Information for an Ingredient Definition Submission

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General Information

- Sponsor, firm, contact person
- Proposed definition
- Rationale for the request
  - Explain why the proposed definition or modification to existing definition is necessary.
- Existing definitions/approvals for other uses or species
Description of the Ingredient

- Chemical name/Botanical name
  - Common or usual name
  - Chemical Abstracts number
  - IUPAC name
- Chemical composition
- Physical, biological, chemical properties
Manufacturing/Processing Information

- General description of the manufacturing and/or processing of the ingredient
- Identify possible contaminants
- Ingredient specifications based on compositional analysis of 3–5 batches
- Stability data of ingredient as marketed
  - Need for expiration date
- Stability data of ingredient in the feed (as needed)
  - Consideration for stability in pelleted feed
Analytical Methods

- Description of analytical methods for the ingredient as manufactured and in the animal feed/premixes
- Validation data for method
Purpose of the Ingredient

- Clear statement of purpose/use the ingredient will serve in the animal feed levels of use in feed
- Should list the animal species the animal feed will be fed to
- Purposes are generally to -
  - Provide a source of nutrition, taste, or aroma for the animal
  - Used to affect the characteristic of feed or ingredient
Purpose, cont’d

- Well written and supported summary of the information to demonstrate
  - the feed ingredient achieves its intended purpose
  - the amounts needed to achieve its purpose
- Copies of referenced literature
- Complete reports of other studies
  - Studies should be well-designed, well conducted and amenable to statistical analysis
- Information on conditions that may limit use
Safety Information

- Well written and supported summary of the safety/toxicity studies in applicable species to confirm the ingredient is safe for its intended use
  - Should describe what levels were found to result in statistically significant effects and the effects found (carcinogenicity, mutagenicity, chronic effects, dermal effects)
- Copies of referenced literature
- Complete reports of other studies
  - Studies should be well-designed, well conducted and amenable to statistical analysis
Draft Label

- Follow label format in Model Bill Regulation 3 or Model Regulations for Pet Food and Specialty Pet Food
- Claims must be truthful, not misleading, and appropriate for an animal feed
  - See CVM Program and Policy Procedures Manual Guide 1240.3605
Investigator Actions

- Decide
  - whether the ingredient is in their area of concern
  - whether the ingredient meets an existing definition
  - whether the ingredient definition request is complete

- Send to CVM for review
  Division of Animal Feeds, HFV-220
  7519 Standish Place, Rockville, MD 20855
CVM Actions

- Review the information provided by investigator
- Response to investigator
  - Food Additive Petition is needed
  - Acceptable to Support an AAFCO ingredient definition
  - Additional information is needed
Future Considerations

- CVM desires all ingredients to be legal under the Federal Food, Drug, and Cosmetic Act
  - Approved food additives
  - GRAS for an intended use
- Modifying the food additive process
Thank you!