FDA U.S. FOOD & DRUG ADMINISTRATION

February 28, 2020

Dr. Martin A. Zaluski, President
United States Animal Health Association
4221 Mitchell Avenue
St. Joseph, Missouri 64507

Dear Dr. Zaluski:

Thank you for the letter dated December 9, 2019, sharing the United States Animal Health Association's (USAHA) Resolution 18, entitled, "Valid Sampling Methods and Protocols for Feed and Feed Inputs." You asked us to respond by March 1, so USAHA leadership could prepare for your next meeting in March, in Washington, DC.

> *Resolution 18: The United States Animal Health Association urges the Food and Drug Administration, Center for Veterinary Medicine and United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to work with the United States (US) pork industry to develop valid sampling methods and protocols to detect pathogens in foreign feed and feed inputs that can be applied at the point of embarkation to the US or upon arrival at the port of entry.*

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) is committed to working with the United States Department of Agriculture (USDA) and the pork industry to address concerns about pathogens in imported animal food (including complete feed, raw material, and other ingredients). We note that this engagement is already occurring through the Feed Risk Task Force, which includes representatives from government agencies, the pork and animal food industries, and academia.

FDA recognizes that appropriate sampling methods are critical to the validity and integrity of an animal food sampling strategy, particularly when dealing with a potential biological contaminant. However, in addition to sampling methodology, we believe there are a number of scientific and policy issues that require further consideration before any sampling strategy could be initiated. These include the application of sampling to both domestic and imported feeds, development and validation of pathogen detection methods, and data interpretation and response considerations. We believe that the discussions in the Feed Risk Task Force could build on existing sampling methods and protocols that currently address some of these issues.

FDA does have experience with sampling animal food and provides guidance to our field staff on techniques. FDA recommends the use of aseptic sampling when analysis for pathogens is intended, regardless of whether those pathogens are viral or bacterial, to avoid cross-contamination of the sample during collection, handling, or processing. The FDA has published a general procedure for aseptic sampling in the Investigations Operations Manual (IOM). See section 4.3.6 of the IOM at https://www.fda.gov/media/75243/download. The Association

of American Feed Control Officials (AAFCO)[1] has also addressed aseptic sampling in its Feed Inspector's Manual (https://www.aafco.org/Portals/0/SiteContent/Publications/AAFCO_Feed_Inspectors_Manual_7th_ed.pdf).

While not addressed in Resolution 18, we understand there are other topics of interest to USAHA that relate to responding to concerns about pathogens in imported animal food, particularly in relation to African Swine Fever (ASF). This includes the use of quantitative risk assessments to assess animal food as a mode of transmission and the development of food additive products to reduce potential ASF exposure risks.

Although FDA has provided input on such efforts, USDA has been leading the U.S. Government's efforts on risk assessment. We understand that USDA is working to finalize an assessment of the risk that non-animal origin feed ingredients present to ASF transmission. In regard to food additives, FDA is committed to fast-tracking the review of potential new food additives that may reduce the risk of ASF. We have engaged with companies that are interested in potential future reviews, but any information related to those meetings is considered confidential business information that cannot be shared at this time.

In conclusion, thank you for your letter and for providing us with the opportunity to comment on Resolution 18. We believe the existing Feed Risk Task Force will provide a good platform for continuing the collaboration to advance this discussion, building upon information currently available. We appreciate USAHA's interest in this important issue and would be happy to discuss this or other issues with the USAHA leadership during their visit to Washington, DC, in March 2020.

Sincerely,

William T. Flynn, DVM, MS
Deputy Director for Science Policy
Center for Veterinary Medicine

[1] AAFCO is a voluntary membership association of local, state, and federal agencies that regulate the sale and distribution of animal food. FDA works closely with AAFCO in the development of its model regulations and guidance.