
**Herd Monitoring and Management Plan
for
Novel Swine Enteric Coronavirus Diseases**

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Herd Monitoring and Management Plan for Novel Swine Enteric Coronavirus Diseases (SECD)

Since its appearance in the United States in April 2013, porcine epidemic diarrhea virus (PEDV) has spread within the swine industry to 30 States. In recent months, an additional related virus, porcine delta coronavirus (PDCoV), has appeared in this country. Infections with these swine enteric coronaviruses can cause significant morbidity and mortality, particularly in young piglets. Actions to date, led by producers, swine veterinarians, and the industry organizations, have focused primarily on biosecurity but have not been fully effective in limiting the spread of the virus. Therefore, the Federal government, States, herd veterinarians and industry need to make a concerted effort to manage these infections in the United States.

The goals of this plan are to:

1. Collect information to characterize and understand the scope of SECD, and inform future control options.
2. Decrease shedding and spread of PEDV and PDCoV or other novel enteric coronaviruses from affected herds.

These goals are intended to address the current outbreak of swine enteric coronavirus diseases in a manner that supports business continuity for commercial pork producers, maintains a plentiful supply of pork for consumers, and is credible to State and Federal animal health officials. The actions necessary to meet these goals are discussed in subsequent sections of this document.

APHIS intends to accomplish these goals through collaboration with State Officials, veterinarians, laboratories and producers by application of the following:

1. No federal regulatory response will be applied to herds that comply with the requirements of the Federal Order.
2. Reporting of affected herds as described below will be required of laboratories, producers, and veterinarians.
3. Affected herds will be required to have and follow a herd management plan.
4. Regulatory action may be taken on entities that do not comply with the Federal Order requirements of reporting, having a herd management plan, and following that plan.
5. Federal funding will be available for various costs that are described within the herd management plan.

Characterize and understand the scope of SECD. To date there are no federal reporting requirements for SECD. Therefore, USDA is issuing a Federal Order requiring laboratories, herd veterinarians, producers, and anyone with knowledge of disease compatible with a diagnosis of PEDV or PDCoV to report that incident to APHIS, Veterinary Services and States. This reporting will be accomplished through the collaborative efforts of producers, herd veterinarians, laboratories, State Animal Health Officials (SAHO), and APHIS.

The goal of herd monitoring efforts is to characterize and understand the scope of SECD and decrease the shedding and spread of PEDV and PDCoV. Herd testing criteria, biosecurity practices, and disease control measures that will be most effective in addressing SECD will require input from herd veterinarians, laboratory diagnosticians, and regulatory officials as the details of this plan are developed. The costs of testing in affected herds will be shared by APHIS.

Inform future disease control options. As part of herd management plans developed by herd veterinarians, producers need to maintain animal movement records on to and off a production facility. While it is not required that this information be reported, it may be used by State and Federal officials for epidemiologic investigations for a greater understanding of how SECD spreads. Additionally, the maintenance or creation of swine health committees in each State is recommended. These committees will be critical to the ongoing evaluation of monitoring data, dissemination of current knowledge of effective disease control methods and in the development of future control options.

Decrease the shedding and spread of PEDV or PDCoV from affected herds. Herd management plans must be established and maintained for affected herds. Producers in collaboration with their herd veterinarians will develop this plan. In some cases, a Federal Veterinary Medical Officer, or a State Veterinary Medical Officer, may need to develop plans where a private veterinarian is not available. Fee-basis funding will be provided by APHIS to support the development of plans by herd veterinarians. Plan components developed by a herd veterinarian will be shared with State and Federal officials to facilitate future standardization of the most effective practices. Herd management plans will specify actions the producer is taking to implement biosecurity steps designed to reduce further dissemination of PEDV or PDCoV. These plans will also specify herd-level disease control procedures. The herd plan should draw from and be consistent with current recommendations from industry-led best management practices for biosecurity and disease control. Biosecurity improvements or actions by producers described in herd plans, such as the costs of truck washing and disinfecting agents will be partially subsidized by APHIS.

