

Pet Food Ingredient Specifications and Ingredient Approvals – Industry Stepping Up to the Plate

Ray A. Matulka, Ph.D.

Burdock Group

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Thank you for the opportunity to speak to you today.

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If you would like receive additional information regarding Burdock Group's capabilities in animal feed safety and regulations, please contact Ray Matulka (rmatulka@burdockgroup.com) or Mr. John Geisler (jgeisler@burdockgroup.com).

Disclaimer: Concepts and examples discussed in this lecture are for illustrative purposes only and do not constitute safety or regulatory advice specific to your situation. Please contact us for an analysis of your particular circumstance to determine the best pathway for your product and team.



Current Issue

- Under Section 201(s) of the Act, any substance added to an animal feed must be either:
 - Approved for use as a food additive *via* FDA OR
 - Generally Recognized As Safe (GRAS) for its intended use
- AAFCO OP does not meet federal regulatory statutes for pet food ingredients
- FDAAA (2007): mandated regulations addressing pet food ingredient standards and definitions



Feed ingredient “approval” for use:

- FDA/CVM Food Additive Petition
 - Time consuming: 3 – 5 years for approval of petition
 - One company sets standards for one product
 - Data is NOT in public venue – lack of transparency
 - High cost for one company



Feed ingredient “approval” for use:

- AAFCO Ingredient Definition Petition
 - Safety data provided to CVM: Regulatory discretion letter provided by CVM for ingredient
 - FDA General Council demands limitation of “regulatory discretion” and regulatory “home” for AAFCO ingredients
 - Amount and rigor of scientific data is comparable to FAP
 - Lack of transparency on process
 - High cost for one company



Feed ingredient “approval” for use:

- Generally Recognized As Safe (GRAS) Determination
 - Amount and rigor of safety data is equal to FAP
 - Safety and utility data must be in public domain (*e.g.*, published): greater amount of transparency
 - One company sets standards for one product
 - Significant cost for one company
 - Voluntary action to notify FDA of GRAS status
 - Current limitations by State Officials to acknowledge GRAS status



AAFCO Pilot Program

- AAFCO to set standards for feed ingredients?
 - Feed Standards Mandated through FDAAA (2007)
 - AAFCO feed ingredient monographs
 - Monographs: detailed descriptions and specifications for an article/feed ingredient
 - Monographs prepared after ingredient was determined GRAS or a Food Additive
 - Justification for monographs for AAFCO-approved ingredients?



Industry-led Ad-Hoc Committee

- Establish collaboration to assess the safety and GRAS status of an AAFCO feed ingredient(s)
- Some substances have been historically used and would not need GRAS documentation (*e.g.*, salt, ground grass, wheat bran)
- Composed of industry stakeholders sharing cost and benefit
- Precedent for Industry-led GRAS: FEMA

