

The Impending Regulatory Crisis for Pet Food Ingredient Standards and Ingredient Approval – Time for the Industry to Step Up To the Plate



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Thank you for the opportunity to speak to you today.

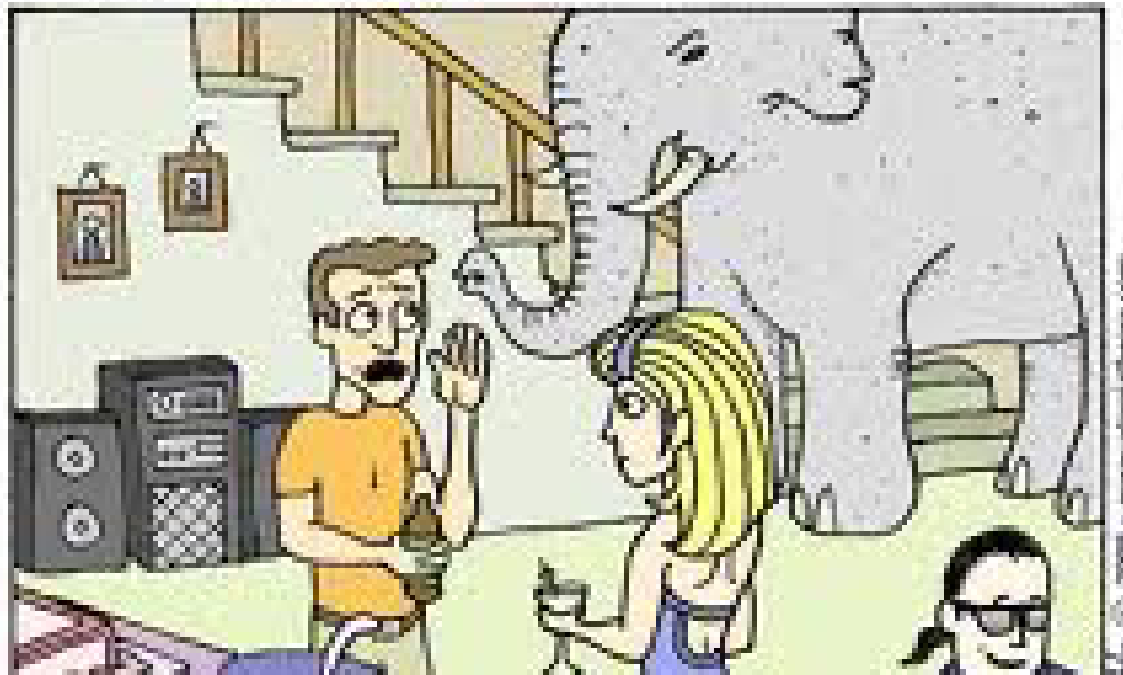
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If you would like receive additional information regarding Burdock Group's capabilities in animal feed safety and regulations, please contact George Burdock (gburdock@burdockgroup.com) or John Geisler (jgeisler@burdockgroup.com).

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.

The Future of Feed Ingredient Approval

The Elephant in the Room



"Yeah, I see him too...but nobody wants to talk about it.."

