Process Options for Substances used in Feed

Mika Alewynse, Ph.D.
Division of Animal Feeds
Center for Veterinary Medicine

Presented at the 2010 AAFCO Midyear Meeting in Redondo Beach, CA
What are Feed Substances?

For this discussion

Substances regulated as foods
- Provide nutrition (nutritive value), taste, or aroma to the animal
- Affect the characteristics of the food
- May indirectly become a component of food thru processing, packaging, etc

→ Typically, food additive, AAFCO ingredient definition, substance GRAS for a use
What are Options for a New Substance?

- Three options
  - Food additive approval
  - CVM use of enforcement discretion
    - AAFCO ingredient definition
  - Safety of use recognized by qualified experts (GRAS)
- Option determined by safety risk of substance and intended use
Food Additive Option

- Safety risk is identified for target animal, human food or environment
  - Larger data requirement and data can be proprietary
    - Tissue residues – human food safety
    - Environmental safety
  - Formal approval process
  - Agency accepts responsibility for approval after review of data
Food Additive Option (cont)

- Substance and use listed in Code of Federal Regulations
- Product cannot be removed from market without legal proceedings
- More resources required for approval from both industry and FDA
Enforcement Discretion Option

- NO apparent safety risk for target animal, human food or environment
  - Lesser data requirement and data can be proprietary
  - Informal process
  - Not legally binding
    - Ingredient is still unapproved food additive
  - Agency accepts responsibility after review of data
Enforcement Discretion Option (cont)

- Substance might be listed as ingredient definition in AAFCO Official Publication
- Enforcement discretion can be easily withdrawn, no appeal process
- Fewer resources needed because NO safety risk
  - If risk identified during FDA review of data and information, substance moves to food additive option
GRAS Option

- GRAS – general recognition that intended use of a substance is safe
  - No safety risk determined by qualified experts, not FDA
  - GRAS Notification represents a firm’s determination that a particular use of a substance is GRAS
GRAS Option (cont)

- GRAS
  - Larger data requirement
    - Same quantity and quality of scientific evidence as required for approval of food additive petition, or
    - Commonly used in food prior to 1958 (rare)
  - Safety evidence must be generally known and accepted
    - Data are generally published
  - Legal process
  - Firm accepts responsibility for safety of use, not FDA
- Firm’s notice and FDA response posted on CVM web page
- Two types of letters
  - “No questions” response
    - FDA has no questions about Notice
    - Firm is responsible party, not FDA
  - “Insufficient basis” response
    - FDA has questions about Notice
      - Safety
      - General recognition
GRAS Option (cont)

- Product cannot be removed from market without legal proceedings
  - Burden on FDA to show substance is unapproved food additive
- Resources
  - More industry resources needed because “same quantity and quality of scientific evidence as for food additive petition”
  - Fewer FDA resources as FDA looks at only summarized information
GRAS Substances

- GRAS substances
  - Neither more safe, nor less safe than approved food additive for intended use
- Difference is “common knowledge” element
- Substance can be food additive for one use and GRAS for another
- FDA approval is not required
  - Self determination of GRAS status
  - GRAS Notification
Where is Information about these Process Options?

- Food additive petition
  - 21 CFR 571

- AAFCO ingredient definition process
  - AAFCO Official Publication

- GRAS notification
  - April 17, 1997 Federal Register notice (62 FR 18937)
  - New CVM Federal Register notice in the works
Thank you !

[Image: Center for Veterinary Medicine
Protecting Public and Animal Health]