

AAFCO ENFORCEMENT STRATEGY FOR MARKETED INGREDIENTS (ESMI) WORKING GROUP

Why the ESMI Working Group was Formed

In December 2000, the Association of American Feed Control Officials (AAFCO) Board of Directors formed the Enforcement Strategy for Marketed Ingredients (ESMI) Working Group to provide regulatory guidance to the states to deal with ingredients found in animal feed. The ESMI Working Group was not given the charge to draft new or amended model feed laws or regulations, but rather to assist the states to more effectively enforce their existing laws pertaining to feed ingredients. This article is intended to provide a background of the events that led to the formation of the ESMI Working Group and an explanation of what this group is charged to do.

The Effects of DSHEA

The entire dietary supplement market changed when the Dietary Supplement Health and Education Act (DSHEA) was passed by Congress in 1994. This law provides for the sale of dietary supplements such as the various herbal and botanical products available for human consumption. Many of these human dietary supplements are also being marketed for feeding to animals, including pets, horses, and livestock. In 1996, FDA published a notice in the Federal Register that explained why it believed that DSHEA does not apply to animals. As a result, some of the ingredients currently sold as human dietary supplements are not accepted or recognized for use in animal feed. FDA is concerned about the safety of these ingredients to animals and to humans who consume animal products as food. A primary concern is the potential for harmful residues in human food as a result of feeding these ingredients to food-producing animals.

As more and more of these ingredients appeared in the feed/food of companion and food-producing animals, state feed control officials expressed concern as to how to regulate ingredients that are not accepted or recognized for use in animal feed. Many of these ingredients are promoted for medicinal or therapeutic purposes and not for traditional nutritional purposes. Because of the growing regulatory concerns, the AAFCO Feed Labeling Committee formed a subcommittee on Nutritional Health Claims and Nutrient Functional Claims in 1998. Chaired by Dr. Clarence Ammerman, this group met to discuss concerns and gather information about these ingredients, typically known at the time as "nutraceuticals." Although much information was shared, the regulatory issues remained unresolved.

NRAP

The AAFCO Board of Directors responded to these regulatory concerns by forming an advisory group called the Nutraceutical Regulatory Advisory Panel (NRAP) that consisted of members from academia, AAFCO, and FDA-CVM. After an extensive review of public comment about nutraceuticals, the NRAP submitted its final report to the AAFCO Board of Directors for the 1999 AAFCO Annual Meeting. This report contained several consideration points, the highlights of some of which were:

- The term "nutrient" should be reviewed and considered for a broader definition than only *essential nutrients*. The report suggested that the term should include *various types of orally ingested substances that provide natural components of the body and/or offers nutrients that affect the physiological well being of the animal*.
- A distinction should be made for food-producing animals and companion animals. Unsure as to how horses would be classified, horse products could bear the disclaimer statement, "Do not administer to horses intended for use as food."
- A new standing committee for botanicals and herbs should be created.
- AAFCO investigators should review current official definitions for their appropriateness as a source of a nutraceutical ingredient(s).
- Non-drug structure-function claims should be considered provided that they apply to normal components of the body. These claims would result in the need for a disclaimer, i.e. "essentiality of this nutrient has not been established or recognized."
- The NRAP document would serve as the interim regulatory framework.

Novel Ingredients Regulatory Framework Task Force

The AAFCO Board of Directors did not accept the NRAP report as a regulatory framework because it simply was not a regulatory document. As a result, the AAFCO Board of Directors appointed the Novel Ingredients Regulatory Framework Task Force (NIRFTF) to develop a regulatory framework for the uniform regulation of these ingredients.

The NIRFTF membership was composed of seven AAFCO members, two FDA-CVM officials, two representatives from the American Veterinary Medical Association, and twelve members representing each major national feed industry association. The industry associations included the Pet Food Institute, the American Feed Industry Association, the National Grain & Feed Association, the Enzyme Technology Association, and the National Association of Equine Supplement Manufacturers.

NIRFTF Issues

The NIRFTF held their first meeting in December 1999, and several issues were identified for discussion. Some of these issues were:

- ◆ The implications of DSHEA for animal feeds;
- ◆ The role of the FDA and feed regulatory agencies;
- ◆ Companion animals versus food-producing animals;
- ◆ Structure/function claims;
- ◆ The AAFCO ingredient definition approval process;
- ◆ The lack of analytical methodology;
- ◆ Proprietary research data;
- ◆ The definition of "feed," specifically the term "nutrient"; and
- ◆ Botanicals and herbs.

NIRFTF Regulatory Framework

With such a large membership, it could have been very difficult for the group to reach any kind of an agreement, but the group worked together surprisingly well. The framework concept focused on a plan that certain ingredients, if they met seven safety criteria, could continue to be marketed for a five-year period while pursuing an official AAFCO definition. These ingredients would be placed on a list that would be recommended to the AAFCO membership for temporary recognition for use in animal feed. Ingredients that did not meet the established criteria could not be marketed without meeting one of the recognized processes for inclusion in feed.

