



RESOLUTION NUMBER: 15 **APPROVED**

SOURCE: **COMMITTEE ON Biologics and Biotechnology**

SUBJECT MATTER: **Categorical Exclusions from Environmental Assessments under the National Environmental Policy Act**

BACKGROUND INFORMATION:

Some of the veterinary biological products regulated by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) are required to undergo an environmental assessment under the USDA-APHIS National Environmental Policy Act implementing regulations. Such assessments typically take up to 18 months to complete. To date, all of the environmental assessments conducted on veterinary biologics have resulted in a Finding of No Significant Impact (FONSI). Because of the substantial experience with veterinary biologics, USDA-APHIS has been working since 2005 to amend their regulations to allow categorical exclusions, when appropriate, for veterinary biologic products. Such categorical exclusions are currently available for animal drugs regulated by the Food and Drug Administration. USDA-APHIS has created a draft proposed rule that was reviewed by the President's Council on Environmental Quality (CEQ). The CEQ responded to USDA-APHIS with process questions that were not specific to veterinary biologics. USDA-APHIS has currently been working on a response to CEQ for approximately three years.

Having the ability to grant categorical exclusions, where appropriate, would also allow USDA-APHIS to move more quickly to respond to outbreaks or emerging disease. For example, when the managers of the National Veterinary Stockpile desired to obtain vaccines for potential use to combat the recent outbreak of H5 avian influenza, rather than granting a categorical exclusion, USDA-APHIS had to conduct an environmental assessment that published in the Federal Register on October 7, 2015, despite USDA-APHIS having extensive experience with the technology. If such a rule were in place USDA-APHIS could have granted a categorical exclusion and moved more quickly.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) to expeditiously respond to the Council on Environmental Quality request for information regarding USDA-APHIS' implementation of the National Environmental Policy Act, and to propose and finalize a rule to amend 7 Code of Federal Regulations 21 § 372.5(c) to allow USDA-APHIS the ability to grant categorical exclusions for veterinary biologic products in appropriate cases.

INTERIM RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services shares the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. The proposed rule for revisions to APHIS' National Environmental Policy Act Implementing Procedures is being cleared by the Office of Management and Budget (OMB). During this time it will also be formally reviewed and cleared by the President's Council on Environmental Quality (CEQ). If CEQ has any additional questions or other issues with the proposed changes, APHIS will respond as quickly as

possible. After CEQ and OMB clear the proposed rule, it will be ready for publication in the *Federal Register*.