

A Convulsive Change in Pet Food (and Animal Feed) Regulation

Ray A. Matulka, Ph.D.



Where the **Global Petfood Industry** does business

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Thank you for the opportunity to speak today.

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If you would like receive additional information regarding Burdock Group's capabilities in safety and regulations for human food ingredients, dietary supplements or animal feed, please contact Amanda Roche (aroch@burdockgroup.com) or John Geisler (jgeisler@burdockgroup.com).

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Animal Feed Ingredient Approval

Three Routes to Approval

Feed Additive
Petition (FAP)

Generally
Recognized as
Safe (GRAS)

AAFCO
Ingredient
Definition



Primer on Food Regulation

- Do we need regulations?
- Who benefits from regulations
- Evolution of human food regulations
-
- Evolution of animal feed regulatory control and AAFCO involvement



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Why do we need regulation?

Upton Sinclair – *The Jungle*

- Economic adulteration
- Misrepresentation (misbranding)
- Safety



Regulations – Who Benefits?

Industry

- Levels playing field
- Expectations
 - Government
 - Consumers
- Basis for innovation (not indemnification)

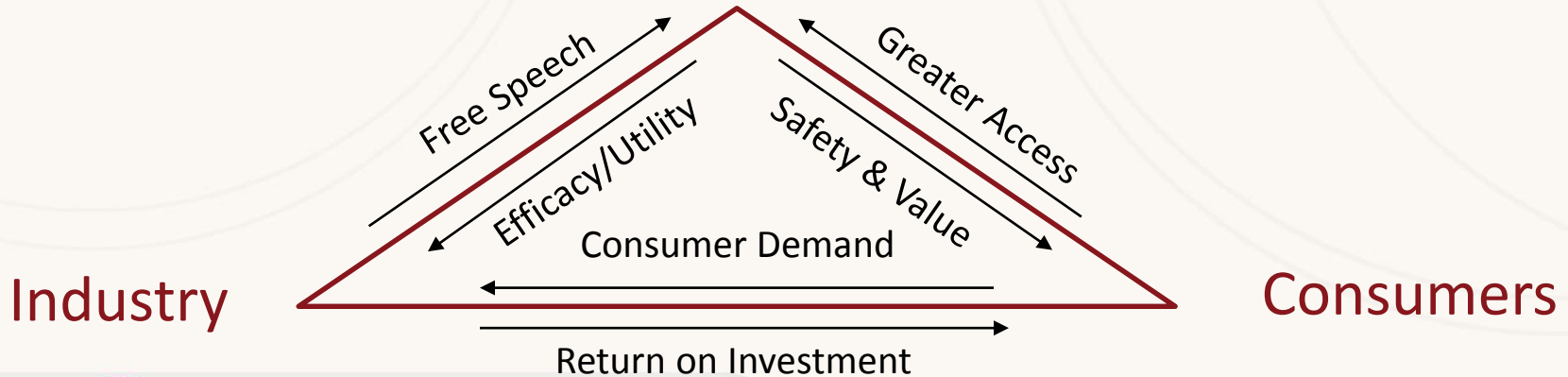
Consumers

- Safe products
- Standardized products
- Assured value
- Improves basis for making choices



Animal Feed: Players and Tension

Center for Veterinary Medicine (CVM)



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Evolution of Food Regulations

Pure Food and Drugs Act (1906)

Meat Inspection Act (1906)

Food Drug & Cosmetic Act (1938)

Food Drug & Cosmetic Act (1958)

Eliminated "...filthy, putrid, or decomposed substance, or if it is otherwise unfit for food..."



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Evolution of Food Regulations (Cont.)

Nutrition Labeling & Education Act
(1990)

Dietary Supplement Health & Education Act (1994)

FDA Modernization Act (1997)

FDA Amendments Act (2007)

FDA Food Safety Modernization Act (2011)



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Definitions within the FDCA (1958)

- § 201(f) The term "food" means (1) **articles used for food or drink for man or other animals**, (2) chewing gum, and (3) articles used for components of any such article.
- § 201(g)(1) The term "drug" means ... (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles **(other than food)** intended to affect the structure or any function of the body of man or other animals...
- § 201(w) The term "animal feed" ... means an article which is intended for use for food for animals other than man and which **is intended for use as a substantial source of nutrients** in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal. *[This paragraph is likely not intended to revise or extend the term "animal feed", but only to clarify §201(v) which refers to addition of drugs to animal feed.]*



Definitions within the FDCA (1958)

§ 201(s) The term "**food additive**" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), **if such substance is not generally recognized**, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) **to be safe under the conditions of its intended use**; except that such term does not include ...