Goal 1: Collect information to characterize and understand the scope of SECD, and inform future control options

Reporting Requirements for Novel Enteric Coronaviruses

A Federal Order states that anyone, including producers, veterinarians, laboratory personnel, or others with knowledge of the disease, who identifies a new occurrence of suspected PEDV, PDCoV, or other novel enteric coronavirus must report the occurrence to State and Federal authorities. A new occurrence may be the initial detection or a reoccurrence of previously detected disease. This includes both presumptive positive and confirmed positive cases originating from swine herds in the United States or its Territories. If a sample is submitted to a National Animal Health Laboratory Network (NAHLN) laboratory for testing and is found positive, duplicate reporting by the herd owner, producers, veterinarians, and others with knowledge of the disease is not required.

Reporting should follow existing channels to the State animal health official (SAHO) or Federal Assistant District Director (ADD). For laboratories, reporting of all test-positive animals will also be submitted electronically to the Laboratory Messaging System (LMS). Reporting will include: premises identification number (PIN) or an alternative premises identifier; date of sample collection; type of herd being sampled (sow, nursery, finisher); test methods used to make the diagnosis; and test results. The case must be reported as soon as the herd is believed infected because of laboratory test-positive samples or other

knowledge of herd infection, except when positive samples are reported by NAHLN laboratories, as above. Laboratory characterization and reporting of undetermined viruses should occur within two weeks of submission, if possible.

Disease Surveillance

Surveillance will be composed of two parts:

- Passive surveillance with required reporting of infected herds.
- Testing of infected herds while they are in a recovery and clean-up phase of the disease.

Goal 2: Decrease the Shedding and Spread of PEDV and PDCoV

APHIS intends to facilitate safe movement of swine by assisting swine producers and veterinarians in control of these viruses and decrease the potential for disease spread in herds using industry recommended best practices. APHIS will further assist by supplementing financial support for SAHO's, producers, and herd veterinarians that are developing herd management plans to include items such as diagnostic testing, cleaning vehicles, and other best practices for disease control.

Affected herds must have and follow a herd management plan. The herd management plan, developed by a herd veterinarian, will address the following:

- Diagnostic testing to monitor the status of herd infection and assess efficacy of control strategies (laboratory costs subsidized by APHIS).
- Herd plans will follow the best management and disease control practices known to date. These practices will be identified and described by herd veterinarians and may change as new information becomes available. (See discussion on "Biosecurity overview" below.)
- Producers will be required to maintain records on pig movements and make them accessible to animal health officials when needed.

Disease Monitoring

Herd monitoring will support normal animal movements. Herd veterinarians will collect samples for herd monitoring tests and submit directly to a National Animal Health Laboratory Network (NAHLN) laboratory, with testing costs subsidized by APHIS. Along with the samples submitted, producers and their veterinarians need to include a validated PIN or an alternative premises identifier on all diagnostic laboratory submission forms. Federal animal health officials will build necessary information technology connections so SAHOs, Federal officials, and industry can access monitoring data when appropriate in the Emergency Management Response System 2.0 (EMRS 2), Surveillance Collaboration Services (SCS), or other databases. A critical aspect of herd monitoring is to determine when a herd may be considered to no longer be affected. Herd veterinarians will define the best methods and criteria to use in determining when a herd may be considered not affected. State swine health committees will assist in evaluating data and in determining criteria for when a herd should be considered no longer affected.

Biosecurity Overview

It is ultimately a producer's responsibility, working with their herd veterinarian, to minimize disease impacts to a herd. Enhanced biosecurity measures will be essential to exclude or, if infected, contain novel coronaviruses. Over time, biosecurity performance standards will be established using industry-led best practices. Biosecurity may initially be focused on breeding sites, since removing disease will eliminate the animal

transmission risk for downstream sites that receive the weaned pigs. There are likely four general areas of biosecurity to address. All of these will be in accordance with best practices as determined by herd veterinarians. Source examples of best practices can currently be found at the National Pork Board's (NPB) PED site: <http://www.pork.org/Research/2641/ResearchLatestNews.aspx#.Uhd3GZJJOKI>.

