The Regulatory Process for Petfood Ingredient Approval

David A. Dzanis, DVM, PhD, DACVN
Regulatory Discretion, Inc.
dzanis@aol.com
www.regulatorydiscretion.com

Methods for acceptance of new petfood ingredients

- Food Additive Petition (FAP)
- Generally Recognized As Safe (GRAS)
  - Self-determination
  - Affirmation
  - Notification
- AAFCO Feed Ingredient Definition
- Prior sanction
- State approval
- New Animal Drug Application
- Approval as pesticide (EPA)
- Approval as veterinary biologic (USDA)
- Approval as color additive, indirect food additive (FDA/CFSAN)

Methods for acceptance of new petfood ingredients

- **Food Additive Petition (FAP)**
- **Generally Recognized As Safe (GRAS)**
  - Self-determination
  - Affirmation
  - **Notification**
- **AAFCO Feed Ingredient Definition**
- Prior sanction
- State approval
- New Animal Drug Application
- Approval as pesticide (EPA)
- Approval as veterinary biologic (USDA)
- Approval as color additive, indirect food additive (FDA/CFSAN)

Food Additives

- Food Additives Amendment (1958)
  - Defines “food additive,” requires FDA approval prior to inclusion in food
- 59 food additives approved for use in animal feed since enactment
- Ethoxyquin = 1st Food Additive Petition received by FDA!

GRAS substances

- Exemption from food additives requirements
- ~582 substances “grandfathered” for use in animal feed, codified in CFR
- Many other substances implicitly GRAS (e.g., salt, sugar, vinegar)
- If neither of above, must be determined to be GRAS by appropriate procedures
  - Experience based on common use in food in US prior to 1958
  - Scientific procedures

GRAS terms

- GRAS Self-determination
  - Company conducts determination, does not submit to FDA
  - Allowed since 1958
  - State feed control officials often reluctant to accept
- GRAS Affirmation
  - Company conducts determination, submits petition to FDA, FDA reviews similarly to Food Additive Petition, codified in CFR
  - Allowed since 1970, FDA stopped accepting petitions in 1997
  - 3 substances affirmed for use in animal feed
- GRAS Notification
  - Company conducts determination, voluntarily files notification with FDA, FDA reviews and posts findings on web site
  - FDA started accepting notifications for human food in 1997
  - Program for animal feed started 2010

AAFCO Definitions

- Defines common or usual names for feed ingredients
- AAFCO formed 1908, first definitions c. 1910
- FDA has assisted AAFCO in process for decades, but assumed primary responsibility for safety/utility review in MOU signed in 2007
- Despite its involvement in process, FDA views AAFCO-defined ingredients as unapproved food additives

How they compare

	FAP	AAFCO Definition	GRAS Notification
Legal status	Formal approval	Enforcement discretion	Legal notification
Type of data	Can be confidential/ proprietary	Can be confidential/ proprietary	Majority of data in public domain
Quantity of data	Extensive	< FAP	= FAP
Data submitted	All studies	All studies	Summary report
Responsible for safety determination	FDA	FDA	Submitter

How they compare (cont'd)

	FAP	AAFCO Definition	GRAS Notification
FDA resources	High	< FAP	< AAFCO
Submitter resources	High	< FAP	≥ FAP
Response time	Years	Years	284 days ?
End result	New regulation in CFR	New AAFCO Definition	"No questions" letter
When can market	After FDA approval	After FDA completes review	After submission (but best to wait for response)
Action to reverse	Legal procedures	Delete definition	Show it is an unapproved food additive

Which method?

- Traditionally:
  - No serious safety concerns – AAFCO Definition
  - Safety concerns – FAP
  - GRAS Affirmation rarely used
- NEW PARADIGM!!
  - MOU between FDA and AAFCO due to expire in 2015
  - At termination of MOU, FDA intends to phase out its role in AAFCO Definition process
  - Why?
    - AAFCO Definitions are based on "enforcement discretion," not formal procedures
    - FDA has been directed by counsel to eliminate its discretionary policies
    - All new ingredients need "legal homes," i.e., Food Additive Petitions or GRAS Notifications

AAFCO's new role?

- Intends to become a "standard setting body"
- Plans to prepare monographs for each feed ingredient (similar to USP Food Chemical Codex monographs for food ingredients)
- Ingredient must be approved food additive or GRAS before monograph prepared
- FDA will not participate in monograph preparation, but will provide a liaison

Monograph components

- Common and usual name (AAFCO Definition)
- Intended purpose
- Chemical and physical description
- List of inert or inactive ingredients (%)
- List of known contaminants or hazards (%)
- Analytical methods – including potential hazards and contaminants, inert materials, nutrients
- Recognition of international approvals – CFIA, EFSA, Japan, FDA (CFR reference)
- Manufacturing process (proprietary information is protected!)
- Required labeling – special directions for use, warning or caution statements
- Nutrient profile if applicable
- Known toxicity levels – feeding limitations
- Required packaging, storage or shipping concerns
- List of verified suppliers?

