

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 !

