

**Guidelines for
Novel H1N1 2009 Virus in
Swine in the United States**

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Veterinary Services



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1. Summary

APHIS has developed guidelines for managing potential cases of the Novel H1N1 2009 Virus in swine. These guidelines were developed in collaboration with the animal health, food safety and public health communities. These guidelines are based on research and observations made since the novel H1N1 2009 virus was first detected:

- The Novel H1N1 2009 influenza virus is not spread by food, so a person can not get the flu from eating pork, pork products or other foods.
- Research results from the United States Department of Agriculture (USDA) Agricultural Research Service, the European Union, and other groups suggest that the Novel H1N1 2009 Virus is capable of infecting and causing disease in swine. Further, epidemiological information from Canada, Argentina, and Australia suggests that infected people and swine can transmit and cause infection within and between species.
- The clinical signs observed in pigs affected by Novel H1N1 2009 Virus are not different than those observed in pigs affected by other influenza viruses commonly detected in swine herds.
- At this time animals (including swine) are not playing a significant role in the spread of the Novel H1N1 2009 Virus in the general human population.
- APHIS guidelines include increasing biosecurity measures to prevent spread of novel H1N1 2009 virus to other pig herds and to people. Herds identified with the Novel H1N1 2009 virus will be monitored so that only swine that have fully recovered are sent to other premises or to slaughter. Quarantines are not recommended.
- The U.S. Department of Agriculture (USDA) operates a food inspection system that ensures the safety and wholesomeness of the United States food supply. Existing safeguards and procedures prevent sick pigs from entering the food supply.
- The animal health and public health communities recognize the need for integrated national influenza surveillance in swine to achieve the following goals:
 - Identify new influenza virus strains that may pose a threat to human and/or swine health in a timely manner.
 - Develop improved reagents for influenza diagnostic tests.
 - Identify influenza viruses against which candidate vaccine viruses are needed.
 - In the event a new influenza virus is identified that causes a significant increase in swine health problems, or that causes a significant new public health threat, the USDA and CDC will work together to provide additional guidance and policy and to share influenza viruses between animal and public health authorities for vaccine development.
- USDA encourages participation in the integrated national influenza surveillance in swine, with a goal of promoting the common animal health and public health needs. This surveillance is not intended to support a regulatory eradication or control program. Instead, it will provide critical information to support the common animal and public health interests in overall influenza planning and preparedness.

2. Background

Swine influenza is a respiratory disease of swine caused by a type A influenza virus. Swine influenza virus (SIV) is commonly found in swine herds of North America, South America, Asia, Europe, and it has been reported in Africa.

In the United States, SIV has evolved from a seasonal disease caused by a single, relatively stable genotype to a year round, endemic respiratory disease caused by multiple SIV genotypes.

It is important to note that the commonly circulating SIV subtypes in swine are not the Novel H1N1 2009 Virus currently circulating in people around the world. However, swine are susceptible to infection with the Novel H1N1 2009 Virus.

Please see Attachment I for an estimate of SIV (H1 and H3) seroprevalence in United States swine operations. Note this estimate does not include the Novel H1N1 2009 Virus currently circulating in people around the world.

In April 2009, a Novel H1N1 2009 Virus was detected in humans in Mexico, the United States and other countries, triggering actions in accordance with the National Strategy for Pandemic Influenza Implementation Plan. Again, it is important to note that the commonly circulating SIV in the United States is not the Novel H1N1 2009 Virus.

In April 2009, the Novel H1N1 2009 Virus was detected in one swine operation in Alberta, Canada. In July 2009, the H1N1 Flu Outbreak Virus was detected in two swine operations in Argentina, and another swine operation in Canada. It is likely that similar detections will be found in swine herds around the world.