Food Ingredients = Food Additives + GRAS substances



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What is a Food Ingredient?

***A food ingredient* means any substance the intended use of which:**

- results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food
- including any substance intended for use in:
 - Producing, Manufacturing, Packing, Processing, Treating and Packaging
 - Transporting or Holding food
 - Any source of radiation
 - Covers X-radiation or γ -rays, but not microwave



Learning the Lexicon

Types of Food Ingredients

Food Additives

Generally Recognized as Safe (GRAS) Affirmed

Prior Sanctioned Ingredients

Secondary Food Ingredients and Processing Aids

Packaging Ingredients (Indirect Additives)

Dietary Ingredients vs. Nutrient Ingredients

Color Additives



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Learning the Lexicon

Types of Food Ingredients

Food Additives ✓

Generally Recognized as Safe (GRAS) Affirmed ✓

Prior Sanctioned Ingredients ✓

Secondary Food Ingredients and Processing Aids ✓

Packaging Ingredients (Indirect Additives) ❌

Dietary Ingredients ❌ vs. Nutrient Ingredients ✓

Color Additives ❌



Animal Food Categories

- Forage (hay, alfalfa, etc.)
- Nutritive substances (proteins, fats, carbs, including from plants, animal products and rendered animals)
- Medicated feeds (feeds to which drugs have been added to increase production or prevent disease)
- Exceptions to animal food categories
 - Generally, any ingredient that contributes to the *production* of the animal is considered a drug. (Production: increased production of meat, milk, eggs, etc.)
 - No medical foods for animals
 - No dietary supplements for animals