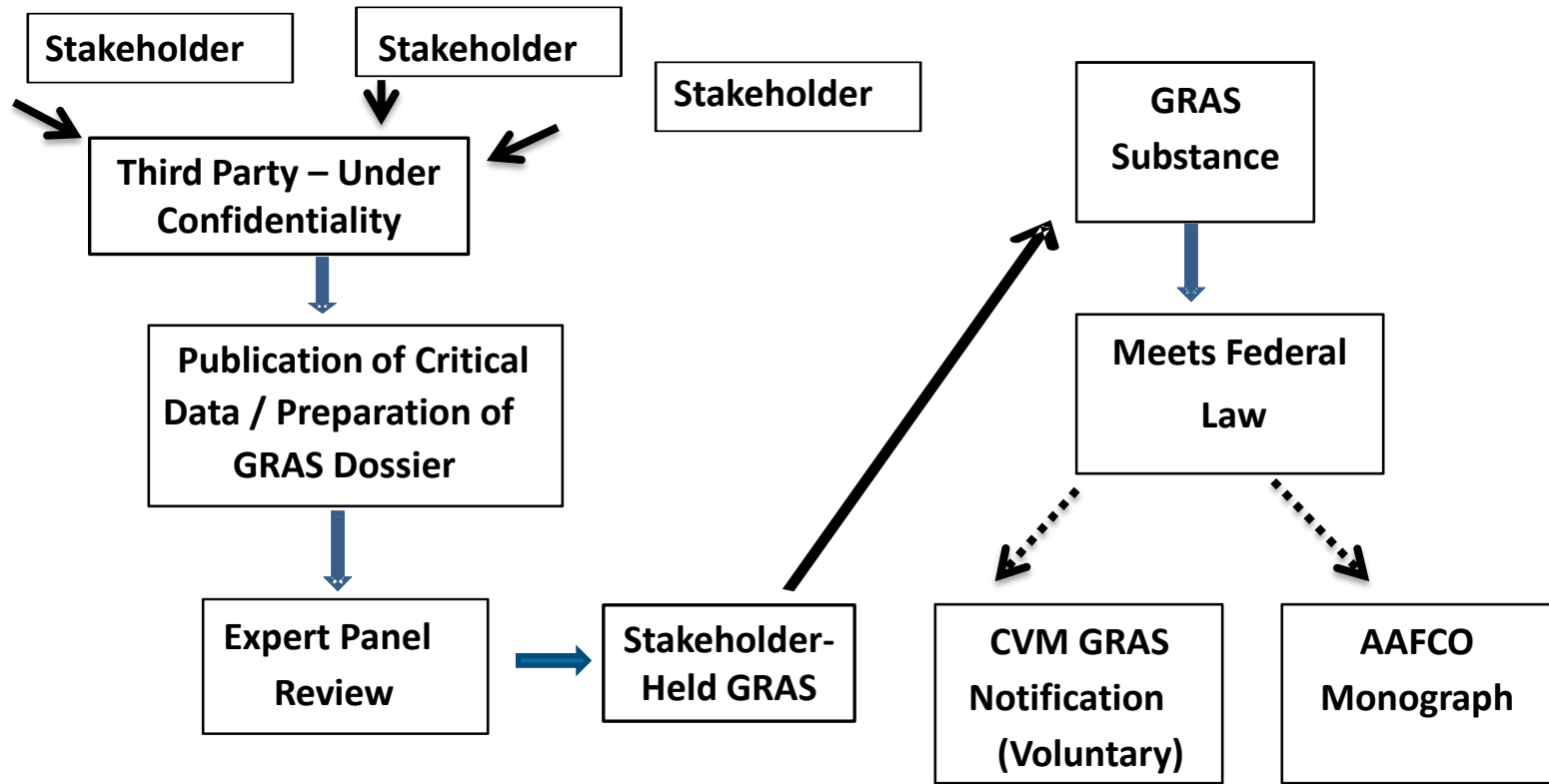


Flavor Extract Manufacturer's Association (FEMA)

- GRAS program began in 1959
- Longest-running and most widely recognized GRAS assessment program
- Open to active members of Association
- Establishment of Expert Panel independent of Association and Industry to evaluate GRAS status



Ad-Hoc Committee-led GRAS Process



Development of GRAS dossier

- Data provided by industry stakeholders that produce ingredient
- Data provided to non-biased third party for development of GRAS dossier
- Scientific data supporting GRAS status of individual ingredient published as a whole in a peer-reviewed scientific journal
- Production levels (*e.g.*, tonnage) by ingredient producers (stakeholders) as basis for sharing of overall cost to determine ingredient GRAS



GRAS Expert Panel

- Is composed of scientists of disciplines directly related to proposed GRAS ingredient
- Works through unbiased third party – not directly with companies requesting GRAS determination
- Is NOT affiliated with stakeholder companies
- Stakeholder companies NOT allowed direct contact with Expert Panel (*i.e.*, no lobbying)



GRAS status and AAFCO OP

- GRAS status provides regulatory “home” for AAFCO-approved ingredients
- GRAS determination MAY be provided to AAFCO to prepare monograph
- Monograph based on specifications set by those in industry that have stake in GRAS status
- Meets FDAAA (2007) requirements for “standards” for pet food ingredients

