



Stakeholder Announcement

USDA Licenses First Vaccine for Porcine Epidemic Diarrhea

WASHINGTON, June 16, 2014— The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) today issued a conditional license to Harrisvaccines, Inc. of Ames, Iowa for a vaccine that may aid in the control of porcine epidemic diarrhea virus (PEDv) in swine. This is the first licensed vaccine for PEDv. It will be used to vaccinate sows with the intent that they build antibody, and transmit that antibody through their milk to newborn piglets. It is intended to protect the piglets against PEDv.

APHIS licenses veterinary biologics products for use in controlling diseases of animals. Conditional licenses are issued based on full safety, purity testing, and an expectation of efficacy. Preliminary studies have been promising, and they've shown sufficient data that we think the vaccine will be effective. The company will continue working toward completing the requirements for a full license. In the meantime, there are no restrictions on vaccine use under the conditional license.

APHIS supports and encourages the rapid development of new vaccines, particularly in emergency situations. When a company obtains a conditional license they are able to bring an important disease management tool to producers safely and quickly. Full licensing can occur subsequently while producers get the products they need to protect animal health.

Porcine epidemic diarrhea is a disease that causes significant sickness in swine, affecting their growth and health, and causes high mortality in piglets. The disease is common in parts of Asia and Europe, but is not reportable to the World Organization for Animal Health (OIE). PEDv only affects pigs and does not pose any risk to people or pets. It is not a food safety concern.

Licensing this vaccine is another step APHIS is taking to continue to help the pork industry and producers.

Recently APHIS announced the availability of \$26.2 million in funding to combat these diseases and issued a Federal Order requiring the reporting of new detections of PEDv and other new swine enteric coronavirus disease to APHIS or State animal health officials. The Federal Order also requires that operations reporting these viruses work with their veterinarian, USDA or State animal health officials to develop and implement a reasonable management plan to address the detected virus and prevent its spread. Plans will be based on industry-recommended best practices, and include disease monitoring through testing and biosecurity measures. These steps will help to reduce virus shed in

affected animals, prevent further spread of the disease, and enable continued movement of animals for production and processing.

Throughout the PEDv outbreak, APHIS has worked closely with the swine industry to identify risk factors in the transmission of the virus and minimize its impact on producers and industry.

APHIS is part of a task force with the Food and Drug Administration and State and industry stakeholders, including the American Association of Swine Veterinarians, National Pork Producers Council, National Pork Board, veterinary diagnostic laboratories, and State Animal Health Officials.

This task force aims to investigate the virus, identify and trace risk factors in the transmission of the disease, and keep producers informed.

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