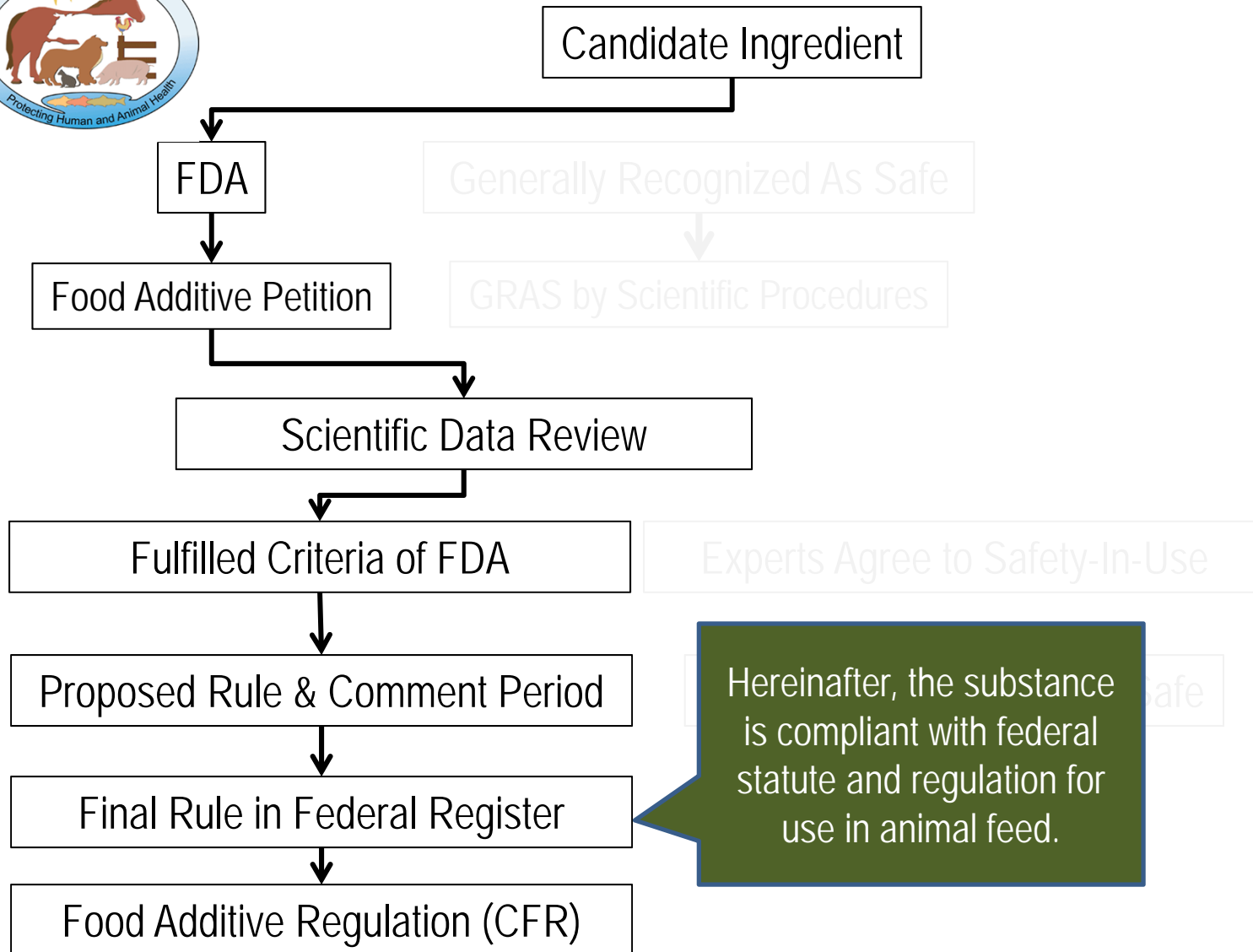
Animal Feed Ingredient Approval

Three Routes

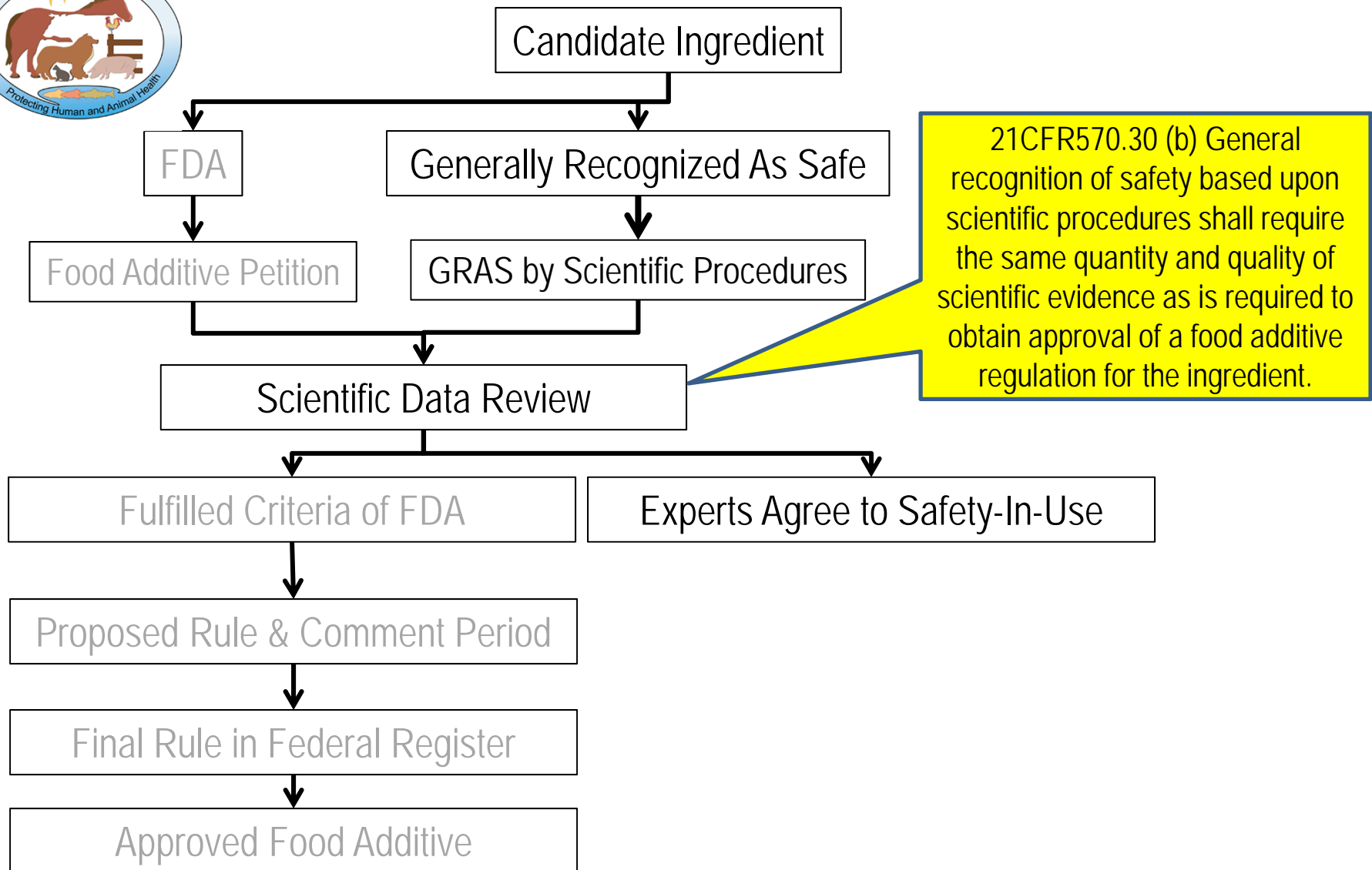
- Feed Additive Petition Approval for a Regulation
- Generally Recognized As Safe (GRAS)
 - Historical usage (prior to 1958)
 - Scientific procedures
- AAFCO Ingredient Definition