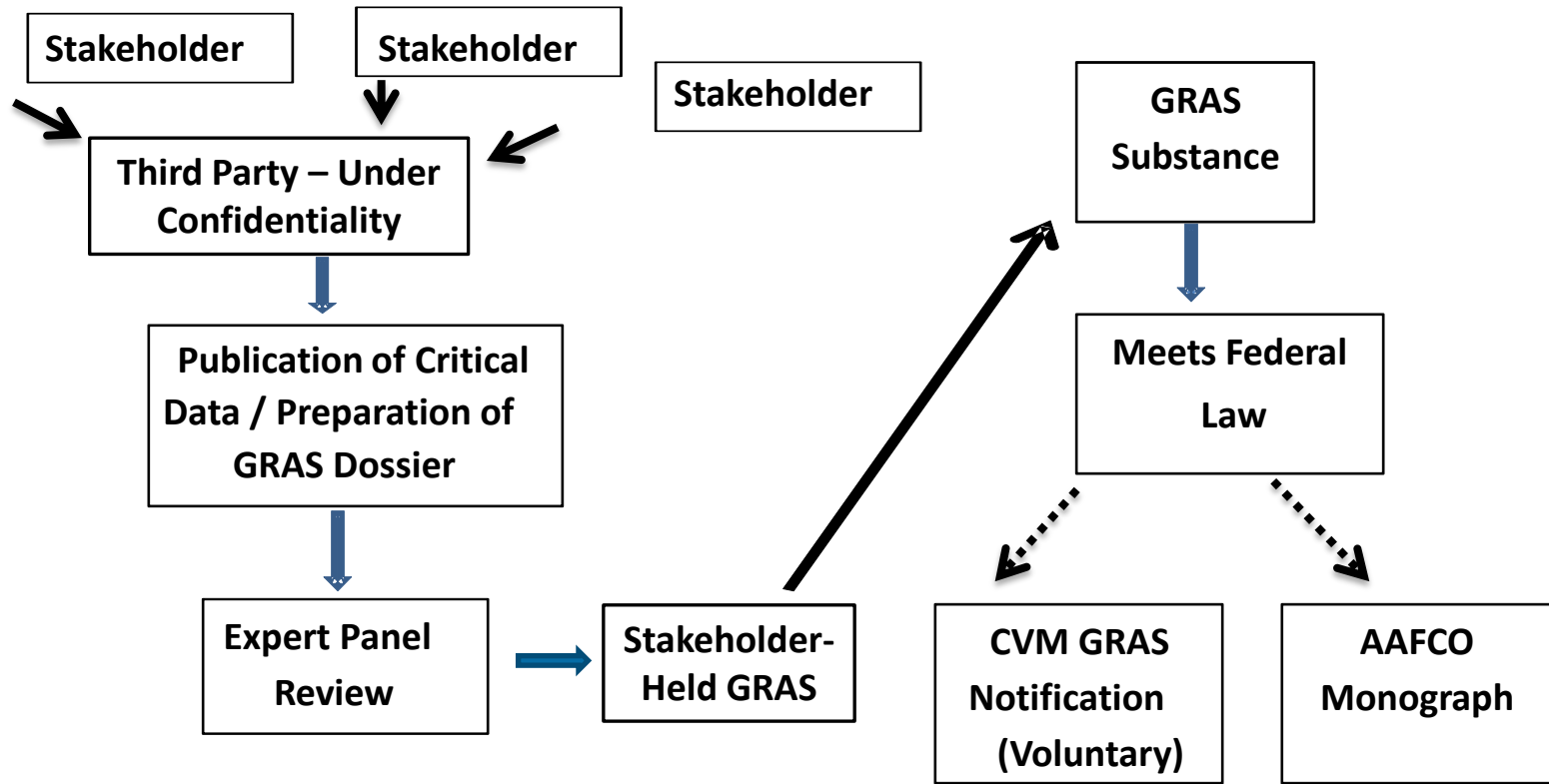


Monographs: Food Chemicals Codex (FCC) Design

- Preparation of monographs: AAFCO
- Used as agreed standards between suppliers and manufacturers
- Generally cover a single ingredient
 - Chemical Structure
 - Chemical Formula
 - Chemical Weight
 - INS Number
 - CAS Numbers
 - Function
 - Definition
 - Packaging
 - Storage
 - Labeling Requirements
 - IR Spectra



Ad-Hoc Committee-led GRAS Process



Questions?

Thank you for your attention

Ray A. Matulka, Ph.D.

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rmatulka@burdockgroup.com

