



# UNITED STATES ANIMAL HEALTH ASSOCIATION

2013 RESOLUTION

117<sup>TH</sup> ANNUAL MEETING

OCTOBER 17-23, 2013 ~ SAN DIEGO, CA

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**RESOLUTION NUMBER: 23 - APPROVED**

**SOURCE: 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 and 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:

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

In addition, the USAHA encourages the Food and Drug Administration to facilitate the licensure of a safe and effective Q-Fever vaccine for humans. The USAHA also encourages VS, Center for Veterinary Biologics to facilitate the importation, for



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investigation and research, of available animal Q-Fever vaccines from the European Union and Australia.

#### **INTERIM RESPONSE:**

In priority order:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association (USAHA) and appreciates the opportunity to respond. The Center for Veterinary Biologics (CVB) stands ready to expedite the review of a Q-Fever (*Coxiella burnetti*) vaccine once an application is received. The CVB has issued several import permits for diagnostics, but to date, an application has not been received to either import the vaccine or manufacture it in the United States. As regulators, the CVB does not solicit industry interest in the manufacture, import, or marketing of a Q-Fever vaccine. However, the CVB will prioritize any such inquiries or requests by the industry and facilitate the review process.

VS will extend the concerns of USAHA and this resolution to the U.S. Food and Drug Administration.

As with any such request to import an unlicensed vaccine for research, the CVB must be provided with adequate information on the source and manufacture of the vaccine to determine that the vaccine will not endanger U.S. livestock populations. As indicated above, the CVB has not received such a request and does not solicit industry interest in vaccine importation. CVB is committed to expediting the review and approval process for the import of a Q-Fever vaccine for investigation and research.