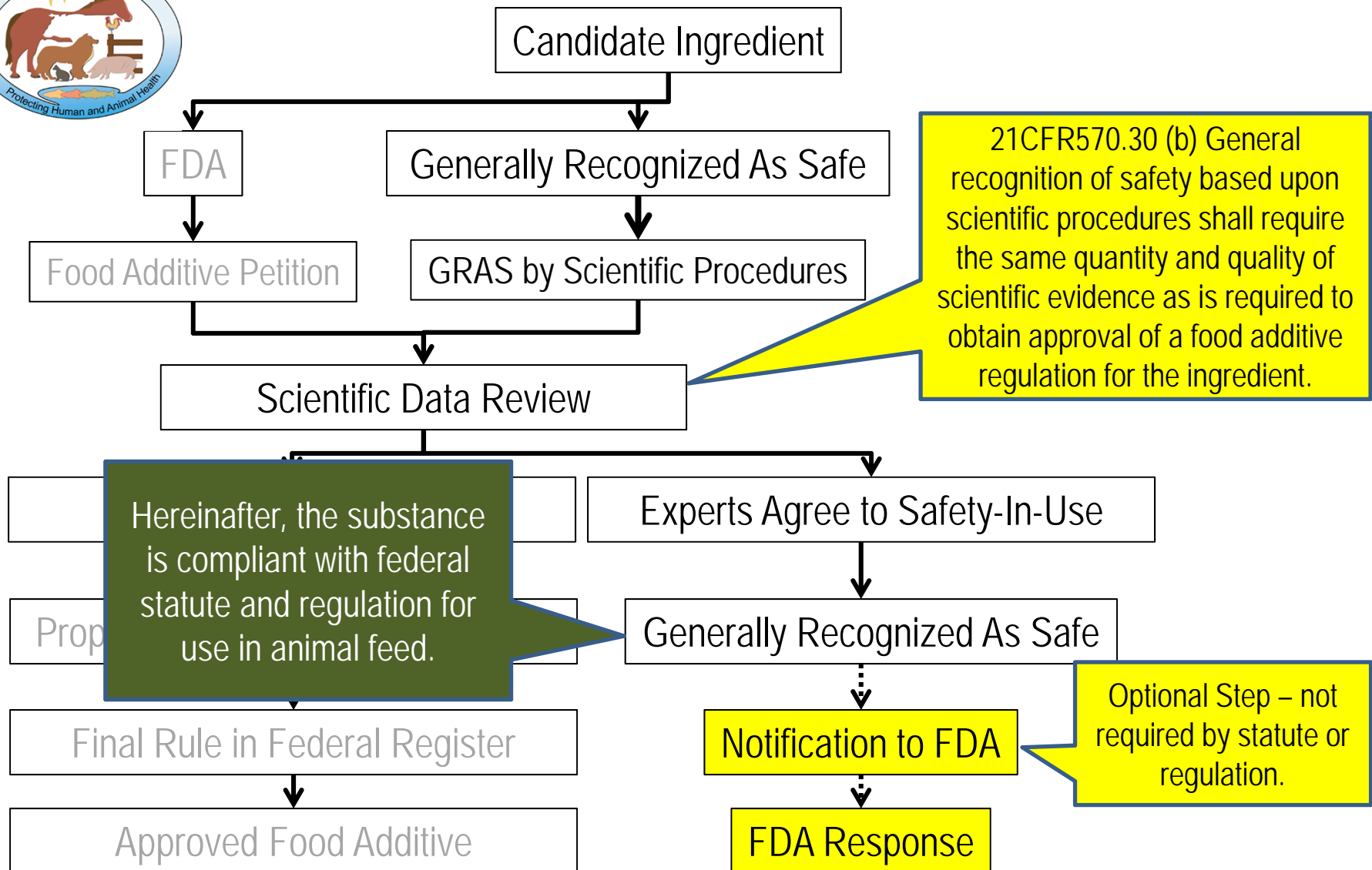
Routes for Feed Ingredient Approval



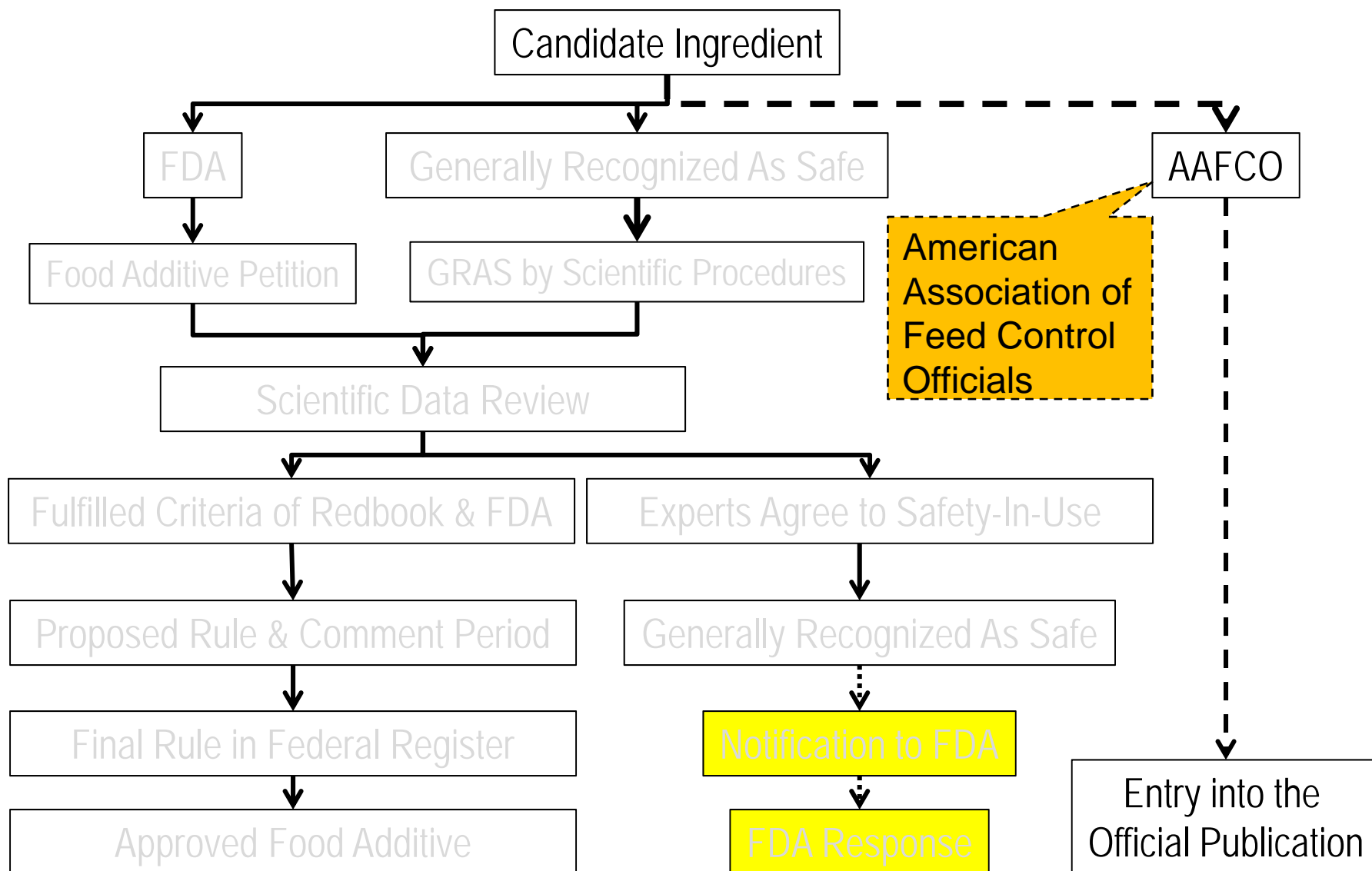
Routes for Feed Ingredient Approval



