decision of 21 June 2005 on the implementation of survey programmes for avian influenza in poultry and wild birds to be carried out in the Member States
Commissions Decision 2004/450/EC	Commissions Decision of 29 April 2004 laying down standard requirements for the content of applications for Community financing for programs for the eradication, monitoring and control of animal disease
Commission Decision 2004/402/EC	Commission Decision of 26 April 2004 approving contingency plans for the control of avian influenza and Newcastle disease
Commission Decision 2004/111/EC	Commission Decision 2004/111/EC of 29 January 2004 on the implementation of surveys for avian influenza in poultry and wild birds in Member States, to be carried out during 2004
Commission Decision 2002/673/EC	Decision 2002/673/EC of 22 August 2002 approving the programs for the implementation of Member States' surveys for avian influenza in poultry and wild birds
Commission Decision 2002/649/EC	Commission Decision 2002/649/EC of 5 August 2002 on the implementation of surveys for avian influenza in poultry and wild birds in the Member States

APPENDIX II.

LOCATION OF THE 2007 HPAI H5N1 OUTBREAKS IN WILD BIRDS [7]



APPENDIX III.
MAP OF GERMANY SHOWING HIGH RISK AREAS FOR MIGRATORY BIRDS AND WATERFOWL
(SHOWN IN RED) [7]

