Use of Bioengineering in Algae–based Animal Foods

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Outline

- Statutes
- Algae in Animal Food
- Regulatory Pathways
- Regulating Bioengineering
- Regulatory Approval of GE Algae
Applicable US Food Law

- Federal Food Drug and
  Cosmetic Act (FFDCA)

- Food Safety Modernization
  Act (FSMA)

- Other Statutes
NON-applicable US Law

- Dietary Supplement Health Education Act (DSHEA)
  - Does **not** apply to Animals*

*1996 Federal Register (FR) Notice 61:17706

Articles for Animals are Regulated as either a **Food**, a **Drug**, a **Device**, or **Color**
Algae in Animal Foods

- 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

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

- Before byproducts like *these* can be fed
  - Detailed scrutiny necessary to ensure safety of food
    - Even if algal *family/genus/species* already used in animal food (differing source)
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\textsuperscript{1} Feed Ingredient Definition

- Color Additive Regulation
  - 21 CFR 70 to 73

\textsuperscript{1} Association of American Feed Control Officials
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Regulating Bioengineering

http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/ucm520998.htm
Regulating Bioengineering

- **FDA’s Role**
  - Ensuring *safety* of all human and animal *foods*
    - Including genetically engineered *(GE)* sources.
  - Regulates products of *GE organisms* under *FFDCA* and other statutes.
  - Regulates *GE animals* under the new animal drug provisions of the *FFDCA*, and regulations for *new animal drugs*.
    - *Regulated article* is the recombinant DNA construct
Regulating Bioengineering

- FDA Committed to:
  - Ensuring Confidence in Regulatory System for Biotech Products
  - Avoid unnecessary barriers to innovation
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Regulatory Pathways

- **Successfully Complete 8–9 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. Bioengineering
  7. Regulation / Definition
  8. Label

**Color Additive \(\Rightarrow\) @ CFSAN

Generally Applies to both AAFCO and FAP (see GFI #221)
Regulation of GE Algae (Foods)

- **Bioengineering Section**
  - Gene Donor & Gene Recipient
    - Non-toxigenic & Non-pathogenic
  - Native vs. Synthetic DNA
  - Complete Sequence
  - Use of Promoters, Terminators, & Codon Optimization, etc
Bioengineering Section (con’t)

- Specificity of Insertion (or lack thereof)
- Stable construct
  - Genotypic and Phenotypic Stability
- orf Analysis
- Spillover Effect (unintended consequences)
Bioengineering Section (con’t)

- GE microorganisms must be **non-viable** in animal foods
  - A *log-reduction* is **not** acceptable
  - GE Microorganisms must be **completely dead**
Regulation of GE Algae (Foods)

- Labeling
  - Everything added to animal foods *(21 CFR 501; AAFCO OP)*
    - ID by official common or usual name *(CPG 665.100)*
  - Disclosure of GE ingredient *voluntary* for animal foods
    - 2016 *National Bioengineered Food Disclosure Standard*
      - Does *not* apply to animal foods
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THE END

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Algae in Animal Foods

- **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* (*Arthrospira platensis*; 21 CFR 73.530)
    - **Not for animal foods!** (unless first amended)
Algae in Animal Foods

- 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
Some Macro-algae may be fed for Nutrition

- 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