Animal Feed Ingredient Approval

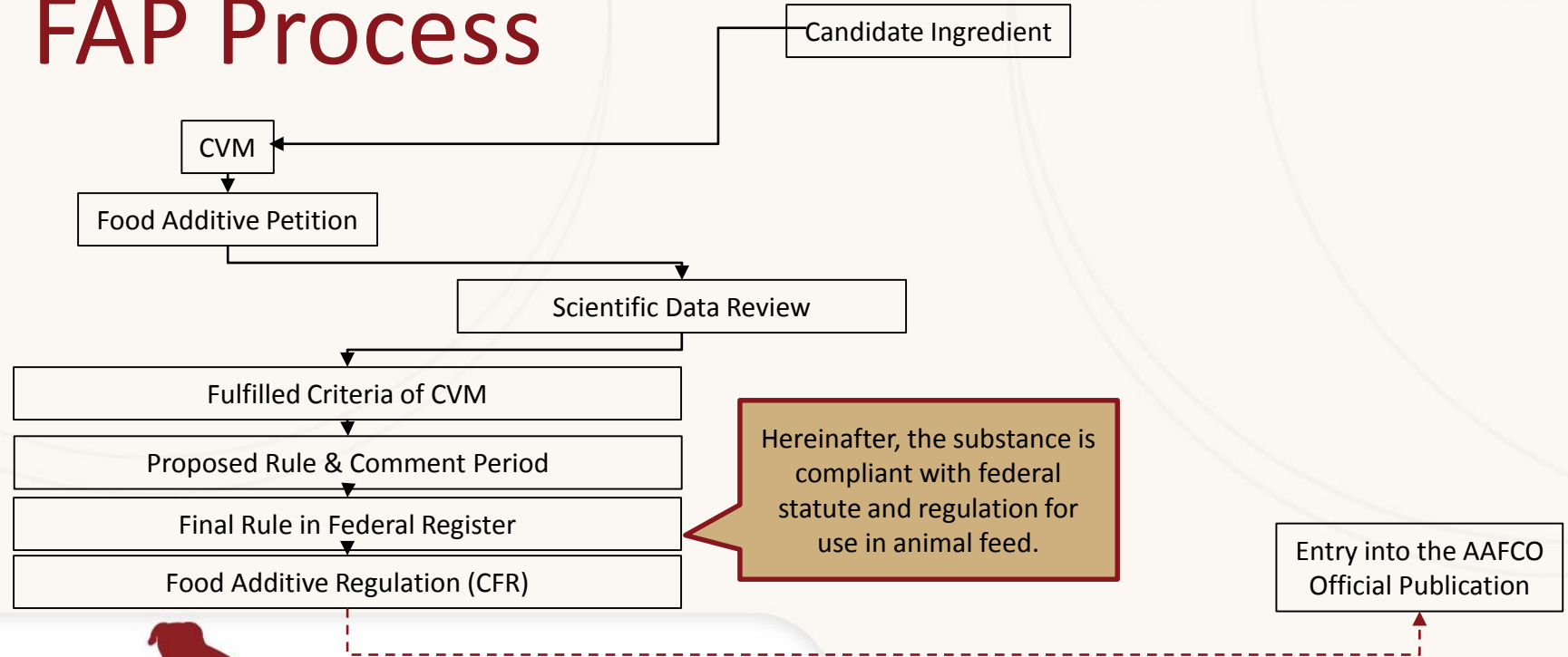
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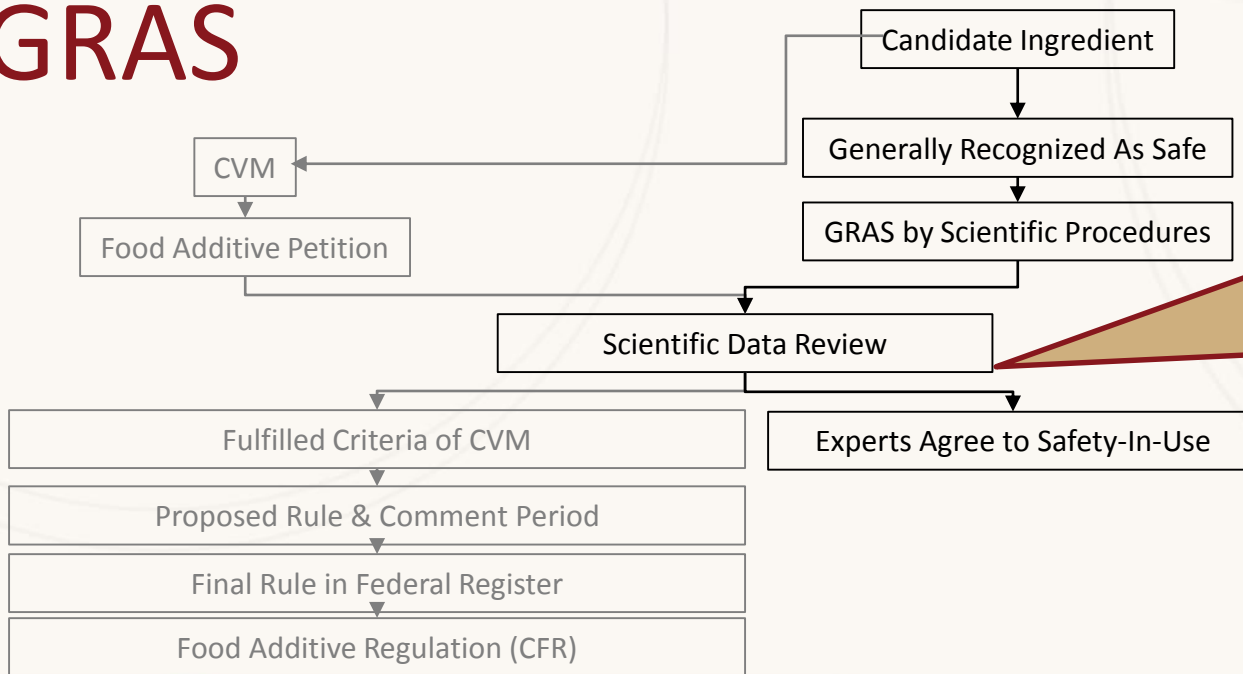
Generally
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AAFCO Ingredient
Definition

