Use of Algae in Animal Foods

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Division of Animal Feeds

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Outline

- Statutes
  - Applicable Food Law
  - Non-applicable Law
  - Definitions
- Algae in Animal Foods
  - Claims
- Regulatory Pathways
- Labeling
Applicable US Food Law

- Federal Food Drug and Cosmetic Act (FFDCA)
- Food Safety Modernization Act (FSMA)
- Other Statutes
Dietary Supplement Health Education Act (DSHEA)

- Does not apply to Animals*

*Federal Register (FR) Notice 61:17706–08, April 22, 1996

Articles for Animals are Regulated as either a Food, a Drug, or a Device
Food
- Articles used for food or drink for man or other animals
  - That which provides nutrition, taste, or aroma
  - No premarket approval for foods or food additives commonly added to foods prior to 1958 (history of use)
Food Additive
  - Any substances reasonably expected to become a component, or affect characteristics of food (directly or indirectly).

  - Animal Food Additives are in 21 CFR 573
FFDCA Definitions

- Color Additive
  - Any material that imparts color to the food or to flesh of animals
  - Unless exempt...
    - 21 CFR 70 to 73
Drug

- Articles intended to diagnose, cure, treat, mitigate or prevent disease in man or other animals.

- Articles (other than food) intended to affect the structure or function of the body (i.e., apart from taste, aroma or nutritive value).
**New Animal Drug**

- Any drug *(new or old)* intended for use in animals, including use in animal feed
  - 21 CFR 510ff *(new animal drugs)*
  - 21 CFR 558 *(medicated feed)*
Why will the algae product be added to animal food?

- **It must either:**
  - Provide source of *Nutrition* to animal
  - Provide *Flavor*
  - Provide *Technical Effect* to Food
    - Defoamers, pH control, anticaking, etc
  - Provide *Color* (to food or animal flesh, eggs, etc)

*If not, it *may* be a “New Animal Drug”*
Algae in Animal Foods

- **Nutritional**
  - Nutrient,
  - Aroma/flavor,
  - Soluble/insoluble fiber,

- **Color**
  - Imparts color

- **Technical**
  - Stabilizer,
  - Emulsifier,
  - Deflocculant,
  - Defoamer
  - Sequestor,
  - Preservative,
  - Antioxidant, and/or
  - Anticaking agent, etc

**NOTE:** Human Food Approvals cannot automatically be used for Animal Foods!
Algae in Animal Foods

- **Claims**
  - Must be limited to attributes of:
    - *Nutrition, Taste, Aroma, Tech. Effect*
  - Unlike Other Counties, "Production Claims" are **not** permitted in U.S.
    - (e.g., Growth promotion, Feed efficiency, Milk production, Egg production)
  - "Drug Claims" **not** permitted, in U.S.
    - i.e., cure, treat, prevent, mitigate disease
Algae in Animal Foods

- **Claims**
  - Structure/Function Claims
  - Regulating Animal Foods with Drug Claims
    - P&P Guide 1240.3605


Materials Regulated by **Intended Use!**
No Micro-algae is currently approved as an animal food

Micro-algae may be fed as Color Additives* (*see Limitations 21 CFR part 73.185 & 73.275)

- Hematococcus pluvialis
- Spongiococcum sp.
  - Ethoxyquin tolerance see 21 CFR 573.380; 172.140

- Spirulina extract (Arthospira platensis; 21 CFR 73.530)
  - Not for animal foods! (unless amended)
Some **Macro-algae** may be fed as **Flavors***
(*see Limitations 21 CFR 582.30 & 582.40)

- *Laminaria spp.*
- *Nereocystis spp.*
- *Porphyra spp.*
- *Rhodymenia palmata* (L.) Grev.
- *Rhyodymena palmata* (L.)

*Minimum amounts to achieve intended effect*
Algae in Animal Foods

- Some **Macro-algae** may be fed
  - Dried Seaweed Meal* (AAFCO 60.76)
    - Rhodophyta, Phaeophyta, Chlorophyta
  - Dried Kelp* (AAFCO 60.19)
    - Laminariaceae, Fucaceae
  - Seaweed-derived Calcium* (AAFCO 57.73)
    - Lithothamnium corallioides
    - Phymatolithon calcareum

* See Limitations & Restrictions in AAFCO OP
Algae in Animal Foods

- By-products of Food Production
  - Manufactured as a food/feed
    - Using Food/Feed–suitable materials
  - Demonstrating Utility and Safety still required for novel materials
    - Suitability for Animal Food Easier to Substantiate
Algae in Animal Foods