3. Surveillance

Swine influenza virus diagnostic testing efforts have been ongoing for decades with the primary purpose of managing animal health. University, State, and private diagnostic laboratories maintain and update extensive databases of swine influenza viruses, including genomic sequences. However, animal health and public health partners recognized the need for a more integrated and coordinated surveillance strategy. As a result of the common concerns related to novel influenza viruses in swine, APHIS, Centers for Disease Control and Prevention (CDC), and other stakeholders initiated the development of a collaborative pilot SIV surveillance program in July 2008. This effort was in the early stages of implementation when the recent human pandemic began. To expedite SIV surveillance activities, the National Surveillance Unit (NSU), within the Centers for Epidemiology and Animal Health, APHIS-VS, worked with stakeholders to expand the pilot surveillance plan into a “National surveillance plan for Swine Influenza Virus: including Novel H1N1 2009 Virus”, which is a separate document.

There are three components of SIV (including Novel H1N1 2009 Virus) surveillance. These components, or surveillance streams, are:

- A) Surveillance of swine that are epidemiologically linked to a human case of SIV (including the Novel H1N1 2009 Virus).
- B) Surveillance of swine observed with influenza-like illness (ILI) on farms from which samples are submitted to veterinary diagnostic laboratories.

- C) Surveillance of swine observed with signs of ILI at first points of concentration or commingling events, especially where exposure to human populations is elevated. These locations may include auction houses, markets, fairs, zoos and exhibitions.

The surveillance plan targets sick swine or swine that demonstrate ILI. Assuming 95 percent sensitivity and 100 percent specificity of the SIV PCR and/or virus isolation diagnostic testing, followed by necessary confirmatory testing, random testing of 10 sick swine (febrile with serious nasal discharge and cough) provides 95 percent confidence in detecting SIV in at least one of the targeted samples, if the virus is present in at least 30 percent of the sick animals in the group.

Sections 5 and 6 of this document provide guidance for actions to be taken in the course of performing activities associated with the three surveillance streams, including actions in the event of a detection of the Novel H1N1 2009 Virus in swine.

4. Report and Investigation of a Possible Case of Novel H1N1 2009 Virus in Swine

In conjunction with the surveillance plan referenced above, the initial report of a possible case of an Novel H1N1 2009 Virus in swine can potentially come from a variety of sources. Swine owners, growers, and producers are encouraged to report signs of illness that may indicate the presence of an Novel H1N1 2009 Virus in swine. Acute respiratory signs associated with other swine influenza viruses include a barking cough, nasal discharge, and sneezing. Reports of possible cases may go to the producer's private veterinary practitioner, to the State Veterinarian or to the USDA-APHIS Area Veterinarian-in-Charge (AVIC). Reports of illness in swine may also come from auction houses, markets, fairs, exhibitions, or from State or university veterinary diagnostic laboratories.

5. Laboratory Confirmation

The National Veterinary Services Laboratories (NVSL) has the capability to differentiate between SIV and Novel H1N1 2009 Virus by polymerase chain reaction (PCR) testing with follow-up gene sequencing of the virus isolate.

PCR and nucleic acid sequencing is necessary since current serology tests do not distinguish between vaccinated swine, swine infected with normal, endemic SIV, and any swine potentially infected with the Novel H1N1 2009 Virus. Reagents (inactivated virus antigen and antisera) for serology are currently under development. These reagents may be used to demonstrate immune responses to vaccination or to characterize vaccine seed organisms.

6. Goals in the Event of Detection of Novel H1N1 2009 Virus in Swine: Biosecurity and Monitored Movement

USDA's primary goals are to prevent additional spread of the Novel H1N1 2009 Virus and limit human exposure to the virus. The strategies used to limit the spread of, and exposure to, the virus will be case-specific but, in general, are:

- Biosecurity measures;
- Monitored movement of swine from affected groups. A monitored movement is one where a cohort group of swine is determined to be free from clinical signs of ILI by or under the

supervision of a licensed veterinarian before the movement can occur. Quarantines are not recommended.

Feral swine are not a component of Novel H1N1 2009 Virus surveillance and the detection of the Novel H1N1 2009 Virus in humans or in domesticated swine should not result in actions being taken on feral swine. Likewise, the detection of Novel H1N1 2009 Virus in feral swine should not result in actions taken on domesticated swine.