FAP Process



GRAS

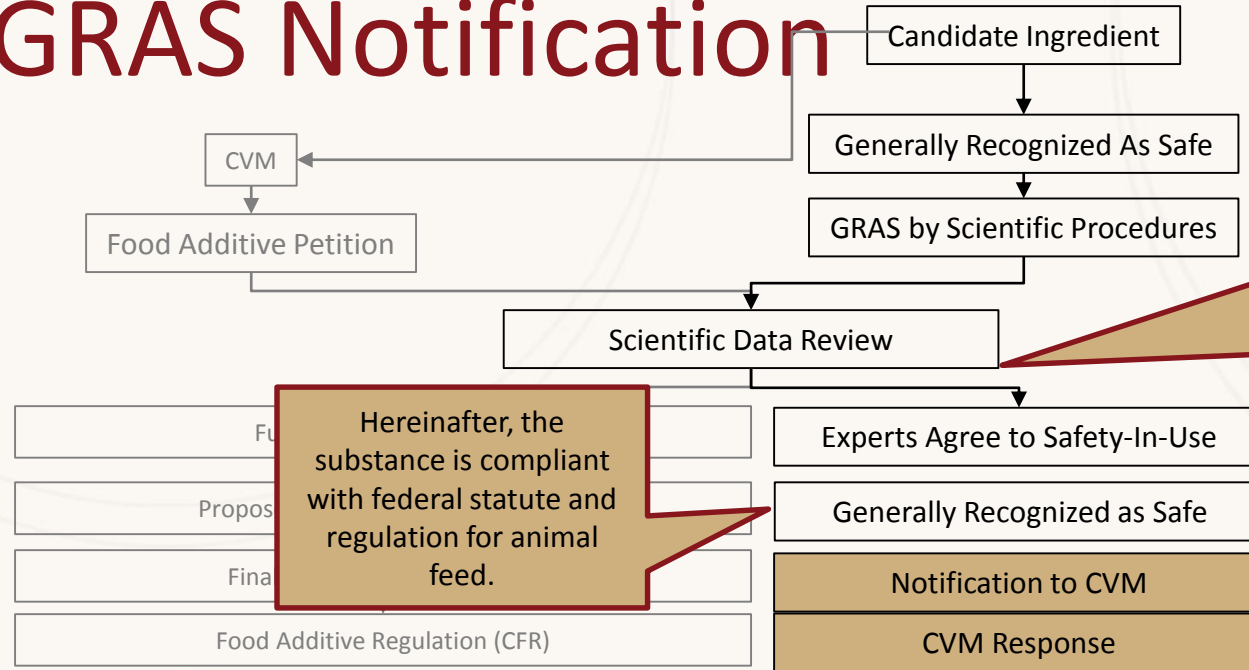


21CFR570.30 (b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. Enforceable?