- **Employee and visitor biosecurity enhancement**
 - While most sites are very restrictive as to who enters the hog houses and how, enhancement may involve factors such as site perimeter restrictions for herds, at least on breeding herds. In other words, employee or visitor vehicles may be excluded from up to a certain distance from the site. Further enhancement could include setting up fogging rooms for employee belongings. See also: <http://www.pork.org/filelibrary/PED-CleanCross.pdf>.

- **Pigs coming onto a site**
 - Aside from bringing the virus into a hog facility, early-weaned pigs transferred from a breeding farm infected with novel coronavirus can easily infect their new home and set up the potential for further spread within and beyond the site.

- **Trucks and trucking personnel**
 - Pigs, feed, and other supplies enter a site on trucks. Cleaning and disinfecting protocols are critical. For example, scheduling of deliveries has been adjusted based on novel coronavirus status (e.g., the affected site is visited after clean sites) and full disinfection of the inside and outside of trucks are more common now. See also: <http://www.pork.org/filelibrary/PED-biosTransport.pdf>.

- **Feed components**
 - As noted previously, feed trucks present a risk for spreading disease. There is evidence that feed ingredients may present a risk of spreading disease (the nucleic acid of novel coronaviruses has been isolated in feed itself, particularly animal protein products) although it is not yet known if this is contamination of the ingredient that survives the production process or post-production contamination.

The biosecurity and biocontainment components briefly described above will be the basis for developing model herd biosecurity and containment programs.

Movement of Swine

As part of herd management plans, producers need to maintain up-to-date records on movements of animals onto and off a facility preferably in an easily accessed electronic format in order to support information needs of Federal and State officials. Producers who have and follow a herd management plan are eligible for APHIS financial support with no restrictions on movements. Producers who do not have or follow a herd management plan may have additional requirements for movement of pigs placed on them by State or Federal animal health officials.

Movement information will allow producers to document that biosecurity and disease control measures are effective or, alternately, that intervention measures need to be adjusted. If newly infected herds arise from a herd that has been deemed clean by testing, knowledge of movements will assist in investigating the new herd.

Appendix 1: Stakeholder Roles

Producer and Industry Group Participation

Participation supports national disease control objectives that provide necessary health assurances to maintain commerce and eventually restore the industry to full health.

Education and training programs should be continued and expanded for veterinarians, producers, haulers, and packer/processors to enhance disease preparedness, recognition, and response. Producers and packers/processors should include specific information about SECD within the context of awareness education for all employees on a regular (annual, biannual, or quarterly) basis. The NPB, AASV and various NAHLN laboratories and Colleges of Veterinary Medicine have produced materials to raise awareness of the current novel coronavirus situation and to provide accurate and applicable information to producers. These materials are posted to public web sites.

Communication is critical. Accurate and consistent messaging from Federal and State officials, producers, packers/processors, and the public is imperative to manage SECD as well as perception of its consequences. Best practices for disease control and biosecurity should be industry-led in collaboration with State and Federal officials and will require enhanced commitment and discussion by all organizational groups. Because much is yet to be learned about SECD, management and control options may change in light of new information.

Herd Veterinarians Participation

Producers, SAHOs, and APHIS must rely on herd veterinarians to develop management plans appropriate for individual producers. Producers with positive PEDV or PDCoV diagnoses will continue to develop herd plans with their veterinarians to address biosecurity and ongoing diagnostic monitoring. It is not likely that all pathways for introduction of these viruses into herds have been identified so uniform biosecurity practices that are successful in all cases are not yet defined. As herd veterinarians, SAHOs, and APHIS gather more information about pathways, transmission, and control strategies and how best to define the status of a herd, standard practices will be established.

SAHOs Participation

Participating SAHOs can support pork producers in their States by supporting biosecurity and disease control protocols, implementing cooperative agreements and through frequent and effective communication.

Biosecurity and disease control practices: Biosecurity and disease control practices are a cornerstone of the program. SAHOs take an active role in working with producers and industry in their States to manage disease. Specific herd-level biosecurity and disease control plans with clear, actionable mitigations will be managed by herd veterinarians.

Cooperative agreements: Various activities with the SECD Program will be achieved through cooperative agreements between States and APHIS. The engagement and follow-up of SAHOs in establishing and implementing cooperative agreements will be critical to the success of the program. Activities that may be carried out through cooperative agreements might include, but are not necessarily limited to, sampling of herds, supply of disinfectants, reviewing biosecurity and disease control practices, and investigation of newly affected herds.

