So You Want a New Feed Ingredient Definition?

Sponsored by the AAFCO Ingredient Definitions Committee

AAFCO Mid-Year Meeting

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Why are we holding this workshop?

- The "New and Modified Ingredient Definitions: A Guide" (2004 Official Publication, p.247) needs updating & we want your input.
- Quality of submissions received varies widely. Submissions missing information take longer to review and arrive at decision.
- We want to share some ideas on how to improve the quality of the submissions.

Options for recognition or approval of new feed ingredients in the US

- There are a number of options available to get a new substance approved or recognized for use as a feed ingredient in the United States
- Today we will emphasize the AAFCO Ingredient Definition Process

Food Additive Petition

- Process described in Code of Federal Regulations (CFR), 21 CFR 571.
- Food additives currently approved in animal food or drinking water listed in 21 CFR 573.
- Ingredients only used within scope of the applicable regulation.
- Most of these additives are listed in section 87 of the Official Publication, Special Purpose Products.

General Recognition of Safety (GRAS)

- GRAS for a specific use in feed if there is consensus about its safety for that use among experts
- An ingredient is usually only GRAS for the use identified in the determination, not for any and all uses
- A GRAS determination consists of two parts, safety and common knowledge.

Common or Usual Name

- Some ingredients so commonly used in feed they do not require a definition
- AAFCO Model Regulation 6(a) allows this
- Salt, sugar, water, corn & oats are examples
- Materials that are uncommon or not well understood by animal feeding experts may not meet this common knowledge threshold.

Approved by the Secretary or Commissioner

- AAFCO Model Regulation 6(a) allows state Secretary or Commissioner of Ag to approve ingredients & their names.
- Allows use of products available locally that are suitable for use in feeds.
- Intrastate commerce only.

Other options for recognizing the use of a substance in animal feed

- New animal drug approved for feed use
- Pesticides approved by EPA for use in feed
- Biologic products approved by USDA
- Color additives approved by FDA (CFSAN) for use in feed (21 CFR 70)
- Bioengineered plants. (Federal Register, V. 57, No. 104, May 29, 1992, p. 22984-23001)

AAFCO Ingredient Definition Process

- Process described in the AAFCO Official Publication (p.247 in the 2004 OP)
- Sponsor works with AAFCO Investigator
- Looks at safety & utility of product, usually for specific use
- Review manufacturing chemistry & analytical methods

Regulatory discretion

The use of regulatory discretion to allow specific products to be marketed is done to conserve agency, state and industry resources, without jeopardizing human or animal health or subjecting the consumer to fraud. If a problem is found with a product, which is allowed on the market under regulatory discretion, the product can quickly be removed from the marketplace.

What This Means

- There are a number of methods to get a new ingredient approved or defined for use in animal feed.
- Each method has advantages & disadvantages.
- Nature of the proposed ingredient may dictate the method chosen.

Our Speakers Today Are

- Karen Ekelman--safety assessment
- Mika Alewynse—nutritional utility
- Dennis McCurdy--utility for technical effect, manufacturing chemistry and analytical methods
- Sharon Benz—submitting the proposal

Thanks for your interest!

- We hope you gathered some good information from this workshop
- Let us know if you have questions or comments on the workshop, and/or if you would like to make comments on revision to "The Guide...".

Please send comments to:

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