Routes for Feed Ingredient Approval



Routes for Feed Ingredient Approval

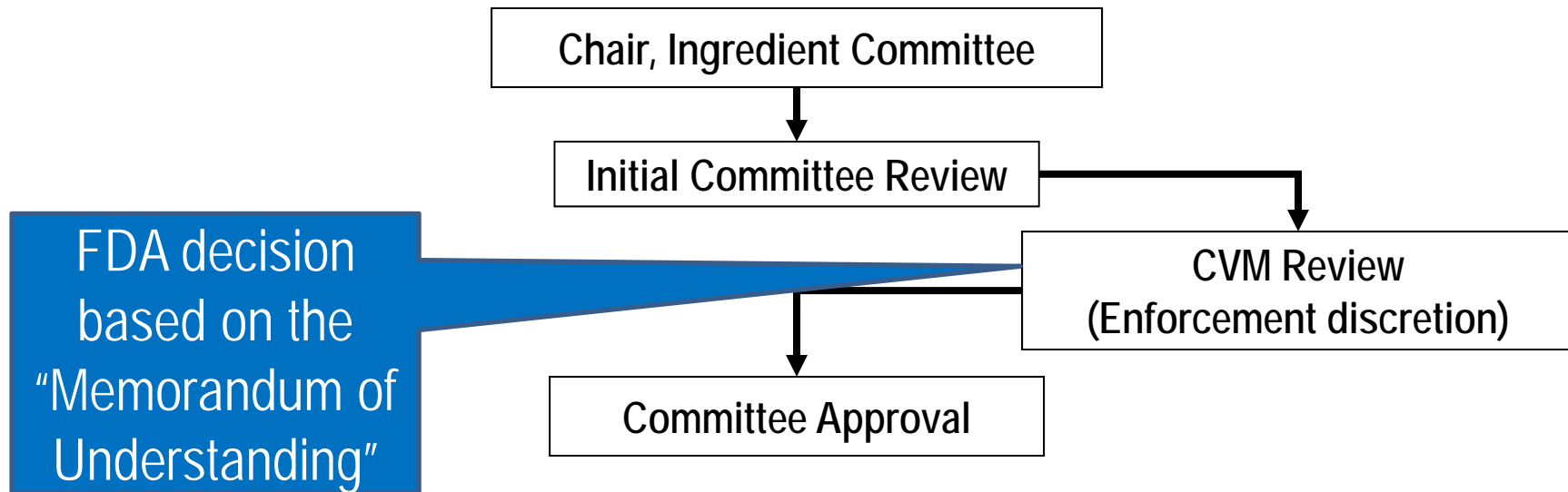




AAFCO
Association of American Feed Control Officials

What is AAFCO?