7. Guidelines for Activities Associated with Collection of Surveillance Samples and Detection of Novel H1N1 2009 Virus in Swine

Licensed veterinarians, accredited veterinarians, and State and Federal veterinarians, within their current roles and responsibilities, are considered qualified to diagnose or identify swine with ILI, swine that do not have ILI, and swine recovered from ILI.

USDA will work closely with State Animal Health Officials (SAHOs), licensed veterinarians, accredited veterinarians, Federal and State public health officials, and the swine industry, in the collection of samples for each of the three surveillance streams identified and in the event of a detection of Novel H1N1 2009 Virus in swine.

A) Surveillance of swine populations that are epidemiologically linked to a human case of SIV (including the Novel H1N1 2009 Virus).

In the event of a human case of SIV (including the Novel H1N1 2009 Virus) infection in which exposure to swine may have been involved, USDA will work closely with Federal and State public health officials, the SAHO, and the swine industry to determine the appropriate course of action. If it is determined that there is an epidemiological link between swine and an infected person, the health status of the swine should be assessed under direction of the SAHO and in cooperation with the licensed veterinarian having a valid VCPR with the operation.

I. No swine with ILI are observed.

If swine linked to a human infection with SIV (including the Novel H1N1 2009 Virus) are observed to have no signs of ILI, actions may be limited to enhancement of biosecurity, as appropriate, to prevent any ongoing exposure of swine to the human illness.

II. Swine with ILI are observed.

If swine linked to a human infection with Novel H1N1 2009 Virus are observed to have signs of ILI that meet the case definition established in the “National surveillance plan for Swine Influenza Virus: including 2009 Novel H1N1 Virus ” collection of samples from animals of cooperating owners should be undertaken as described in Section 1.8(A) of that plan. These nasal swab and/or tissue samples should be collected by or under the supervision of a licensed veterinarian and submitted to a participating veterinary diagnostic laboratory. Movements of swine from the group should be carried out through a monitored movement process under the authority of the SAHO. Biosecurity should be appropriate to protect caretakers and minimize exposure of unexposed swine.

If testing of samples does not confirm the presence of Novel H1N1 2009 Virus in the sick swine, normal operations shall continue. Continuation of biosecurity practices is recommended to prevent possible human-to-swine transmission of influenza viruses.

If testing of samples confirms the presence of Novel H1N1 2009 Virus in the sick swine, those animals may be moved using a monitored movement process under the authority of the SAHO, on a case-by-case basis, with consideration of all factors associated with the specific circumstances of a given incident.

B) Case-compatible swine accessions submitted to Veterinary Diagnostic Laboratories.

If swine on a farm are observed to have signs of ILI that meet the established case definition, nasal swab and/or tissue samples may be collected from those swine and submitted to a participating veterinary diagnostic laboratory (see Section 1.8(B) of the “National surveillance plan for Swine Influenza Virus: including 2009 Novel H1N1 Virus”) as part of the normal and routine disease monitoring and/or diagnostic plan for the herd. Samples may be collected by or under the supervision of a licensed veterinarian.

Contact between sick swine and humans, or between sick swine and unexposed swine, should be controlled under the specific biosecurity procedures that exist at the premises involved or by initiating enhanced biosecurity procedures.

If testing of samples confirms the presence of Novel H1N1 2009 Virus in the sick swine, those animals may be moved using a monitored movement process under the authority of the SAHO, on a case-by-case basis, with consideration of all factors associated with the specific circumstances of a given incident.

C) Surveillance of sick swine at first points of concentration or commingling events, such as auctions, markets, fairs or other swine exhibition events.

For swine at an auction, market, fair, or other swine exhibition event, swine that are showing clinical signs of any disease, including ILI that meet the established case definition, are not allowed to be off-loaded according to State and Federal regulations. Groups of swine that are exhibiting ILI that meet the established case definition after off-loading should be isolated and:

- Held until the group has recovered as determined by a licensed veterinarian or has been tested and found to be negative for the Novel H1N1 2009 Virus or,
- Relocated using a monitored movement plan to an offsite location where the group can be isolated, cared for and allowed to recover.