**NOTE:**
- Waste Remediation Products
- Ethanol Byproducts
- Butanol Byproducts
- Other such materials

Byproducts of Food Production
Algae in Animal Foods

- Before byproducts like *these* can be fed
  - Detailed scrutiny necessary to ensure safety of animal food
    - Even if algal *family/genus/species* already used in animal food
      (differing source)
    - Safety Evaluation (TAS, HFS, Environmental)
Algae in Animal Foods

- **Address Safety Through:**
  - Manufacturing Process
    - Everything added to growth media could be in “food”
      - Substances in Human Food *not* automatically acceptable
        - i.e., Different Species
Algae in Animal Foods

- Address Safety Through:
  - Composition
    - Contaminants
  - Nutritional Value
  - Substances Accumulating in Algae
    - Intentional/Unintentional
  - Specifications Needed
    - Produce consistent ingredient
Algae in Animal Foods

- Bioengineering Safety
  - See Afternoon Session for details

Monday October 24th
4 to 5:30pm
Tract 4 – Emerging Topics: Biotech Regulation
Modernizing the Biotechnology Regulatory System: Relevance to Algal Biotechnology
Regulatory Pathways

- Food Additive (FA) Regulation
  - 21 CFR 570 to 573

- Generally Recognized as Safe Conclusion (GRAS)
  - Final Ruled Published Aug. 2016 (81 FR 54959)

- AAFCO\(^1\) Feed Ingredient Definition

- Color Additive Regulation
  - 21 CFR 70 to 73

\(^1\) Association of American Feed Control Officials
Regulatory Pathways

Food Additive (FA) Regulation
- 21 CFR 570 to 573
- Food Additive Regs. not Proprietary
  - Anyone meeting the specs can go to market
- GFI # 221 published June 2015
  - Recommendations for Preparation and Submission of Animal Food Additive Petitions
- Printed in 21 CFR 573 & AAFCO Official Publication
Regulatory Pathways

- **AAFCO**<sup>1</sup> Feed Ingredients
  - FDA–CVM Recognize ingredients in AAFCO<sup>1</sup>– OP
    - CPG Sec. 665.100
  - CVM serves as Scientific Experts to AAFCO
    - Reviewing requests for new ingredients
  - Memorandum of Understanding (MOU)
    - Current Until **October 2017**
      - [http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115778.htm](http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115778.htm)

<sup>1</sup> Association of American Feed Control Officials
AAFCO\textsuperscript{1} Feed Ingredients

- Guide to submitting an Ingredient definition
  - [http://www.aafco.org/Portals/0/SiteContent/Regulatory/Committees/Ingredient-Definitions/definition_request_guidelines_020112.pdf](http://www.aafco.org/Portals/0/SiteContent/Regulatory/Committees/Ingredient-Definitions/definition_request_guidelines_020112.pdf)
Successfully Complete 7–9 Technical Sections

1. Utility (nutrition or technical effect)
2. Target Animal Safety
3. Human Food Safety
4. Environmental Safety
5. Chemistry and Manufacturing
   a) Composition
   b) Analytical Method Validation
   c) Specifications
   d) Stability (?)
   e) Mixability (?)
6. Regulation / Definition
7. Label
8. Bioengineering

**Color Additive ➔ @ CFSAN

** Generally Applies to both AAFCO and FAP (see GFI #221)
FAP vs. AAFCO

- Items with **Safety Concerns** (TAS or HFS or Environmental) **cannot** be AAFCO Ingredients
  - Food Additive Regulation

- Items Intended to Alter Human Food (e.g., DHA, EPA)
  - Food Additive Regulation
  - Aquaculture and DHA an exception
Generally Recognized as Safe (GRAS)
- A substance cannot be GRAS
- The use of a substance may be GRAS
- A Firm’s Conclusion
  - Same Quantity and Quality of Information as FAP, but Safety & Utility Data are Public
- Under US Law Color Additives cannot be GRAS
- States not Obligated to Accept GRAS Conclusions
Generally Recognized as Safe (GRAS)

- GRAS Inventory On FDA Website (differs from CFSAN’s list!)
  
  http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm192224.htm

- Notifying FDA–CVM Voluntary
  - 7 Parts of GRAS Notice

- Final Ruled Published – Aug. 2016
  - For details see 81 FR 54959
  
  http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm516332.htm
Getting Started:

- Before Conducting Studies
  - Contact Our Office
  - We Review Study Protocols
  - See GFI #56 (protocol development)
Labeling (see 21 CFR 501; AAFCO-OP)

1. Product Name
2. Purpose Statement
3. Ingredients List
   - Label everything added to animal foods
     - Including: preservatives,
   - ID by official common or usual name (CPG 665.100)
   - In Order of Predominance (by weight)
4. Guaranteed Analysis
5. Directions for Use
6. Warning / Cautionary Statement
7. Manufacturer / Distributor
8. Country of Origin Statement
9. Net Contents
Use of Algae Animal Foods

THE END

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