

## **ESMI BLITZ - Questions and Answers**

- Q. How is animal feed regulated in the United States?**
- A. In the U.S., animal feed is regulated at both the federal level by the US Food and Drug Administration (USFDA) and by individual states, typically through their Departments of Agriculture.
- Q. What is the purpose of these federal and state animal feed regulations?**
- A. In regulating animal feed, federal and state feed officials strive to:
- 1.) Safeguard the health of man and animals;
  - 2.) Provide protection for the consumer as well as the feed industry; and
  - 3.) Provide a structure for orderly commerce.
- Q. What is AAFCO?**
- A. The Association of American Feed Control Officials (AAFCO) is an association of federal and state regulatory officials that provides a forum to deliberate and discuss issues affecting the sale and distribution of animal feeds and feed ingredients.
- Q. What is AAFCO's role in regulating animal feeds and feed ingredients?**
- A. AAFCO is not involved in feed regulation directly. Rather, AAFCO develops model laws and regulations, uniform feed ingredient definitions, and appropriate labeling requirements to ensure the safe use of animal feeds and feed ingredients.
- Q. Why was the ESMI Working Group formed?**
- A. AAFCO formed the Enforcement Strategy for Marketed Ingredients (ESMI) Working Group to provide regulatory guidance to State Feed Control Officials on how to deal with the use of ingredients that are not accepted or recognized for use in commercial animal feeds (including pet food) and recognized ingredients with unapproved uses already in the marketplace.
- Q. Does the ESMI Working Group intend to change the way feeds and feed ingredients are regulated?**
- A. No, the ESMI Working Group will not write new feed laws or revise existing feed laws. ESMI will provide informational and regulatory tools to assist states in more effectively enforcing their existing laws pertaining to feeds and feed ingredients.

**Q. What is The Dietary Supplement, Health and Education Act (DSHEA)?**

A. DSHEA defines what is considered a dietary supplement, such as the various herbal and botanical products, and permits their sale for human consumption without pre-market approval by the FDA.

**Q. Does The Dietary Supplement, Health and Education Act (DSHEA) apply to animal feeds and feed ingredients?**

A. No, the FDA published a notice in the Federal Register in 1996 explaining why it believed that DSHEA does not apply to animals.

**Q. May all supplements intended for human consumption be used in animal feeding?**

A. No, some of the substances allowed for sale as human dietary supplements contain ingredients that are not accepted or recognized for animal use

**Q. Why are some supplements that are approved for human use not accepted or recognized for use in animal feeding**

A. Some ingredients marketed as human supplements have not undergone any assessment regarding their safety or usefulness in animal feeding. As a result, there are concerns about the safety of some of these ingredients to both the animals and to the humans who consume animal products as food. One of the primary concerns is that there is no evidence that substances fed to food-producing animals do not leave harmful residues in human food.

**Q. Is AAFCO proposing to remove products and ingredients from the market?**

A. No, AAFCO has no regulatory authority. AAFCO will be providing educational information to the regulated industry and the general public concerning the status of ingredients that are not accepted or recognized for use in commercial animal feed and recognized ingredients that are being used for other than their accepted purpose. AAFCO will also provide the State Feed Control Officials with informational and regulatory tools to conduct a uniform enforcement strategy. AAFCO is encouraging the manufacturers and suppliers of these ingredients to comply with the existing laws and regulations.

**Q. Will State Feed Regulatory Programs remove products and ingredients from the market that I may find beneficial for my animals?**

A. Withdrawal from distribution is one of many regulatory tools that feed regulators have to address violations of existing laws and regulations. This tool is recommended when the health, safety or the environment would be put at risk from the distribution of a feed or feed ingredient or when other tools have failed to achieve compliance for serious administrative violations or gross labeling violations. Other regulatory tools may be utilized to encourage the manufacturers and suppliers to gain the necessary acceptance

and recognition for these ingredients. There are growing concerns regarding the sale of ingredients that have not been accepted or recognized for use in animals. These concerns related to consumer protection, protection of animal health, and food safety. While the primary concern is food safety, feed regulation is about more than just food safety. Feed must also be safe for the animals they are intended for. To establish a lower standard of compliance and safety for companion animals (pets) would be unwise and would not serve the public interest. Therefore, feed laws and regulations make no distinction between feeds approved for food-producing animals and for pets.

**Q. How will these ingredients that have not been accepted or recognized for use in animals be targeted?**

A. State feed regulatory programs, with the informational and regulatory tools provided by AAFCO and guidance from the USFDA, will participate in a uniform enforcement strategy, starting this summer/fall, which will target specific ingredients (that have not been accepted or recognized for use in animals) and their distribution through all channels of commerce, including catalogs and via the Internet. An ingredient or ingredients will be identified that pose human or animal health issues or both. The feed industry and the public will be notified of the selected ingredient(s) ninety days prior to any recommended enforcement action.

**Q. Some of these unaccepted ingredients have a history of many years of safe use. Why is AAFCO taking action against these ingredients now?**

A. There are concerns about the increasing number of ingredients marketed as dietary supplements for the prevention or treatment of disease. Although some of the ingredients may have “a history of safe use,” this does not include a history of safe use in animals. Animals may react very differently to substances than people, and even small doses may cause adverse effects or leave residues in human food. For example, aspirin and chocolate, are both substances used by people every day without ill effect and can be toxic to pets and even cause death.

**Q. Some of these unaccepted ingredients are sold as safe and natural remedies. Do they work?**

A. While the promise of a “safe” and “natural” remedy for disease is very appealing; these ingredients have not undergone the same testing for safety and efficacy that is required for approved drugs and it is not known whether these products work or if they are safe.

**Q. How do ingredients get accepted for use in animal feeding?**

A. Detailed information about current ingredient assessment and acceptance procedures are provided in the document entitled, “Options Available for Acceptance of a Proposed Feed Ingredient” that can be found on the AAFCO web site ([www.aafo.org](http://www.aafo.org))