Attachment 2

Options Available for Acceptance of a Proposed Feed Ingredient

There has been a great deal of interest the last few years in using "novel ingredients", sometimes called nutraceuticals or dietary supplements, in feeds for all types of animals. One problem involved in using these ingredients is that very few of them have undergone any of the evaluation processes normally used for feed ingredients (AAFCO ingredient definition, general recognition of safety (GRAS), food additive approval, etc.). Because there is a great deal of interest in securing acceptance to use some of these products in feeds, it was thought that it would be helpful to develop a fact sheet explaining the different types of processes available for approving, defining or recognizing proposed feed ingredients. Below are listed a number of options to have a new ingredient accepted for feed use:

AAFCO Ingredient Definition—This process is described in the AAFCO Official Publication (p.225 in the 2001 publication). The ingredient sponsor works with the AAFCO Investigator to submit a package of information about a proposed ingredient to the Food & Drug Administration (FDA) for review. The review principally establishes the safety of the product, usually for a specific use. Product effectiveness for the proposed use and manufacturing chemistry are also addressed. Upon favorable completion of the review, FDA often issues a "regulatory discretion letter", saying that FDA does not anticipate taking regulatory action against that ingredient in feed as long as safety problems do not develop and use of the ingredient stays within the limits established in the AAFCO ingredient definition.

Food Additive Petition—This process is described in the Code of Federal Regulations (CFR), 21 CFR 571. Food additives currently permitted by FDA in the food or drinking water of animals are listed in 21 CFR 573. These ingredients may only be used within the scope of the applicable regulation. Most, but not all, of these additives are listed in the Official Publication in section 87, Special Purpose Products.

General Recognition of Safety (GRAS)—A substance can be generally recognized as safe for a specific use in feed if there is consensus about its safety for that use among experts who are qualified by scientific training and experience to evaluate the ingredient. An ingredient cannot be GRAS for any and all uses, but is GRAS only for the use specifically identified in the GRAS determination. A GRAS determination consists of two parts, safety and common knowledge. The safety determination, which is done by qualified experts, can be based on 1) scientific procedures, i.e., the same quantity and quality of data/information needed to gain approval of a food additive petition or 2) common use of the ingredient in feed prior to 1958. The second part of a GRAS determination involves the general recognition element, i.e.; there is common knowledge about the ingredient in the scientific community knowledgeable about substances added to feed. The common knowledge elements require that the information used as the basis of a GRAS determination be in the public domain, i.e. is published. A GRAS determination cannot be solely based on private or proprietary information/data.

> **FDA Affirmation**—Formal processes established by FDA to determine GRAS status are described in 21 CFR 570.30 and 21 CFR 570.35(b)(1). Substances currently affirmed as GRAS by FDA for use in animal feed are listed in 21 CFR 582. These substances are considered GRAS only for the purpose under which they are listed, and only at a usage level that provides the stated effect.
>
> **Self-Affirmation**—Groups other than FDA, also may make a GRAS determination. However, the basis of the organization's determination must be as described above, i.e., the burden for a GRAS determination is the same regardless of who does the affirmation.

Common or Usual Name—Some ingredients are so commonly used in feed and are ordinarily understood, that they do not require a definition, as is provided by Regulation 6(a) of the AAFCO Model Regulations. Salt, sugar, water, corn, oats and barley are good examples of ingredients, which are described by common and usual names. Materials that are uncommon or not well understood by individuals involved in animal feeding, may not meet this common knowledge threshold.

Approved by the Secretary of Agriculture—If a state has adopted Regulation 6(a) of the AAFCO Model Regulations, the Secretary or Commissioner of Agriculture in that state has the authority to approve feed ingredients and their names. This regulation permits state authorities to allow the use of products available locally that are suitable for use in feeds.

New Animal Drug Application (NADA)—This process is described in 21 CFR 514. A drug that is the subject of an approved new animal drug application can be used in feed only within the boundaries established by its NADA.

Other possibilities—There are several other possible options for recognizing the use of a substance as a feed ingredient, including: pesticides approved by EPA for use in feed, biologic products approved by USDA, color additives approved by FDA (CFSAN) for use in feed, and bioengineered plants.

In most cases, once an ingredient obtains some type of acceptance (food additive approval, GRAS determination, "regulatory discretion letter", for example) AAFCO tries to establish a definition for placement in the AAFCO Official Publication as soon as possible. Publishing a definition serves to advise the industry and its customers that an ingredient is available for use, and to advise control officials that an ingredient is acceptable for feed.

Due to meeting schedules and publication lag time, an ingredient that is the subject of a "regulatory discretion letter", Federal Register notice or CFR listing (in the case of approved food additives and NADAs, GRAS affirmations, etc.), may not be listed in the Official Publication for as long as two years after FDA has allowed its use. Control officials and industry personnel need to be aware of this possible time lag. Ingredient sponsors may need to be able to provide a copy of the letter from FDA, a CFR citation, or other reference material to support the use of their ingredient. Control officials should remember that they can ask for this information from the manufacturer or users of the ingredient.

An ingredient or product containing an ingredient, when that ingredient or its use is not recognized through any of the processes listed above may be subject to regulatory action.