GRAS Notification

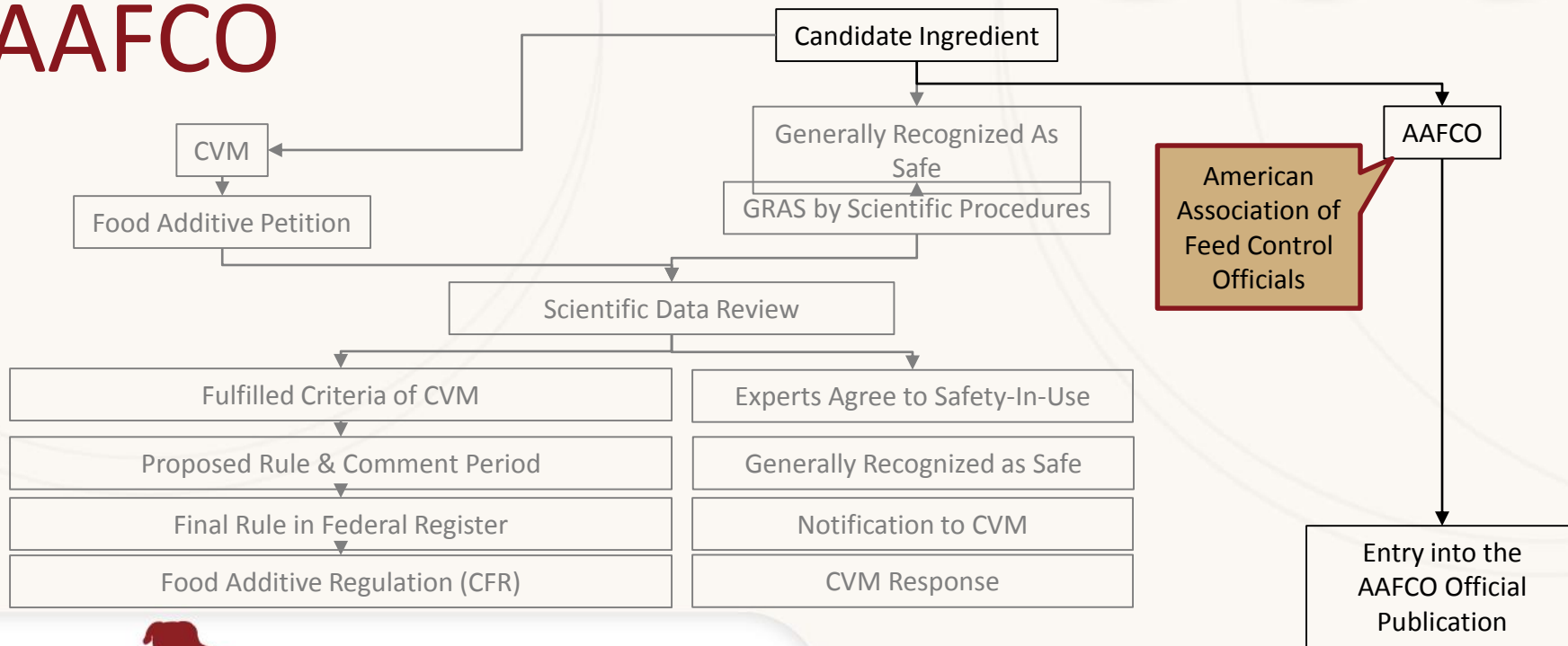


21CFR570.30 (b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. Enforceable?

Hereinafter, the substance is compliant with federal statute and regulation for animal feed.

Optional – not required by statute or regulation

AAFCO





What is AAFCO?

- Formed in 1909
- Feed control officials from all states
- Publishes Official Publication (OP)
- USDA (and later) FDA sit in on proceedings
- 1958 FD&C, 1960's CVM adds human ingredients to OP
- Early 1990's CVM sits on AAFCO Committees



AAFCO
Association of American Feed Control Officials



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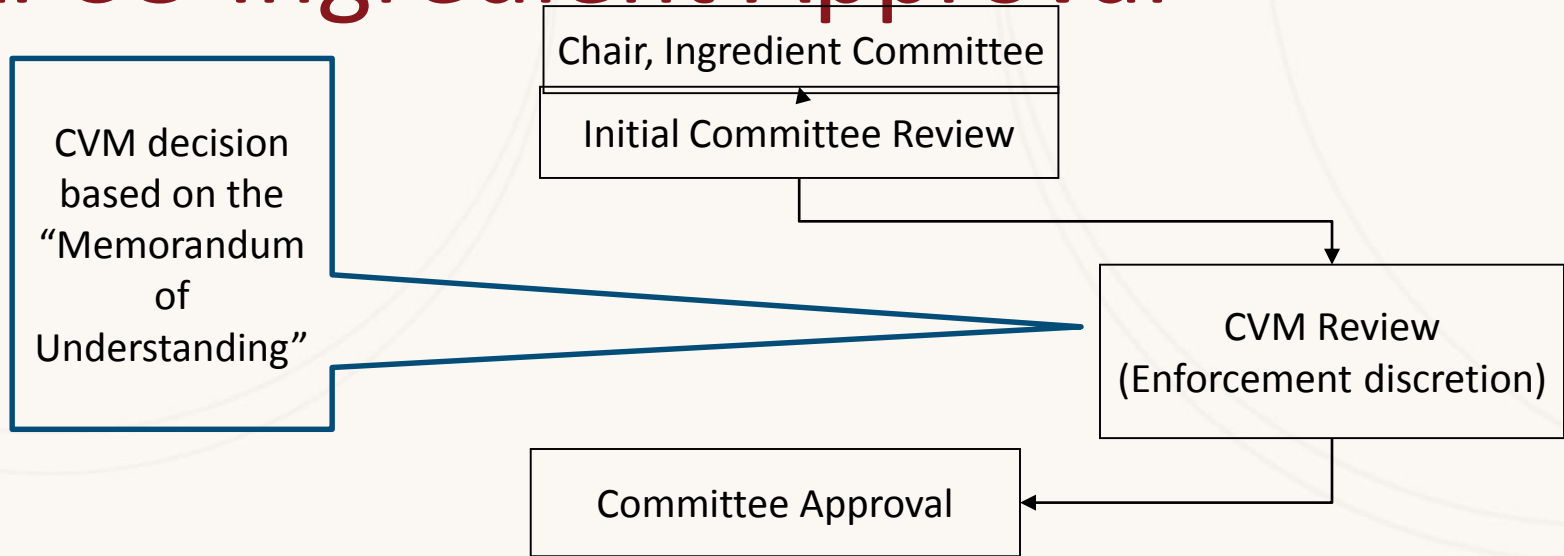


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AAFCO Ingredient Approval





AAFCO Ingredient Approval

Chair, Ingredient Committee

Initial Committee Review

CVM Review
(Enforcement discretion)