American Association of Feed Control Officials

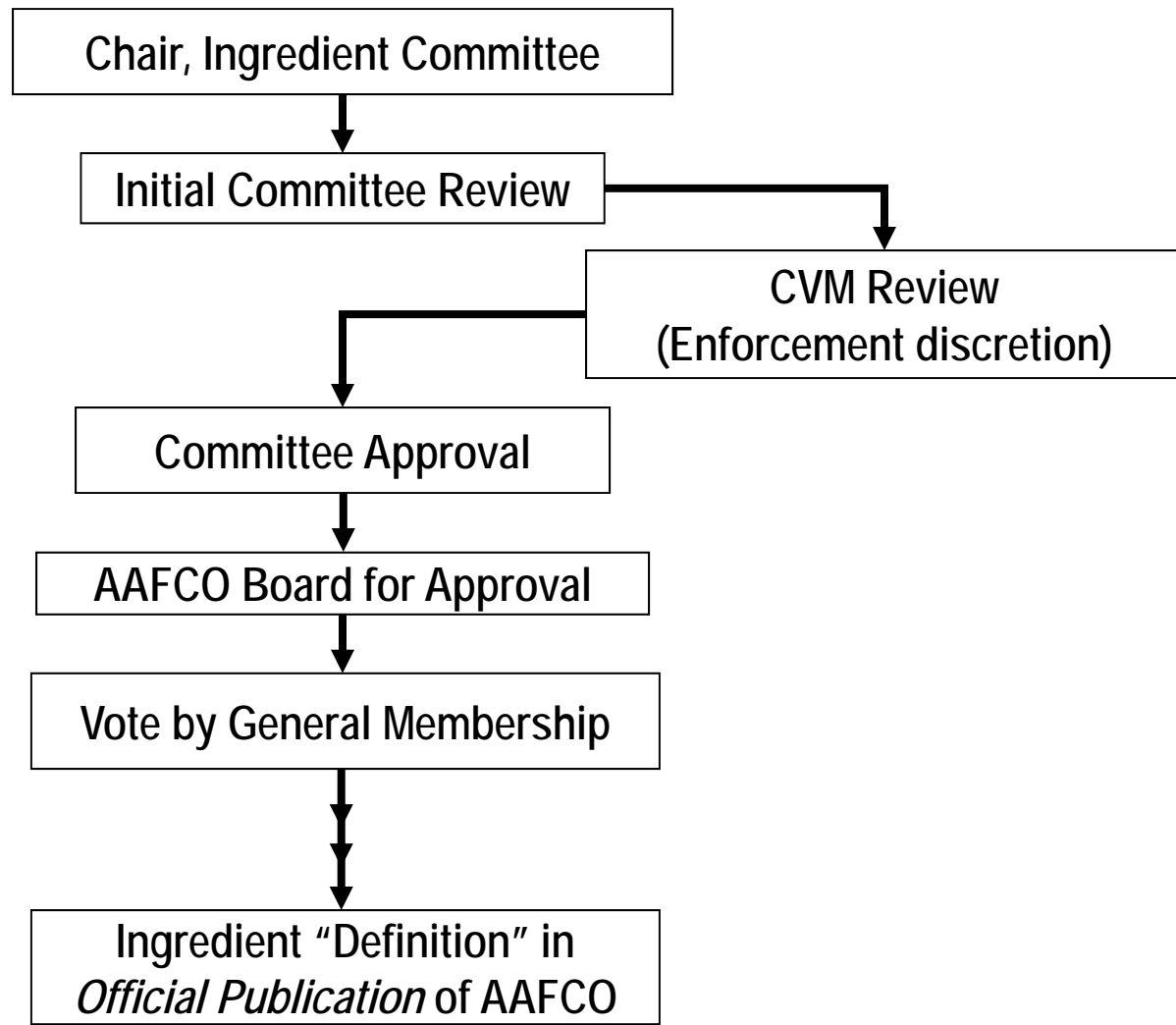




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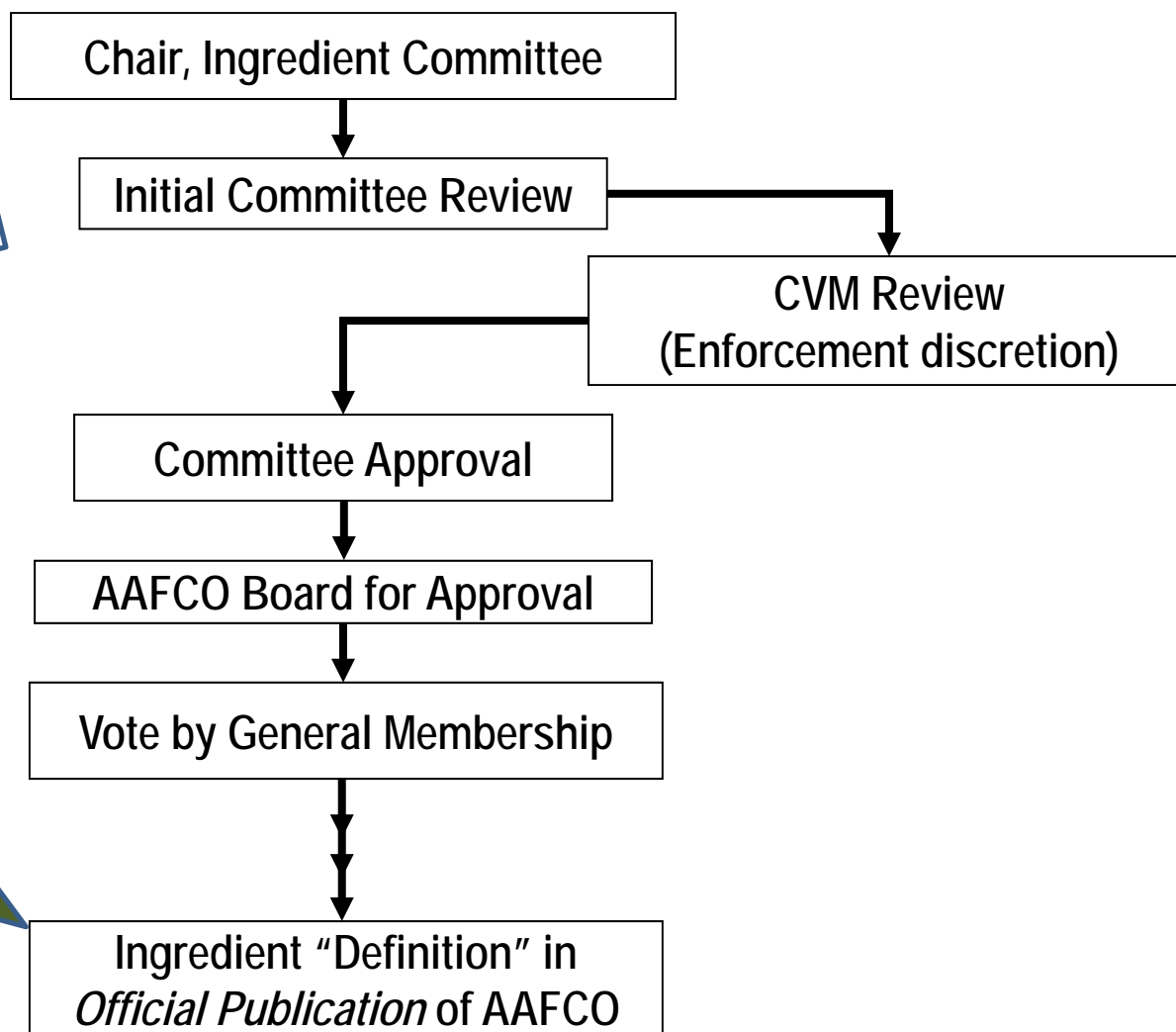


What is AAFCO?

