

**The Wall Street Journal**  
**New Vaccines Target Deadly Virus in Pigs**  
October 2, 2014

Drug companies are racing to create vaccines to stifle a deadly swine virus that has roiled the U.S. meat industry and pushed pork prices to record highs.

Two companies—tiny Harrisvaccines Inc. and larger animal-health firm [Zoetis Inc.](#) ZTS - 0.94% —received conditional regulatory approval this summer to market vaccines for porcine epidemic diarrhea virus, which has spread to 31 states and killed millions of young pigs since it was first identified in the U.S. in April 2013. At least two other drug makers— [Merck MRK +0.86%](#) & Co. and Germany's Boehringer Ingelheim GmbH—say they are researching potential vaccines for PED.

Hog farmers and meatpackers hope the vaccines can slow a disease that has confounded scientists and regulators, who remain uncertain of its causes and all of the pathways by which it spreads. The virus is fatal only to young pigs, and poses no threat to human health or food safety, according to scientists. PED has reduced U.S. hog supplies, raising costs for meat processors, retailers and consumers. Average retail pork prices jumped 12% in the 12 months through August to a record \$4.20 a pound, according to federal data.

The fast-track approval of the new vaccines by the U.S. Agriculture Department reflects the urgency with which the government and the animal-vaccine industry are pursuing solutions—much as experimental vaccines are being deployed to tackle human-health crises like the Ebola outbreak in Africa. Animal health companies fetch an estimated \$6 billion in global sales of vaccines annually, according to Vetnosis Ltd., an Edinburgh, Scotland-based research firm.

Major pig producers including Cargill Inc. and Maschhoffs LLC are experimenting with the vaccines, though many in the industry say they don't expect them to become panaceas because previous vaccines for similar swine viruses have had limited success.

Pork producers and veterinarians "are extremely frustrated and are looking at all viable options to control the virus," said Aaron Lower, a veterinarian with Carthage Veterinary Service, an Illinois firm that advises hog farmers.

According to industry estimates, roughly eight million pigs have died from the virus since it was first discovered in the U.S., with some farms experiencing repeat outbreaks. U.S. pork production has fallen 1.8% this year, according to the USDA, lifting futures prices for slaughter-ready hogs to a record \$1.33875 a pound in July. Prices have eased in the past two months, in part because fewer PED outbreaks occurred this summer compared with the start of the year. That is likely because warmer temperatures make it harder for the virus to survive, according to veterinarians.

"Whether or not these interventions are effective is a question that will not be answered until we get through this winter," said Mr. Lower, who has administered the vaccine in some of his clients' herds.

Mike Martin, a spokesman for Cargill, the fourth-largest U.S. pork processor, said the company is optimistic that both of the approved vaccines will help more piglets survive. He noted that Cargill's use of the Harrisvaccines product so far "has helped in that regard."

Harrisvaccines, an Ames, Iowa, firm founded in 2006 by a former Iowa State University animal-science and microbiology professor, in June became the first company to receive conditional USDA approval to sell its PED vaccine. The designation means the company can distribute the treatment directly to hog farmers or veterinarians while it works toward a full license.

The USDA's conditional licensing system, which has been available to animal-health companies since 1985, requires that companies demonstrate in field trials that their treatments are safe. They also must furnish data from trials indicating the product likely would be effective in combating disease. The Food and Drug Administration offers similar fast-track review programs in human medicine.

Before receiving USDA approval, Harrisvaccines sold its vaccine as an experimental treatment. Hog farmers had to obtain a prescription from a licensed veterinarian, who had no assurances it would be safe or effective. The company said it has sold 2.6 million doses since introducing the vaccine in August 2013. The vaccine, which costs \$3 a dose, is administered to sows—adult female pigs—in hopes they will pass on immunity to their offspring. The company recommends sows receive two doses.

Harrisvaccines's technology uses genetic sequencing to identify a gene in the PED virus that its researchers think will create immunity. The researchers insert that genetic material into a chemically weakened virus, creating what is known as a vector vaccine. Similar technology is being used in one of the experimental Ebola vaccines.

Quickly developing its vaccine has been a boon for the privately held company, which employs about 40 people. Revenue likely will double to about \$8 million this year from 2013, said Joel Harris, head of sales and marketing and son of the company's CEO and founder, Hank Harris.

Such vaccines potentially could be used on many of the roughly six million sows in the U.S.

On a recent afternoon, the elder Mr. Harris walked through an Iowa State research lab where he and other researchers have tested products designed to combat highly infectious livestock diseases. He said the technology Harrisvaccines uses for the PED

virus could be promising in other arenas.

"Ten or 20 years from now, someone will get cancer and the cells in their body will be analyzed for a gene that's important to that process, and researchers will plunk it into a platform like this one and you'll start vaccinating immediately," he said.

Zoetis, which was spun off from [Pfizer Inc.](#) PFE -0.38% in 2013 and earned \$4.6 billion in revenue last year, received conditional approval for its own PED vaccine in early September.

Zoetis used a more conventional approach for its vaccine, in which drug makers grow a full virus in a lab and alter it in a way that triggers an immune response in animals but doesn't cause them to get the disease.

