## Federal Order

Reporting, Herd Monitoring and Management of Novel Swine Enteric Coronavirus Diseases

## [Effective June 5, 2014]

The Secretary of Agriculture is authorized by the Animal Health Protection Act (AHPA), as amended (7 U.S.C. 8401 et seq.), to issue regulations and orders and to carry out operations and measures to prevent, detect, control and eradicate diseases and pests of livestock. The Secretary has delegated these authorities and responsibilities to the Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS). This Federal Order is issued in accordance with 7 U.S.C. 8305, 8308, 8310, 8313 and 8315.

APHIS-VS is issuing this Federal Order to establish a mandatory disease reporting requirement and a herd monitoring and management requirement for novel swine enteric coronavirus diseases (SECD). During the past year, USDA has confirmed for the first time the presence of two SECDs in the United States — porcine epidemic diarrhea virus (PEDV) and porcine delta corona virus (PDCoV). Infections with these coronaviruses can cause significant morbidity and mortality, particularly in young piglets. Accordingly, APHIS-VS is issuing this Federal Order to address the novel SECD outbreak that the United States is currently experiencing.

Since the U.S. swine population has no immunity against these coronaviruses, the U.S. swine population is at risk. In addition, the viruses can spread easily, since no commercially licensed vaccines are available. PEDV has now spread to 30 States with approximately 7 million piglet deaths. This disease causes significant sickness in swine, affecting their growth, production potential, and health. In addition, another novel coronavirus that causes a disease similar to PEDV — PDCoV — was confirmed in February 2014.

Therefore, APHIS, in consultation with the swine industry, needs to take immediate action to find out important information about these viruses and to manage these infections with a plan that includes: 1) mandatory disease reporting; and 2) the development of herd monitoring and management plans. Until now, APHIS-VS did not have sufficient information and the necessary funds to take any proactive type of regulatory action.

However, with the increase in the number of positive accessions of PEDV for the first 5 months of this year, plus eroding confidence among both domestic and international stakeholders, and the introduction of PDCoV, it became evident to APHIS-VS that the continued lack of basic disease information typically obtained through mandatory disease reporting was having significant unintended negative consequences. We have not been able to adequately identify, characterize, and assess the extent of the SECD outbreak and the introduction pathways to develop appropriate options for controlling these diseases at a national level. To develop these options, APHIS-VS needs mandatory reporting that allows for determining the total number of currently infected and newly infected herds and where they are located.

When PEDV was first confirmed in May 2013, only minor trade impacts occurred. As the disease has spread, with concurrent media attention, negative trade impacts have recently increased. Trading partners are unfortunately beginning to restrict not only live animals, but also animal-derived products such as blood products and other byproducts. While no restrictions have yet been imposed on pork meat exports, some U.S. trading partners have begun to discuss such restrictions. The lack of sufficient information to describe the current disease situation and to outline specific State and Federal government actions taken to control the disease only increases the concern from our trading partners.

This Federal Order requires the following:

- I. Mandatory reporting of confirmed occurrences of PEDV, PDCoV, or other novel swine enteric coronaviruses. These reporting requirements are essential to assist APHIS-VS in providing the basis for progressive mitigation assessment and evaluation for SECD, accomplished in partnership with and through State and industry collaboration. An occurrence may be the initial detection of disease or a reoccurrence of previously detected disease.
- II. Herds in the United States or its Territories that meet the case definition for either presumptive or confirmed positive from the effective date of this Federal Order *must* be reported as soon the herd is determined to be affected through positive laboratory test samples or other knowledge of herd infection. The case definition is located on the APHIS Web site at http://[LPA will insert]
- III. The following individuals are required to report presumptive or confirmed positive cases of SECD: Anyone, including herd owners, producers, veterinarians, laboratory personnel, or others with knowledge of the disease, who identifies an occurrence of PEDV, PDCoV, or another novel swine enteric coronavirus. 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. A list of NAHLN testing laboratories is located on the APHIS Web site at <u>http://nsu.aphis.usda.gov/animal\_health/nahln/labs.shtml</u>
- IV. Any occurrences of PEDV, PDCoV, or novel swine enteric coronavirus must be reported to the <u>State animal health official or State Veterinarian</u> or the <u>APHIS Assistant District Director</u>.
- V. The following specific reporting information must be submitted:

   Premises identification number (PIN) or an alternative premises location identifier;
   Date of sample collection;
   Type of unit being sampled (e.g. sow, nursery, finisher);
   Test methods used to make the diagnosis; and
   Diagnostic test results.
- VI. Herd owners whose herds meet the case definition for SECD must have, follow, and provide the APHIS Assistant District Director a copy of their herd management plan developed

through a relationship with a herd veterinarian. If a herd veterinarian or State veterinarian is not available, an APHIS veterinarian will provide assistance.

VII. The herd management plan must address:

Biosecurity of visitors and vehicles entering or exiting the premises
Monitoring employee biosecurity
Periodic herd health observation
Animal movement (both into and out of the herd)
Cleaning and disinfection of facilities
Diagnostic testing to monitor the status of the herd infection and assess efficacy of control strategies
Maintenance of records on pig movement that are accessible to State or Federal Animal Health officials upon request

- VIII. For guidance on herd management plan components, refer to: http://www.pork.org/Research/4316/PEDVResources.aspx
- IX. Herd owners with a case of SECD who do not have or do not follow a herd management plan may be subject to civil penalties and may have additional requirements (hold order, quarantine, permitting or other restrictions for movement of pigs) placed on their premises by State or Federal animal health officials.