American Association of Feed Control Officials



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





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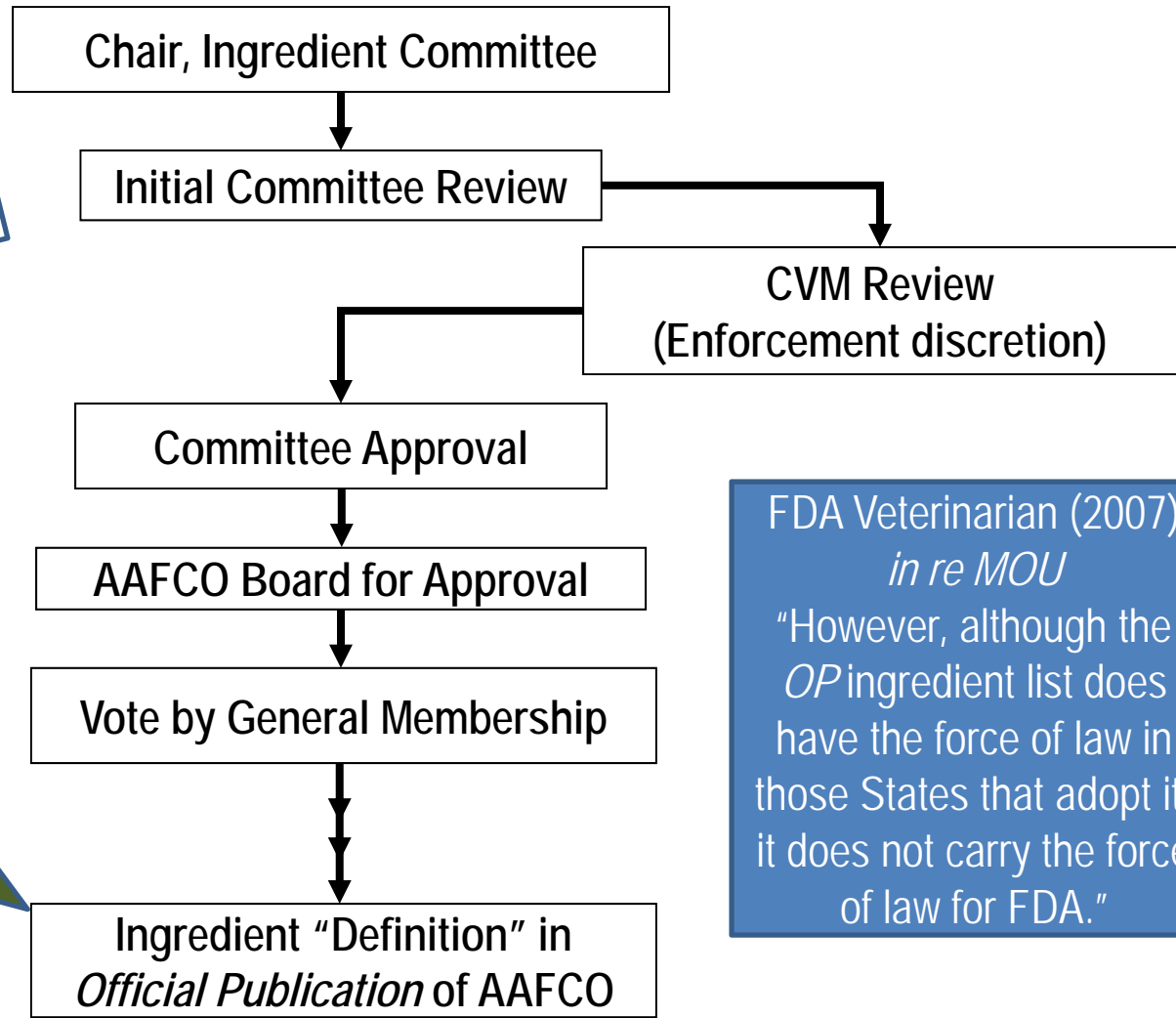
What is AAFCO?

