
RESOLUTION NUMBER: 4 APPROVED

SOURCE: COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY

SUBJECT MATTER: Reaffirmation of Commitment of the United States Department of Agriculture, Animal and Plant Health Inspection Service, Center for Veterinary Biologics to Continue Risk-based Policy Development

BACKGROUND INFORMATION:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB) is tasked with regulating the production, labeling, distribution, and usage of a large multitude of veterinary biologics used to protect animal and human health. USDA-APHIS-CVB's guiding principles must balance effective regulation of the industry to ensure products are pure, potent, safe, and efficacious, with making certain the regulations are accomplished using risk-based decision making to ensure availability of critical and needed products.

Newly proposed regulations and guidance documents from USDA-APHIS-CVB appear to be based on a hazard-based or "precautionary principle" approach rather than the stated "risk-based" approach, which has been the traditional position of the USDA. This can adversely affect the availability and cost of products which could, in turn, have severe effects on the health of animals and humans. The apparent lack of a risk-based approach is resulting in a potential situation of lack of production materials and, therefore, lack of vaccine availability.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB) to reaffirm their commitment to risk-based policy development and continue dialogue with industry throughout the policy development process.

INTERIM RESOLUTION

USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. CVB continues to affirm and apply a risk-based approach to decision-making and policy development. We plan to continue discussing regulatory developments with industry both at the spring trade association meetings (Animal Health Institute and Association of Biologics Companies), as well as on an as-needed basis with individual firms as appropriate.

FINAL RESOLUTION

The USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. CVB continues to affirm and apply a risk-based approach to decision-

making and policy development. We plan to continue discussing regulatory developments with industry both at the regularly scheduled trade association meetings (Animal Health Institute and Association of Veterinary Biologics Companies), as well as on an as-needed basis with individual firms as appropriate.