The company's approach came down to "what gives us the best shot of safety and efficacy, and our ability to consistently manufacture" a treatment, said Catherine Knupp, president of research and development at the Florham Park, N.J., company.

Merck, whose animal-health unit ranks second in the U.S. after Zoetis by revenue, said earlier this year that it was researching a PED vaccine in partnership with Utrecht University in the Netherlands. A Merck spokeswoman declined to elaborate but said "the project remains on track."

At the animal-health unit of Germany's Boehringer, developing a PED vaccine is the highest priority of its North American operations, said Dale Polson, a senior veterinarian for the company. Boehringer is focused on slowing the spread of the disease rather than eliminating it, he said, noting it has been more difficult for the company to understand than other diseases Boehringer has studied.

"As an industry, I think PED served as a wake-up call," Mr. Polson said. "Our approach is not a silver bullet...but will provide another tool in a producer's toolbox."

**The New York Times**  
**Farmers Gain Weapon Against Devastating Pig Virus**  
October 9, 2014

A disease that killed off at least 10 percent of the nation's hogs in the last year is starting to threaten farmers again as colder weather approaches.

But they have new tools to fight the ailment, porcine epidemic diarrhea virus. The Agriculture Department has conditionally approved two vaccines, and a third is on the horizon.

"I've been in this industry for 37 years, and I have never seen it pull together like it has in this crisis," said Bill Marks, chief executive of [MJ Biologics](#) in Mankato, Minn., which is hoping to get the Agriculture Department's approval soon for the third vaccine. "The leadership of our trade associations has been fantastic, and the collaboration between universities and private industry has been phenomenal."

The virus infects sows and is passed from them to their piglets, which are particularly vulnerable. About half of the nation's six million sows have contracted it, and some have lost entire litters to the disease, according to the [National Pork Producers Council](#).

Howard Hill, the council's president, told attendees at the World Pork Expo this summer that 1.3 million pigs died from the virus last January alone. The need to bury so many carcasses has even raised concerns about the effect on groundwater.

Circle Four Farms, a unit of Smithfield Foods that is the largest hog farm in Utah, was among the latest operations hit by the virus, said Dr. Tom Burkgren, executive director of the [American Association of Swine Veterinarians](#). For reasons that are unclear, the virus is not as active in warm weather, but since temperatures have started falling, more farms are reporting outbreaks.

"We're concerned going into the fall that we will see the same uptick we saw last fall and winter," Dr. Burkgren said. "January, February and March were really tough, so everyone is holding their breath and keeping their fingers crossed."

In June, the Agriculture Department set aside \$3.9 million to develop vaccines against the disease, but none of that money has gone to the two it has licensed for use thus far. One is made by [Zoetis](#), a titan of veterinary medicine; the other by [Harrisvaccines](#), a company founded by a veterinarian and former animal science professor at Iowa State University, where much of the research on the virus has been done.

**CNBC**

**US confident new vaccine will help fight pig virus**

June 18, 2014

By Reuters

U.S. Agriculture Secretary Tom Vilsack said on Wednesday he was confident a vaccine approved this week by the U.S. administration would help fight a deadly virus that has killed millions of pigs in the United States.

The U.S. Department of Agriculture said on Wednesday preliminary studies of a vaccine developed by Harrisvaccines "have been promising" in controlling Porcine Epidemic Diarrhea virus (PEDv). The virus has killed up to 8 million pigs and pushed pork prices to record highs since it was first identified in the United States last year.

"I don't want to say the virus will be eradicated, but I think you will see we're on the other side of this," Vilsack said after a speech to representatives of the French farm sector at the U.S. embassy in Paris.

He added that warmer temperatures over the summer would weaken the virus, while systematic notification by farmers of new PEDv cases and higher biosecurity measures at farms will help in the fight against PEDv.

Earlier this month, Vilsack ordered farmers to start reporting cases of the deadly pig virus and pledged more than \$26 million in funding to combat the virus, pushing back against criticism of his handling of the outbreak.

**Settling Down**

Harrisvaccines' product is the first to win U.S. Department of Agriculture conditional approval, which means it can be sold over the counter but the company must continue to test its effectiveness.

"Hopefully by the end of the year we will be in a situation where we can say, 'Yes, folks, (the vaccine) works,' (and) start producing mass quantities of it so that farm producers around the world will not have to worry about this," Vilsack said.

He said the virus, which causes diarrhea and vomiting and is nearly always lethal to piglets, was a global issue and not just a U.S. problem. PEDv has been found in other countries, including Japan, Canada and Mexico.

The crisis and the severity of the virus have disrupted international pig trading, with 11 countries or regions, including Russia, the European Union, China and Japan, limiting imports of live hogs.

The head of the Paris-based World Animal Health Organization OIE, which met Vilsack earlier in the day, welcomed the new vaccine and said there were indications the virus, which has wiped out an estimated 10 percent of U.S. pigs, was subsiding in North America.

"We have the feeling that it's settling down in the United States and Canada. It's going in the right direction," Bernard Vallat told Reuters by phone.