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Is this law?

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

Here the substance is not compliant with federal statute and is not used in animals.



FDA Veterinarian (2007)
in re MOU
"However, although 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."

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

Timeline

- 2007: FDAAA – pet food ingredient standards required
- 2007: MOU recognizes practice in play for 49 years
 - “...the OP ingredient list...does not carry the force of law for FDA.”
 - “The MOU went into effect on August 30, 2007, and remains in effect until September 1, 2012.”
 - Real purpose of MOU?
- ~ 2008-9: Dr. Sundlof initiates a GRAS notification procedure
- ~2010: FDA legal counsel publicly announces a definition in OP is not a legitimate regulatory harbor
- 2012: Dr. Benz (and others) initiate a search of the OP to find non-food additives/non-GRAS substances and find >500

If AAFCO Definitions are Not a “Legitimate Home”, What Can Happen?

- All ingredients in OP (not FA or GRAS) can be declared “adulterants”
 - No protection from Administrative Procedures Act
 - Immediate recalls possible
 - Criminal and civil prosecution possible under FSMA
- Lawsuits
 - Class actions: demanding FDA “clean up” animal feed industry
 - California Plaintiff’s Bar
 - CA Legal Remedies Act
 - Unfair Competition Law
 - False Advertising Law
 - State AG’s looking to fill state coffers





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

- Industry Initiatives -

- Extension of MOU
- Regulatory/Statutory “fix”
- “Grandfather” OP substances
- FDA GRAS





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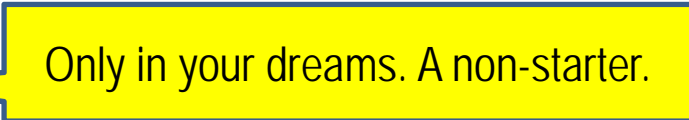
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- Extension of MOU  Temporary at best. Not a permanent solution.
- Regulatory/statutory "fix"  Dead in the water.
- "Grandfather" OP substances  Only in your dreams. A non-starter.
- FDA GRAS  Why now? CVM has done only 3 GRAS affirmations since the 1970's.

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

- Industry Resolution -

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

This is a Propitious Moment

There is a tide in the affairs of men, which taken at the flood, leads on to fortune. Omitted, all the voyage of their life is bound in shallows and in miseries.

William Shakespeare

Precedent is on your side – Time is not

The Impending Regulatory Crisis for Pet Food Ingredient Standards and Ingredient Approval

FDA, Congress,
Consumer
Groups &
Plaintiff's Bar

Deny-ers

You

The Impending Regulatory Crisis for Pet Food Ingredient Standards and Ingredient Approval – Time for the Industry to Step Up To the Plate



Speakers

David Dzanis, DVM, PhD, DACVN – President, Regulatory Discretion, Inc.

"The Regulatory Process for Pet Food Ingredient Approval"

David R. Schoneker, BS, MS – Director, Global Regulatory Affairs, Colorcon

"Overview of Self-regulating Industry Organizations"

Ray A. Matulka, Ph.D. – Director of Toxicology, Burdock Group

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