Communication: SAHOs will communicate with NAHLN labs concerning testing results for samples submitted through the program, and work with SAHOs in surrounding states to share disease information and management practices. They serve a primary role working to support their industry and accredited veterinarians with herd management plans, biosecurity, and other disease control measures.

APHIS Participation

Federal animal health officials with APHIS will assist pork producers and herd veterinarians by supporting the following: 1) disease monitoring; 2) herd management plan development; 3) biosecurity and herd-level control procedures; and 4) data integration. Producers affected by PEDV or PDCoV understand that APHIS officials may, when needed, access disease monitoring and biosecurity evaluation information.

Disease monitoring: APHIS will subsidize laboratory diagnostic testing costs associated with the herd testing in affected herds.

Herd management plan development: APHIS personnel will be available to develop or assist in the development of individual herd management plans for producers without access to a herd veterinarian.

Biosecurity and herd-level control procedures: APHIS will financially subsidize enhancements to producers' biosecurity programs to meet criteria established in herd plans. This may include payments for disinfectants, truck wash upgrades, or other specific biosecurity-related activities. APHIS may also financially support herd-level disease control procedures.

Information technology and data integration: EMRS 2 is the System of Record for information management of SECD Monitored Herds, while SCS may be implemented in some States and for use in later stages of managing the diseases. Implementing the Monitoring and Management Program will include APHIS developing necessary connections to fully integrate the LMS with the pertinent data management systems (e.g., EMRS 2, SCS). In addition to direct entry and electronic messaging, data may be entered onto a spreadsheet, delivered to a designated location, and then directly uploaded to either EMRS 2 or SCS.

NAHLN Participation

NAHLN laboratories will continue to play a crucial role in the testing and reporting of novel enteric coronaviruses.

Testing

- Recognizing that NAHLN laboratories have developed and are utilizing various diagnostic assays for the novel enteric coronavirus, the Methods Comparison process will be utilized to provide a scientific statement of equivalency of new tests based on specific criteria and evaluation panel. The National Veterinary Services Laboratories (NVSL) Diagnostic Virology Laboratory and NAHLN Methods Technical Working Group will be engaged in developing the criteria.
- Initially, the standardization and reporting will involve only polymerase chain reaction (PCR) testing. However, antibody testing and advanced diagnostics such as genomic sequencing will be addressed and may be incorporated in the future.
- NVSL will not provide routine confirmation of the PEDV and PDCoV testing at NAHLN laboratories. However, novel or unusual findings should be worked up in consultation with NVSL, including sharing of diagnostic material and virus, if isolated, for the purpose of supporting NVSL's national reference

laboratory functions. NVSL should be notified of Genbank deposits.

Data Collection

- NAHLN laboratories will require PINs or an alternative form of premises identifier on all swine diagnostic specimens submitted for swine enteric coronavirus testing. Producers and veterinarians will be required by the Federal Order to include PINS with laboratory submissions.

Process for Affected Herd Submissions

NAHLN laboratory personnel will do the following for samples from affected herds:

- Receive samples with accompanying producer information in accordance with the reporting requirements.
- Scan validated PIN into the LIMS, and associate it with the accession/case.
- Pass through the PINs associated with diagnostic samples and other pertinent information as required by Federal Order.
- Conduct testing on samples submitted and report results to producers/veterinarians as part of routine reporting of results.

Data Sharing

- NAHLN will report the PIN and other pertinent information through the LMS. Current NAHLN protocols will be followed for reporting swine testing including reporting to State and Federal animal health officials.
- If sequencing is incorporated into the program, sequence will be deposited in the public domain (GenBank) and deposit information provided as part of the results reporting.

Other recommended actions that benefit monitoring of the novel swine enteric coronaviruses:

- Ensure that novel swine enteric coronavirus diagnostic tests meet NAHLN validation requirements and are available for surveillance testing.
- Recommended: adding a statement on the diagnostic submission form that reminds producers of what participation in the SECD Program entails.