

BREAKING - USDA Approval Imminent for H5N1 Bird Flu Vaccine in Cattle

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By **Nicolas Hulscher, MPH**

According to a Medgene **press release**:

Medgene's H5N1 vaccine for dairy cattle has met all requirements of USDA's platform technology guidelines and is in the final stages of review for conditional license approval.



Medgene advances H5N1 vaccine availability across animal species on platform technology

South Dakota company signs agreement to support the dairy industry; accelerates vaccine testing for turkeys, egg-laying hens, and companion animals

(Brookings, SD) – Global animal health company, Medgene, reports recent successes in making H5N1 vaccines commercially available to animal owners and veterinarians.

One recent success is the signing of a distribution agreement with Elanco Animal Health to accelerate the company's support of the U.S. dairy industry, pending a final decision by the U.S. Department of Agriculture (USDA) to vaccinate dairy cattle. H5N1-infected dairies have experienced mortality, significant milk production loss with limited recovery, and abortion storms in pregnant heifers.

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Medgene CTO, Alan Young explains, "We have been working with USDA-CVB who has been reviewing the data for our H5N1 vaccine for several months. We believe our most recent data will completely satisfy the standard for 'reasonable expectation of efficacy' and conditional license approval. Vaccines need to be made available quickly to animal owners and veterinarians who need them, so the partnership with Elanco helps to make sure our H5N1 vaccines for dairy cattle can be distributed without delay once the USDA makes a final decision to vaccinate."



Medgene has also just signed a **distribution agreement with Elanco Animal Health**, which includes "commercialization of a highly pathogenic avian influenza (HPAI) vaccine for use in dairy cattle."

According to Mark Luecke, CEO of Medgene:

With our critically important H5N1 vaccine for dairy cattle in the final stages of approval, we're excited to partner with Elanco to quickly bring this much needed solution to U.S. dairies.

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The Medgene H5N1 vaccine is a **protein-based subunit vaccine** developed using the company's "prescription platform technology". The production process involves a baculovirus expression system in insect cell culture, where only specific viral proteins, such as the hemagglutinin (HA) protein, are generated. The vaccine is created by inserting the H5N1 gene sequence into the platform vector, leading to the production of the target protein, which is then purified, inactivated, and combined with an adjuvant to enhance the immune response.

Mass vaccination of cattle against H5N1 using a non-sterilizing vaccine amid a widespread animal pandemic can lead to serious risks:

- **Accelerated Viral Evolution:** Non-sterilizing immunity allows the virus to replicate in vaccinated hosts, applying selective pressure that can lead to antigenic escape mutations.
- **Increased Risk of Zoonotic Spillover:** Mutations under immune pressure could enhance the virus's ability to bind human receptors, raising the risk of cross-species transmission and human infection.
- **Silent Reservoirs in Vaccinated Cattle:** Subclinical infections in vaccinated cattle could create undetected viral reservoirs, allowing the virus to mutate and circulate without obvious signs of illness.
- **Inadequate Testing of Rapidly Updated Vaccines:** The prescription platform technology enables quick adaptation of the vaccine, but there is a risk that insufficient testing could fail to catch safety or efficacy issues in new formulations.

For field testing of H5N1 livestock vaccines, the USDA Center for Veterinary Biologics has **stated**:

Studies that are limited to non-viable, non-replicating vaccines do not cause virus shedding. Vaccinated cattle will not transmit virus to other animals, milk, meat, people or into the environment. Therefore, these cattle and their products do not present a risk to human health and will stay in normal production.

In other words, meat and dairy products from cattle vaccinated with the Medgene H5N1 vaccine have likely already entered the food supply, as these cattle were included in the field testing phase.

In conclusion, approval of mass cattle vaccination against H5N1 using a non-sterilizing vaccine poses significant risks, including the potential for accelerated viral evolution, antigenic escape, and the creation of silent viral reservoirs in vaccinated cattle. Given these dangers, moving forward with a mass vaccination campaign could worsen the current outbreak, leading to more resilient and transmissible H5N1 strains.



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