



Putting It All Together

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Definition Process

- Described in the AAFCO Official Publication (p.222 in the 2003 publication).
- Ingredient sponsor works with the AAFCO Investigator to submit information for FDA review about a proposed ingredient or to modify an existing definition.

Role of AAFCO Investigators

- Assist in developing feed definitions that are just and equitable
- Assure production, sale and use of ingredients will result in safe feeds
- Assure definitions are non-proprietary

Advisable to consult the appropriate AAFCO Investigator early in the process

Role of FDA

- FDA Review confirms
 - there are no safety issues.
 - establishes the utility of a product, usually for a specific use.
 - manufacturing process is under control and analytical methods are acceptable.

Role of FDA

- 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.

Components of the Submission

- Firm and contact person
- Proposed definition
- Rationale for the request – history, other uses (including CFR)
- Manufacturing including processes, specifications, stability, analytical methods
- Contaminants- known and potential

Components of the Submission cont'd

- Utility information: Nutritional effects in animals or technical effects in feed, including
 - purpose of ingredient
 - intended animal class
 - typical/proposed use levels
 - maximum use level
 - supporting data, including copies of literature
- Safety/toxicity – all relevant information
- Use limitations
- Label/labeling/technical info

Before you submit, did you?

- Include all requested information/data
- Review to see that it's well-organized
- Check to see all pages are readable
- Include a cover letter (reference DAF # if previously assigned).



Making your submission

- Send the submission to the appropriate AAFCO Investigator (2 copies) and may send a copy directly to FDA/CVM
 - Investigators are on the AAFCO internet site
- May also electronically submit all or part of the information (e.g. data and statistics) on CD
- Check to see it was received
- Review submission again for problems



Additional submissions

- State reason for submission
- Include the tracking or DAF #
- Include the sections/pages of original submission that the new information/data are relevant to



Initial Review

- After receipt, AAFCO investigators
 - Determine if it's in their area
 - Determine type of request
 - Typically contact/forward submission to CVM
- FDA/CVM will conduct an initial review for completeness of the submitted package
 - Sponsor will be notified if package is not complete

Submission review

- At FDA/CVM, submissions are entered into the DAF tracking database and assigned a DAF number and a reviewer.
- Submissions to FDA/CVM are reviewed on a first in, first out basis.
- Regulatory discretion letter is issued to the sponsor recommending the new definition, requesting additional information, recommending the definition not be considered by AAFCO.



Ingredients Definition Committee (IDC)

- Once FDA/CVM concurs with proposed definition, the Investigator is informed
- The Investigator submits proposed definitions by Dec. 15 of each year for consideration by IDC at mid-year meeting
 - If accepted at January meeting, voted on by membership at August meeting and included in following year's Official Publication



Additional information

- Official Publication of AAFCO
- www.aaafco.org
- <http://www.fda.gov/cvm/index/animalfeed/animalfeed.htm>