



# UNITED STATES ANIMAL HEALTH ASSOCIATION

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**RESOLUTION NUMBER: 34 and 32 Combined      APPROVED**

**SOURCE:** COMMITTEE ON PUBLIC HEALTH AND RABIES  
COMMITTEE ON SHEEP AND GOATS

**SUBJECT MATTER:** Q-FEVER (*COXIELLA BURNETTI*) VACCINE FOR SHEEP AND GOATS AND FOR HUMANS IN THE UNITED STATES

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## **BACKGROUND INFORMATION:**

Q-Fever is a zoonotic disease caused by the bacterium *Coxiella burnetti*. *Coxiella* infection is found in many species in many countries of the world, including the United States. The disease is a major cause of abortion in sheep and goats, which results in significant economic losses to producers, but also results in significant risk of transmission to human beings. Exposure to the products of abortion (or raw milk products) either directly or through environmental contamination poses a significant public health risk, as demonstrated by the recent Q-fever epidemic (human and goat) in the Netherlands.

Currently there is no vaccine available in the United States to prevent *Coxiella burnetti* infection or abortion in sheep and goats. Such a vaccine is available in Europe. The availability/approval of a safe and effective sheep and goat vaccine for *Coxiella burnetti* in the United States would serve to safeguard human health and prevent production losses due to this potentially devastating disease. Humans not in direct contact with aborting animals also face some risk of indirect environmental exposure, so effective vaccination of sheep and goats could play a key role in minimizing human exposure. Additionally, the availability and approval of a safe and effective human vaccine would provide protection for those with occupational risk of exposure to *Coxiella burnetti*.

## **RESOLUTION:**

In priority order:

First, the United States Animal Health Association (USAHA) encourages the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to facilitate the licensure of a safe and effective Q-Fever (*Coxiella burnetti*) vaccine for sheep and goats.

Second, the USAHA encourages the Food and Drug Administration to facilitate the licensure of a safe and effective Q-Fever (*Coxiella burnetti*) vaccine for humans.

Third, the USAHA encourages USDA-APHIS-VS, Center for Veterinary Biologics to facilitate the importation, for investigation and research, of available animal Q-fever (*Coxiella burnetti*) vaccines from the European Union and Australia.



**INTERIM RESPONSE:**

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services appreciates your concerns about the availability of a vaccine for Q fever in the United States.

Our Center for Veterinary Biologics (CVB) has reviewed the public information report for Coxiella Burnetii Vaccine, known as Coxevac, published by the European Medicines Agency. The CVB believes the product profile developed by the manufacturer, Intervet, could adequately meet USDA standards for product potency, safety, and efficacy. Full USDA regulatory approval (i.e., a permit to import Coxevac "For Distribution and Sale" or a veterinary biologics license for a U.S. manufacturer) would require the following:

- Submission of product information for Coxevac (including a license or permit application as well as an outline of production and information supporting product purity, potency, safety, and efficacy) to the CVB from a U.S. licensee or permittee for official review and confirmation of the suitability of this information.
- CVB inspection and approval of Coxevac manufacturing facilities.
- Satisfactory CVB confirmatory testing of Coxevac Master Seed Stocks, Master Cell Stocks (if applicable), and a representative sample of the final product (vaccine) for testing purposes to ensure purity and potency.

The CVB would provide an expedited review and inspection of Coxevac to support efforts to control Q fever in the United States.

The public information report for Coxevac is available at [http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000155/vet\\_med\\_000219.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1c&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000155/vet_med_000219.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1c&jsenabled=true).