Nasal swabs and/or tissue samples may be collected from those swine and submitted to a participating veterinary diagnostic laboratory (see Section 1.8(C) of the “National surveillance plan for Swine Influenza Virus: including 2009 Novel H1N1 Virus”). Samples may be collected by or under the supervision of a licensed veterinarian. If not already implemented, biosecurity measures to prevent interspecies transmission should be adopted until the animals have recovered from ILI as determined by or under the supervision of a licensed veterinarian.

Normal operations are allowed to continue for groups of swine not showing ILI.

Sampling of swine at slaughter or processing facilities is not a component of Novel H1N1 2009 Virus surveillance. Swine with signs of ILI that arrive at federally inspected facilities should be handled according to standard protocols and procedures of the USDA Food Safety and Inspection Service.

8. Veterinary Biologics

The U.S. Department of Agriculture (USDA) is authorized, under the 1913 [Virus-Serum-Toxin Act](#) as amended by the 1985 Food Security Act, to ensure that all veterinary biologics produced in, or imported into, the United States are not worthless, contaminated, dangerous, or harmful. Federal law prohibits the shipment of veterinary biologics unless these are manufactured in compliance with regulations contained in [Title 9 of the Code of Federal Regulations, Parts 101 to 118](#). Veterinary biologics for commercial use must be produced at a USDA-licensed establishment, and under an unexpired and unrevoked U.S. Veterinary Biological Product License.

The APHIS Center for Veterinary Biologics (CVB) has provided guidance that allows for expedited licensing for viral strain changes in killed swine influenza vaccines, provided that the production methods are not significantly different than those used in the original licensed or permitted product. Full-scale efficacy and field safety studies, as well as interference studies for combination products where antigen interference studies have already been satisfactorily completed, are not required. More information about the CVB can be found at: http://www.aphis.usda.gov/animal_health/vet_biologics/

APHIS is committed to working with State animal health officials, veterinary practitioners, swine industry officials, and public health officials to further develop and implement vaccine knowledge and strategies with respect to the Novel H1N1 2009 Virus, to include the continuum of small swine operations to large or complex swine operations.

9. Health and Safety Guidance for APHIS Employees

Health and Safety Guidance for APHIS Employees Related to Potential Exposure to Novel H1N1 2009 Virus is found in Attachment II.

10. National Veterinary Stockpile (NVS)

The NVS countermeasures consist of supplies, personal protective equipment (PPE), and support services. Supplies include enough antiviral drugs (Tamiflu and Relenza) to support 3000 people for 40 days, and equipment includes PPE for responders. The NVS has in place, indefinite delivery and indefinite quantity contracts for continuous flow of PPE into the outbreak. It has reach-back capabilities for additional antivirals from the Department of Health and Human Services and the manufacturer, if needed.

The NVS support services include the capability of deploying large numbers of trained commercial personnel with equipment to support States that do not have enough of their own personnel to perform actions like depopulation, disposal, and decontamination, if those actions are ever needed. More information about the NVS can be found at: http://www.aphis.usda.gov/animal_health/emergency_management/nvs.shtml

11. Biosecurity Recommendations and Guidelines

Biosecurity recommendations and guidelines are included in Attachment III. Guidelines from Iowa State University, Center for Food Security and Public Health (CFSPH), are also included.

12. Potential Disinfectants to Use Against Influenza A (H1N1) Virus in Farm Settings

Influenza A virus survival in the environment is influenced by temperature, pH, salinity and the presence of organic material. Various avian influenza A viruses are reported to survive for four weeks at 18°C (64°F). Influenza A viruses are readily inactivated by a wide variety of Environmental Protection Agency (EPA) approved disinfectants.

The EPA registers pesticide products, including disinfectants. Currently, over 500 disinfectant products are registered for use on hard, non-porous surfaces against influenza A viruses. The most up to date information can be found at <http://www.epa.gov/oppad001/influenza-disinfectants.html>. EPA approved disinfectants for Type A influenza viruses are found in Attachment IV.

Attachments – Located in Separate Document

- Attachment I Swine Influenza Virus (H1 and H3) Seroprevalence on U.S. Swine Operations
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