"The fact that (the vaccine) successfully passed the tests to be authorized is good news," he said.

However, he said that further tests would need to be done on whether there is a risk that vaccinated animals can continue to be contagious without being sick.

This week Vilsack is on a European tour that started in Luxembourg and Brussels, where discussions focused on the U.S.-European Union Transatlantic Trade and Investment Partnership (TTIP), which he insisted should sweep away "non-scientific barriers" to U.S. sales.

## **Feedstuffs**

### **USDA extends conditional license on PEDv vaccine**

June 16, 2014

By Sarah Muirhead

The U.S. Department of Agriculture has extended a conditional license on a vaccine for porcine epidemic diarrhea virus (PEDv).

The vaccine is the first to be licensed for PEDv and 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.

The vaccine, called "iPED," was developed by Harrisvaccines, Ames, Iowa. Since its introduction, approximately 2 million doses of the vaccine have been prescribed by veterinarians. The approval, issued June 16, widens the marketing and distribution channels for the product and acknowledges that the technology offers a reasonable expectation of efficacy.

"The approval validates our product and our technology," said Joel Harris, head of sales and marketing for Harrisvaccines. "There's still a lot to learn about PEDv, but we know that we're increasing an immune level" beyond what natural exposure achieves, he said, noting that the vaccine used in combination with natural exposure has proven to boost immune levels significantly.

USDA issues conditional licenses 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, USDA said in its press statement. 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, said USDA.

PEDv, first seen in the U.S. in the spring of 2013, is not harmful to humans nor a food safety risk but causes diarrhea, vomiting and dehydration in hogs and can result in death, particularly in piglets. To date, the virus is estimated to have killed some 7 million pigs in the U.S. It has been found in 30 states as well as in Canada, Mexico, Japan and South Korea.

At the World Pork Expo in early June, agriculture secretary Tom Vilsack called the virus a "tremendous hardship for many American pork producers."

Harris said its vaccine is predominately being used in herds that are already affected by the virus. The pigs have either already been exposed to the virus or it is being used when bringing in animals where the virus is already present. "What we've seen is there is a statistically higher antibody level in those vaccinated sows versus non-vaccinated

ones,” he said.

The USDA conditional licensing opens up the availability of the vaccine for veterinarians to buy and distribute without the direct involvement of the company and allows producers to buy direct if they so wish. Harris said it also opens up opportunities to export the vaccine on a larger scale.

The USDA generally grants conditional licenses in order to meet an emergency or unmet need. A conditionally licensed product must show a reasonable expectation of efficacy and all safety and purity requirements must be met. Harrisvaccines has received USDA licensure in the past using SirraVaxSM technology for its Swine Influenza vaccine (September 2012) and an Autogenous Vaccine, RNA for Rotavirus C (January 2013).

Essentially the process used by Harrisvaccines is that of taking data from the virus (RNA) to develop what look like virus particles using the gene sequence from the RNA. Once injected, the particles target the pig’s cells to replicate the RNA to generate an immune response inside the animal that is very targeted. When the pigs then encounter the actual live virus in the field, they already have a strong immunity against it.

The company now plans to move forward to receive full USDA approval so it can market the vaccine even more broadly to distributors and veterinarians.

Licensing this vaccine is another step USDA is taking to continue to help the hog industry and producers. Recently USDA 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 or 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, said USDA.



## **The Pig Site**

### **World Pork New Product Award for PED Vaccine**

July 16, 2014

Animal vaccine producer, Harrisvaccines, has been chosen as the recipient of the 2014 World Pork Expo New Product Tour Producer's Choice Award for its vaccine against porcine epidemic diarrhea (PED).

The award honors a product for its exceptional quality and unique technology. Based in Ames, Iowa, Harrisvaccines is proud to receive this honor for Porcine Epidemic Diarrhea Vaccine, RNA, the only PEDv available on the market today. This year, 30 products competed for the Producer's Choice Award in the World Pork Expo New Product Tour and every Expo attendee had a chance to vote for their favorite product.

Dr. Hank Harris, President and CEO of Harrisvaccines, commented: "Harrisvaccines is honored to be the recipient of this year's Producer's Choice Award. It is an incredible achievement to have esteemed members of the industry recognize and award our vaccine for the significant impact it has had on the pork industry during this difficult PED disease outbreak."

Joel Harris, Head of Sales and Marketing for Harrisvaccines, said: "This demonstrates how far our PEDv vaccine has come in such a short amount of time. Our rapid response technology allowed us to produce a viable vaccine in August 2013, and less than one year later we proudly receive this award."

Produced using Harrisvaccines' revolutionary SirraVaxSM RNA Particle technology, Porcine Epidemic Diarrhea Vaccine, RNA, has played a critical role in treating PEDv since it was first introduced in the United States in April 2013. Weeks after the virus was discovered, Harrisvaccines produced a working vaccine, which was sold via veterinary prescription, the company has since sold approximately two million doses. In June 2014, Harrisvaccines received conditional licensure from the United States Department of Agriculture (USDA) allowing the vaccine to be sold directly to the veterinarians and swine producers battling PEDV.

The Award was sponsored by *National Hog Farmer*.