Committee Approval

AAFCO Board Approval

Vote by General Membership

Ingredient "Definition" in *Official Publication*



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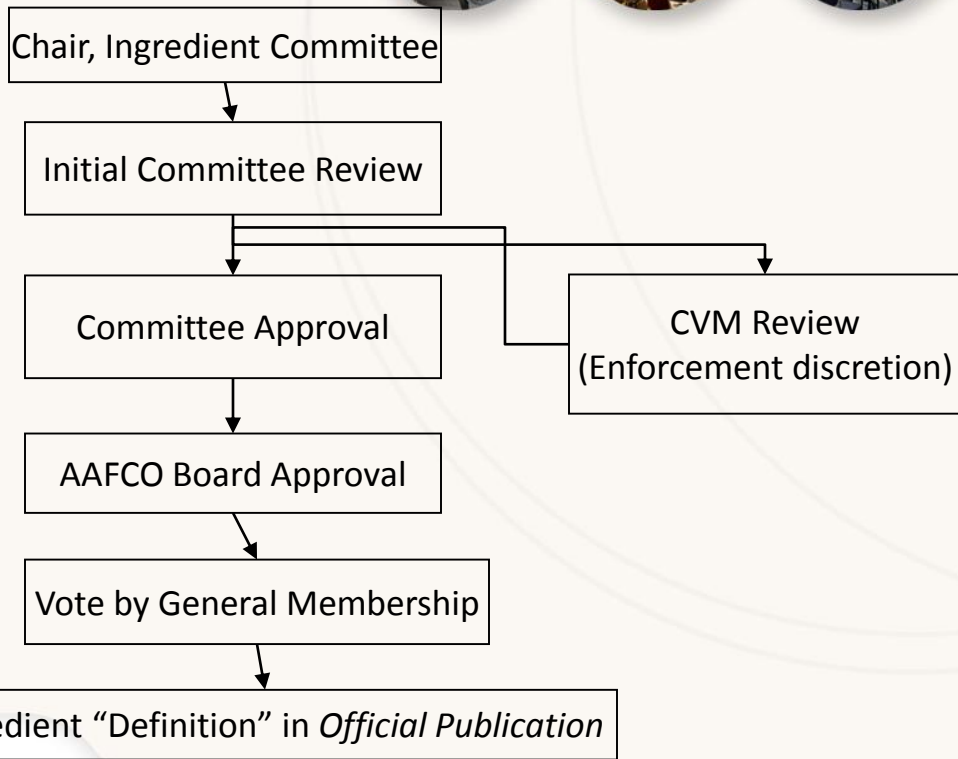
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AAFCO Approval?



Hereinafter, the substance is compliant with federal statute and regulation for use in animal feed.



AAFCO Approval?



The substance is neither a food additive nor GRAS and is not compliant with the federal statute.

Hereinafter the substance is compliant with the federal statute and regulation for use in animal feed.



Chair, Ingredient Committee

Initial Committee Review

CVM Review
(Enforcement discretion)

Committee Approval

AAFCO Board Approval

Vote by General Membership

Ingredient "Definition" in *Official Publication*

FDA Veterinarian (2007) *in re MOU*
"...[A]lthough the *OP* ingredient list does have the force of law in those States that adopt it, it does not carry the force of law for FDA."



History of CVM and AAFCO

2007 FDAAA

2007 MOU
between
CVM and
AAFCO

2008-9 CVM
GRAS
Notification
process
initiated

2010 FDA
legal team
announces
OP not
legitimate

2012 CVM
announces
search of OP
for
noncompliant
ingredients

March 2015
CVM
announcement



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If AAFCO Definitions are Not “Legitimate”, What Happens Now?


- Industry and Trade Association Initiatives
 - Extension of MOU
 - Regulatory/ Statutory “fix”
 - “Grandfather” OP substances
 - CVM GRAS





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Temporary at best.
Not a permanent solution and only perpetuates the problem.



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Not Moving. An initiative to change the law and has been ignored by Congress.



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Won't happen. A non-starter.
(Tried prior to 1958 Amendment.)



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Possible, but CVM has done only 3 GRAS affirmations since the 1970’s.

If AAFCO Definitions are Not “Legitimate”, What Happens Now?



Formation of industry *ad hoc* committees to share in the cost of legitimizing the status of feed ingredients according to Federal Law

Precedent

- Flavor and Extract Manufacturers Association (FEMA)
- Cosmetic Ingredient Review (CIR)
- Excipients Council
- Certified Color Manufacturers Association
- And others



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Any questions?

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- *Available upon request info@burdockgroup.com



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AAFCO Ingredient Review and Approval

