

Options for Including Ingredients in the Official Publication



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What is Food (Feed)?



- Federal Food, Drug and Cosmetic Act states
 - articles used for food or drink for man or other animals including components of such articles
- Includes grains, vegetable meals, minerals, vitamins, anticaking agents, processing aids, antioxidants, etc.

How can I get a new substance approved or recognized for use in feed?

- Approval at the state level by Secretary or Commissioner – Regulation 6(a) of the AAFCO Model Regulations for local use ingredients
- AAFCO Ingredient Definition Process
 - For FDA, the AAFCO ingredient definition process is a use of our enforcement discretion
- Food Additive Petition - 21 CFR 573
- New Animal Drug Application – 21 CFR 514
- Color Additive Petition – 21 CFR 71
- Bioengineered plants – May 29, 1992 FR consultation process with FDA
- Eventually- GRAS notification
 - CVM developing its notification program

Which process do I use?

- Depends on the substance and intended use
 - Substances regulated as drugs
 - For diagnosis, cure, mitigation, treatment or prevention of disease,
 - To affect the structure or function of the animal other than by providing nutrition, taste, or aroma,
 - To improve animal productivity, such as growth rate, milk production, carcass leanness
- New Animal Drug Application

Which process do I use?

- Substances regulated as foods
 - Provides aroma, taste, or nutritive value to the animal
 - Affects the characteristics of the food
 - May indirectly become a component of food thru processing, packaging, etc
- Food additive petition, GRAS notification, Bioengineered plant consultation, AAFCO Ingredient Definition (FDA enforcement discretion)

Food Additive Petition Requirements

- Identity/ manufacturing process
- Proposed use, amount, labeling
- Utility data
- Analytical methods
- Safety
 - Human
 - Animal
 - Environment
- Proposed tolerances for residues
- Regulation

Food Additive Formalities

- There are established timelines for process milestones
- Federal Register publications at the start and conclusion of the cycle
- Procedures & data requirements spelled out in the regulation
- Results in a food additive regulation if approved
- Review of FAPs takes precedence over informal projects (such as AAFCO Ingredient Definition submissions)

AAFCO Ingredient Definition Process

- Process described in the AAFCO Official Publication (p.318 in the 2009 publication)
- More information available on the AAFCO website at: <http://www.aafco.org/AAFCONewsInformation/IDCIngredientDefinitionsCommittee/tabid/166/Default.aspx>
- Ingredient sponsor works with the AAFCO Investigator to submit a package of information about a proposed ingredient to FDA for review
- Submission should include information on safety, manufacturing and ingredient specifications, analytical methodology, safety, and utility

What Information is required for an AAFCO Ingredient Definition?

- Contact
- Proposed definition
- Description/ purpose of the ingredient
 - rationale for request
- Manufacturing chemistry
- Use limitations
- Literature information
- Feeding trials/ controlled observations
- Adverse effects/ contaminants

FDA Review

- Reviews the information in the submission – initial focus is safety
- Submission should include a complete discussion with references on the toxicity, carcinogenicity, mutagenicity, chronic effects, and dermal effects of the substance that demonstrate safety for the intended use

FDA Review

- Review also conducted to determine
 - If the product serves its intended purpose i.e. utility of a product, usually for a specific use
 - If the manufacturing chemistry is clearly identified, can be manufactured consistently, process is under control, and is stable under conditions of use
 - Analytical methods are acceptable

FDA Review

- Upon completion of a favorable review of a request for an AAFCO definition, FDA often issues a letter saying that FDA does not anticipate taking enforcement action against that ingredient when used in feed as long as safety problems do not develop and use of the ingredient stays within the limits established in the letter, which are usually adopted into the AAFCO ingredient definition
- Once FDA issues an enforcement discretion letter, that feed ingredient is available for use

How does a new term get into the Official Publication?

- Not all materials reviewed will necessarily be published in the OP
- Doesn't really matter which current process is used to review the new ingredient
- Once review is completed the item will get forwarded to the IDC, and placed on the agenda for the next meeting

Once on the IDC agenda....

- The ingredient proposal will be heard by the committee in an open meeting
- If IDC votes favorably, it is forwarded to the AAFCO Board in the annual committee report
- If Board supports it, it will be recommended to the Association Membership
- Membership will vote at the Annual Meeting
- If affirmed by the AAFCO members, it will be published in the next edition of the OP

When May the Ingredient Be Used?

- If FDA does the review, the new ingredient is available for use once the Food Additive regulation publishes, or enforcement discretion letter is issued, for example
- For States that have adopted the model bill, once the members vote at the annual meeting
- The OP is only published once/year so it is not necessary to wait to see the ingredient in the OP before using it (although there may be a few states who's law requires this)



Next?

- Geoff Wong will explain what GRAS means and how our GRAS notification process will work
- Mika Alewynse will compare and contrast some of the different methods, and provide some examples