Proceedings of the AAFCO Novel Ingredient Regulatory Task Force (NIRFTF)

Background:
The sale and distribution of all ingredients fed to animals is regulated by the individual States. AAFCO is composed of representatives from every state. In and of itself it has no regulatory powers. It does however, "define" ingredients through an often lengthy process in which FDA participates. Historically, AAFCO will not define an ingredient to which FDA has objections. "Defined" ingredients are published in the annual AAFCO Official Publication. State regulators rely heavily, and often exclusively, on this publication and will often Stop Sale on a product containing an ingredient for which there is no Definition. In recent years there has been a flood in the market place of new ingredients (many of them "nutraceuticals"), most of which have not been submitted to AAFCO for definition. AAFCO, FDA and the states are feeling overwhelmed by this new tide of ingredients and science.

Two years ago the AAFCO Board of Directors created the temporary Nutraceutical Regulatory Advisory Panel (NRAP), with the charge to study the current regulatory situation as it relates to "nutraceutical" ingredients, get input from interested parties, and make recommendations to the AAFCO board for improvement.

Following the final report of NRAP, the AAFCO board created NIRFTF, (the Novel Ingredients Regulatory Framework Task Force) to develop a regulatory framework to guide the board on how to evaluate and regulate so-called "novel" ingredients in animal feeds. Traditionally, AAFCO has required that all "new" ingredients proposed for animal feeds and supplements be submitted to AAFCO for consideration by an AAFCO investigator, the AAFCO Ingredient Definition Committee, and FDA (hereafter referred to as "the IDC process"). There is a growing sense in AAFCO and FDA that so many new ingredients have come to market without going through the IDC process that a special process may be needed for everyone to "catch up".

It's important to understand that, unlike the Herbs and Botanicals Committee, the NIRFTF is not supposed to define or approve "new" ingredients. Instead, NIRFTF is supposed to recommend possible temporary "fixes", a regulatory framework, that will

expedite review of "novel" ingredients now in the market, as well as possible changes to the standard IDC process, consideration of structure/function claims, etc., etc., for the future.

To date the Task Force has met twice, in December in Maryland, and January in Phoenix, Arizona during the annual winter AAFCO meeting. The Task Force consists of AAFCO members, FDA representatives, and industry liaisons from the major trade associations involved in the feed industry. The equine supplement industry is represented through NAESM. Without NAESM, the equine supplement industry would have little or no voice in this process. Jamie Brooks and Susan Domizi have attended for NAESM.

Most of the high points covered in the first meeting are well-described in the official document ("Progress Report to the AAFCO Board, etc."). Progress will be slow, in part due to the number and complexity of issues at hand, in part because of limited opportunities to hold meetings and the traditionally "deliberate" nature of AAFCO proceedings.

However, some important and positive signs can already be noted:

- Dr. Benz of FDA observed that there are several unapproved ingredients that have fairly long track records of safety in the market, citing chondroitin sulfate as an example of an ingredient that FDA would probably not object to, assuming acceptable data for history of use and safety is submitted.

- Dr. Benz suggested that a list of ingredients be submitted by industry for consideration for temporary approval in the AAFCO Official Publication. Industry would then have five years to get these ingredients approved through the IDC process. The general understanding is that these ingredients will have an established record of safety in the market or through research.

Disagreement about food safety standards for equine ingredients is being resolved. Horses are technically classified as food-producing animals, because U.S. horse meat is exported for human food use. Concerns about "fast-tracking" temporary approval of ingredients for equine feeds and supplements centered on potential threats to human food safety.
Some felt that even if the ingredients are considered safe for human consumption, they

may produce toxic metabolites in animals that could then end up in the human food supply. Some members, including industry reps, felt that only companion animals, i.e. dogs and cats, should be considered in the task force's initial work, leaving the more complex issues of ingredients for horses and other food-producing animals for later.

We believe we were successful in keeping horses included, and were supported with information provided by the FDA. Dr. Benz reported that when FDA/CVM reviews a New Animal Drug application for horses, it does not consider issues of human food safety unless it has strong reason to believe the drug will also see off-label use in livestock. The label message, "Not for use in horses intended for food" is typically all that is required by FDA to meet food safety concerns about equine drugs.

Since it makes no sense to apply more rigorous food safety standards to equine feed ingredients than FDA applies to equine drugs, the consensus now seems to be that the task force will consider horses with "companion animals," possibly with required labels for some or all "temporarily approved" ingredients carry the message, "Not for use in animals (or “horses”) intended for food."

NIRFTF Members:
Voting members: State feed regulators (AAFCO members): Teresa Crenshaw (chair, DE), Eli Miller (KY), John Breitsman (PA), Paul Bachman (MN), and Shannon Jordre (SD).

Liaison: Dr. Sharon Benz (FDA/CVM), AnneMarie Brown (FDA/CVM), and representatives of several feed and pet industry trade organizations, including: American Feed Industry Association (AFIA), Pet Food Institute (PFI), Enzyme Technical Association (ETA), American Veterinary Medical Association (AVMA), National Grain and Feed Association (NGFA), Canadian Food Inspection Agency (CFIA), American Pet Products Manufacturers (APPM), and the National Association of Equine Supplement Manufacturers (NAESM).