



## UNITED STATES ANIMAL HEALTH ASSOCIATION

### Resolution

114th Annual Meeting ~ November 11-17, 2010

Minneapolis, MN

**RESOLUTION NUMBER: 34 APPROVED AS AMENDED**

**SOURCE:** COMMITTEE ON BLUETONGUE AND RELATED ORBIVIRUSES

**SUBJECT MATTER:** REMOVAL OF RECENTLY ISOLATED BLUETONGUE VIRUS TYPES FROM THE SELECT AGENT LIST

#### **BACKGROUND INFORMATION:**

In the United States, bluetongue virus (BTV) serotypes 2, 10, 11, 13 and 17 have historically been considered to be endemic. Of these, BTV-2 is restricted to the southeastern United States, primarily Florida, whereas the others are more widespread and occur seasonally or year-round throughout much of the continental United States south of the so-called "sonorensis line." Since 1999, the National Veterinary Services Laboratory has identified 36 isolates of "non-endemic" or "previously exotic" BTVs from wild and domestic ruminants in the southeastern United States. At least one isolate has been obtained from samples taken in each of 6 southeastern states (Arkansas, Florida, Louisiana, Mississippi, Oklahoma, Texas); the majority have been identified in samples originating from Florida. A total of 10 previously unrecognized BTV serotypes have been identified to date (serotypes 1, 3, 5, 6, 9, 12, 14, 19, 22, 24). Of these, BTV-3 has been the most frequent and has now been found in 4 states; isolations of BTV-3 have been made in 7 of the past 12 years. BTV-1, BTV-12, and BTV-14 have also been isolated outside of Florida. None of these "previously exotic" BTVs has caused widespread disease outbreaks. The *Culicoides* spp. vectors responsible for transmission of these new virus serotypes are unknown.

It is important to note that these isolations have been made without comprehensive surveillance. The United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services select agent classification of any "non endemic" BTV serotype (i.e. other than serotypes 2, 10, 11, 13 and 17) restricts the ability of United States' diagnosticians and scientist to improve detection methods or to conduct epidemiological studies or undertake research on these BTV-types, despite the fact they are apparently now well-established and even widespread in a substantial portion of the country.

#### **RESOLUTION:**

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to remove ten serotypes of bluetongue virus (serotypes 1, 3, 5, 6, 9, 12, 14, 19, 22, and 24), formerly recognized as exotic that have been identified in the continental United States since 1999 and epidemiological evidence reported to this committee indicates that these viruses are now endemic in regions of the United States, from the USDA-APHIS-VS list of select agents.

#### **INTERIM RESPONSE:**

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) appreciates the interest of the United States Animal Health Association in removing 10 serotypes of bluetongue virus that are now endemic in the United States from VS' list of select agents. Agricultural select agents such as bluetongue are pathogens that pose a severe threat to animal or plant health. Exotic bluetongue is currently on the list of select agents as a VS-only agent.

The Agricultural Bioterrorism Protection Act of 2002 requires a biennial review of the lists of select agents and revision as necessary in accordance with the law. An internal VS select agent review committee comprised of seven scientific experts from USDA (APHIS, Agriculture Research Service, and the National Institute of Food and Agriculture) and one from the Department of Homeland Security developed a method to evaluate each agent to fulfill this requirement.

In addition, Executive Order (EO) 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," was signed in July 2010. This EO established a Federal Experts Security Advisory Panel (FESAP) from multiple Federal departments to provide recommendations to USDA on, among other things, reducing the number of agents on the select agent list. FESAP forwarded its recommendations to APHIS.

VS published an Advanced Notice of Proposed Rulemaking (ANPR) on July 29, 2010, to solicit public comments on changes to the list of select agents. We have received comments and evaluated them. Recommendations from the VS select agent review committee, FESAP, and ANPR comments are being reviewed and considered for publication. EO 13546 established timeframes for publishing regulatory changes. A proposed rule must be published no later than 15 months from the date of the EO (October 2011). VS encourages USAHA to submit comments regarding bluetongue when the proposed rule is published. A final rule is to be published no later than 27 months from the date of the EO (October 2012).

Removing an agent from the select agent list does not mean that it is no longer regulated. APHIS still regulates animal pathogens under title 9 of the *Code of Federal Regulations*, part 122 (Organisms and Vectors), and the Virus and Serum Toxin Act, which require permitting and laboratory inspection of animal pathogens that are imported or moved interstate.

#### **FINAL RESPONSE:**

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association (USAHA) and appreciates the opportunity to respond.

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