Process Options for Substances used in Feed

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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- Enforcement discretion can be easily withdrawn, no appeal process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

GRAS Option (cont)

- 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 !


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