Concerns with AAFCO monographs

- AAFCO's
  - Liability
  - Conflict of interest
  - Nonprofit or for profit
  - Revenue stream to pay for the process
  - Copyright protection
  - Protection of proprietary information
  - Legal authority or recognition of monograph
- Outside
  - Qualifications of preparers
  - Timeliness of process

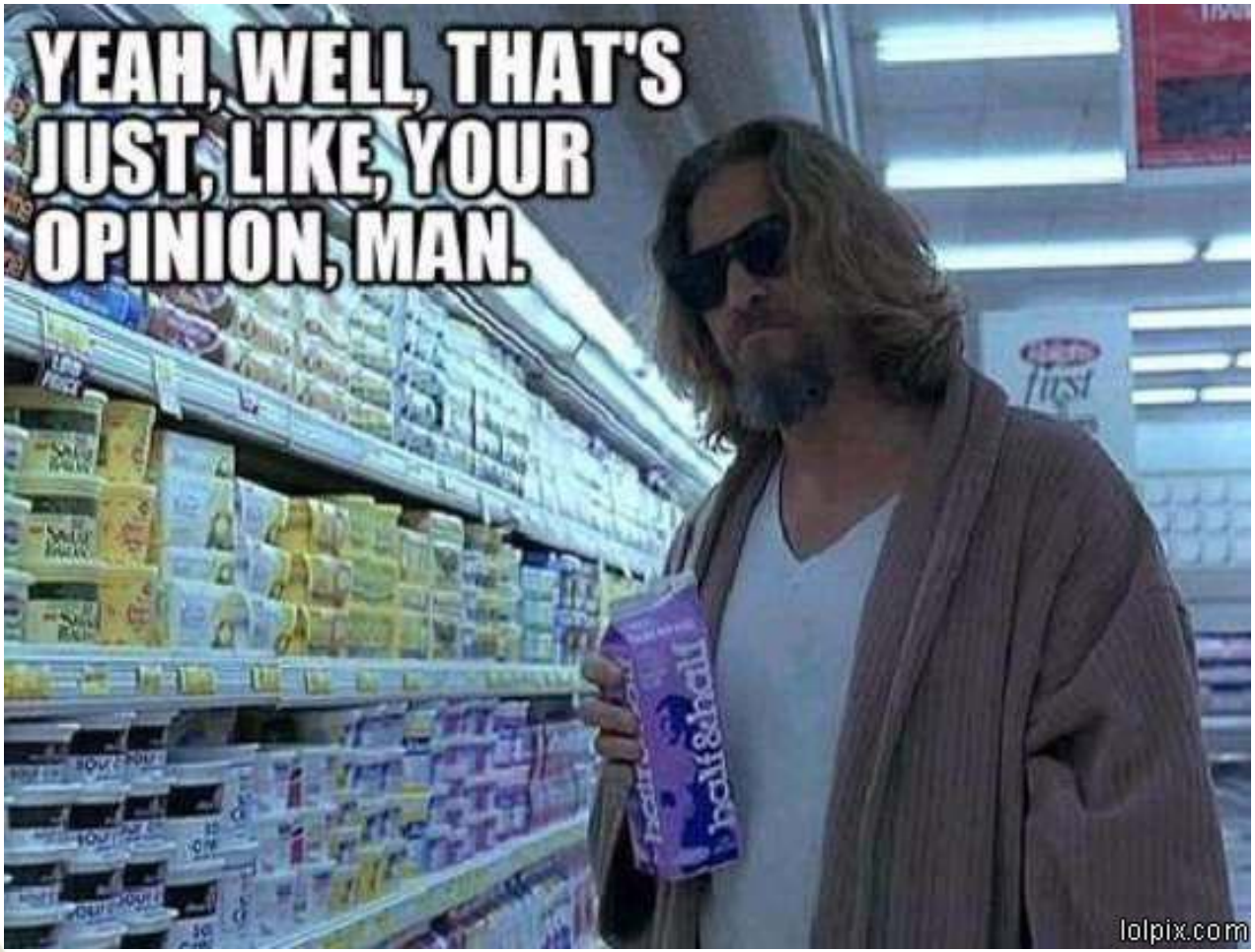
Other issues

- Burden on manufacturers
  - Food Additive Petition and GRAS Notification methods may be unnecessarily burdensome for some ingredients
  - FDA to streamline methods for ingredients with no safety concerns?
- Poor GRAS Notification track record to date
  - Out of 14 FDA responses to notifications for use in animal feeds, only 3 “no questions” (21.4%)
  - For GRAS substances for use in human foods, “no questions” for 369 out of 463 notifications (79.7%)
- Retroactive review?
  - FDA wants to establish “legal homes” for all ingredients, not just new ones
  - AAFCO Definitions published after 1958 may eventually be subject to re-review

Conclusions

- Petfood ingredient acceptance processes in US are generally burdensome, time-consuming, costly
- Phase out of AAFCO Definition process eliminates a useful (and usually less expensive) option
- Future uncertain

Questions?



dzanis@aol.com

www.regulatorydiscretion.com