The criteria was intended as a temporary plan for the control officials to gain control of the large number of animal products entering the marketplace, primarily as a result of DSHEA and what was happening in the human supplement market. The plan was also a message to industry as to the procedures that they would have to follow to market these ingredients for animals.

Investigator's Role

The next fundamental part of the framework document was the investigator's role to monitor the progress of the manufacturers in obtaining AAFCO definitions for the ingredients on the list. A manufacturer who was not working with an investigator within the guidelines of the AAFCO Ingredient Definition Committee (IDC) would not be allowed to keep the ingredient on the list. If an ingredient was not on the list, it would not be recommended to the states for temporary recognition.

To monitor the ingredient's progress or lack of progress through the IDC process, a NIRFTF subcommittee was formed to prepare an Investigator's Guidance Document. It was during this "nuts and bolts" review of the proposed regulatory framework to identify the investigator's role that the entire plan collapsed. During the process of defining the investigator's role, it became clear that the regulatory framework plan would require that AAFCO accept and recommend a process that was in conflict with the existing, time-proven procedure for reviewing ingredients for use in animal feed.

Other Concerns

There were other concerns as well:

1. Manufacturers could use the plan as a five-year "free ride" to market their ingredients with no intention of following through with an approved definition.
2. Industry refused to compromise in their desire to make structure-function claims, even though this issue was unresolved.
3. One industry liaison group had concerns that unapproved, undefined ingredients could be marketed. The NIRFTF plan could be a serious detriment to food safety.
4. A legal review by one state's general counsel questioned why AAFCO would consider such a plan that worked outside the established ingredient review process. The review indicated that the regulatory framework was in conflict with the AAFCO's Regulatory Philosophy, in that AAFCO did not have the authority to make such a recommendation to its members.

Only FDA or individual state regulatory programs have the authority to recognize feed ingredients that do not meet the other processes for use in animal feed. In addition, AAFCO could be held liable for recommending ingredients that were not accepted or recognized for use in animal feed.

Under these circumstances, the AAFCO Board of rejected the proposed regulatory framework plan and disbanded the NIRFTF.

ESMI Working Group

With these issues still unresolved, the Board formed a group to utilize current federal and state law and regulations in developing an enforcement strategy for unrecognized, undefined animal feed ingredients, as well as accepted ingredients that were being marketed for unapproved uses. This group, the ESMI Working Group, formed by AAFCO Board of Directors in December 2000, included all of the AAFCO and FDA members from the NIRFTF membership, plus two additional members: the Chairman of the Botanicals and Herbs Committee; and a member of the AAFCO Board of Directors. At this time, industry liaison members were not assigned to the ESMI Working Group.

At the first meeting of the ESMI Working Group, the AAFCO members responded that the states needed to work together to uniformly regulate these ingredients and that an educational component to the enforcement strategy was very important. To obtain more information, a survey was distributed to all state feed control officials. The survey results provided the ESMI Working Group with what enforcement guidance the states needed to address the marketing of ingredients that were not accepted or recognized for use as animal feed. The survey results also provided the ESMI Working Group with the guidance it needed to develop a uniform enforcement strategy.

AAFCO Recommended Enforcement Strategy

The ESMI Working Group proceeded to develop a plan that worked with the existing regulatory requirements, called the ***AAFCO Recommended Enforcement Strategy for Unapproved Ingredients and Ingredients with Unapproved Claims***. An explanation of the plan can be found on the AAFCO Website at www.aafco.org.

One of the most important aspects of the Enforcement Strategy is education. Informational documents will be developed and made available to state feed control officials, the feed industry, and to the consumer, so that each will clearly understand the regulatory requirements for the distribution of animal feeds and ingredients. These educational documents will be made available on the AAFCO website.

Although the Enforcement Strategy is not yet complete, the first step identified by the ESMI Working Group is to identify unapproved animal feed ingredients that pose known safety concerns to animal and/or human health. This information will be made available to the AAFCO members with a recommendation that these products be subject to regulatory action, using the legal authority granted under each state's feed law.

Summary

The AAFCO Board of Directors formed the ESMI Working Group to provide guidance to the states in regulating animal feeds and feed ingredients. With the adoption of DSHEA, many dietary supplements for human consumption are being marketed for animals. Since DSHEA does not apply to animals, some of these ingredients may not be accepted or recognized for animals, and some feed ingredients that are accepted are being marketed for unapproved uses.

The existing processes for reviewing and defining feed ingredients are proven to be sound. The ESMI Working Group was not charged by the AAFCO Board of Directors to develop a new regulatory strategy for accepting or recognizing feed ingredients. Instead, the ESMI Working Group was charged to provide assistance to the states to effectively administer existing feed laws. Every attempt will be made to ensure that feed control officials, feed manufacturers, and consumers understand the laws and regulations that apply to animal feeds and feed ingredients. By following these procedures that have been in place for many years, we can safeguard the health of man and animals, provide consumer protection and create a structure for orderly commerce.