The FDA and Food Administration (FDA), and more specifically FDA’s Center for Veterinary Medicine (CVM), is responsible for protecting public and animal health by assuring the safety, identity, functionality, and security of animal foods and drugs. Our legal mandate comes primarily from the Federal Food, Drug, and Cosmetic Act (FFDCA) and its amendments. In addition, there are other laws that influence what FDA does, such as the National Environmental Policy Act, which ensures that CVM assesses a substance’s impact on the environment before approval of the additive.

The FFDCA definition for food is very broad:

“articles used for food or drink for man or other animals”...

Therefore, many articles that are intended to be used as an animal food ingredient, to become part of an ingredient or animal food, or are added to an animal’s drinking water are considered “food” and used as an animal food ingredient, to become part of an ingredient or animal food.

In 1958 the FFDCA was amended to:

- Define “food additive”
- Require approval of food additives before they are marketed
- Create an exemption in the food additive definition, i.e., GRAS status for a particular use of a substance

These amendments require that any substance added to an animal food must be used as stated in a food additive regulation unless the use of a substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety under the conditions of its intended use.

There are two regulatory paths to legally market a substance for use in animal foods:

- Food additive petition (FAP) to establish a regulation
- Intended use of substance is GRAS

Issues Specific for Animal Foods

- Intended use – what is the product being used for:
  - Food use
  - Color use
  - Drug use

- Which animal species?
- Companion animals
- Livestock/Aquaculture species
- Need to think about potential residues in meat, milk and eggs, i.e., human food safety

- Biobased engineering
- Bioengineered feed require specific consideration. Contact us for information.

Color Additives & Algae

A color additive is defined in the FFDCA as any compound capable of imparting color. Color additives used in animal foods are regulated by the FDA Center for Food Safety and Application (CFSAN). Approved color additives are published in 21 CFR 73, and algae products are listed among the approvals (21 CFR 73.275 and 73.185).

Many algae contain known color-impacting pigments that can intentionally or unintentionally color an animal food or edible animal products (e.g., fat, meat). Because color additives are regulated separate from “food additives,” an algae color additive is added to animal food, in addition to addressing the regulatory status of the food additive itself, its status as a color additive must also be addressed, even if the product is not intended to impart color to animal food or edible animal products.

CFSAN may grant an exemption from creating or amending a color additive regulation. If an exemption is not suitable, the regulatory status of the algae color additive must be addressed.

Substances that are GRAS for an Intended Use

There are two parts to a GRAS determination:

- Safety which is defined in 21 CFR 570.3(i).
- Same standard as for a food additive, - - general recognition to the extent that there is reasonable certainty of no harm
- General recognition as discussed in 21 CFR 570.30.

The safety determination needs to address all data and information. “Inconvenient” or contradictory data and information cannot be ignored. Regulation 21 CFR 570.3(i) lists factors to consider:

- Consumption
- Cumulative effect/ exposure
- Appropriately safe factors
- For food animal species, need to consider possibility of residual residues for human food safety.

The information needed for GRAS determination must be generally available and generally accepted by qualified experts. The information is typically presented in peer-reviewed journals. The information needed to establish the GRAS status of an intended use of a substance cannot be confidential.

Experts must be qualified and may base their safety conclusions on:

1. Experience based on common use in animal food before 1958,
2. Scientific procedures. Use of scientific procedures, which is most often utilized, requires the same quality and quantity of scientific evidence as required to obtain approval of a FAP.

GRAS status is more difficult to establish than a food additive regulation due to the added requirement for general recognition. A GRAS determination can be completed without notifying FDA.

Food Additives and the Petition Process

A food additive regulation is established by publication of the approval of a FAP based on information that a food additive is safe and achieves its intended use. The firm or person submitting the petition (petitioner) must provide data and information needed for approval.

The regulations that apply to food additives used in animal foods and that describe the FAP process are in Federal Regulations (Title 21, Part 73 of the Code of Federal Regulations (CFR) (21 CFR 731)). These regulations discuss the types of data that should be present in a FAP and the required format. Typically, the petition needs to include the following information (see 21 CFR 731.4):

- The name and all pertinent information concerning the additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and other specifications.
- Information on the source (e.g., systematic name, genus, species, variability) should be provided.
- Information in sufficient detail to permit evaluation regarding the method of manufacture and analytical controls used during manufacturing, processing, or packing of the additive that are relied upon to establish that the additive is of reproducible composition and stability.
- Amount of the additive proposed for use and purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use, as well as examples or labeling.
- Data establishing that the additive will have the intended effect and the amount necessary to accomplish the effect.
- Description of practicable analytical methods to determine the amount of the additive in raw, processed, and, or finished animal food.
- Data and information demonstrating safety, meaning that there is reasonable certainty of no harm from the proposed use of the additive. The safety assessment must include:
  - Human food safety when the additive will be used in food producing animals, including whether a tolerance for tissue residues must be established.
  - Target animal safety for the animal species that will consume the additive.
  - Studies to do cross-species comparisons.
  - Studies in target species are often necessary.
- Environmental safety as described in 21 CFR 25.
- Proposed regulation for the additive addressing the intended use(s).

FAPS must be submitted and organized as described in 21 CFR 571.1 (in lieu of a triplicate submission, a single hardcopy may be accompanied by a CD/DVD). Any data or information are in a foreign language, accurate and complete English translations must be provided. See 21 CFR 571.1 for the complete requirements for submission of FAPS for animal foods used.

GRAS Notification

CVM announced its implementation of a pilot notification program in a June 4, 2010 Notice in the Federal Register. The pilot is based on 1997 proposal to review GRAS notification petitions.

Eighteen notices for animal food have been received to date

A GRAS Notice informs FDA of the notifier’s determination that a particular use of a substance is GRAS. It is the notifier’s determination and responsibility. A GRAS notice is a summary document. FDA transmits its response to the notifier by letter. An inventory of GRAS notices and FDA responses is on the internet. (http://www.fda.gov/animalveterinary/products/animalfood/GRAS/GeneralRecognizedAsSafeGRASNotifications/default.htm).

Two points to remember:

- Substances are not GRAS, it is a particular use of a substance that is GRAS. For example, sodium aluminosilicate is GRAS as an anticaking agent in animal food. It is not GRAS to bind mycotoxins.
- Animal food use of substances varies with the animal species. Thus, animal food GRAS determinations must address intended use in the intended animal species.

Algae Products

There are only two codified GRAS uses of algae products:

1. Natural substances used in conjunction with spices and other natural seasonings and flavorings (21 CFR 582.40).  
2. Natural extracts (solvent-free) used in conjunction with spices, seasonings, and flavorings (21 CFR 582.40).

Note: generics restrictions, and use rate limitations (i.e., only as related to spice/flavor)

Ingredient Definition Process

The Association of American Feed Control Officials (AAFCO) is composed of state, federal, and international regulatory officials who are responsible for the enforcement of laws regulating the safe production and labeling of animal food.

FDA and AAFCO work together in the area of animal food regulation, particularly in the establishment of definitions to describe new ingredients. Establishment of an animal food ingredient definition is possible when there are no apparent safety concerns about the intended use and composition of a substance.

Each year AAFCO publishes its Official Publication (OP), which includes a model feed bill for states to adopt in regulating animal food products and a list of accepted animal food ingredients.

Algae product ingredients include definitions 87, 1.019, and 56.76 within the AAFCO OP. Note restrictions to specific plant family, genus, and intended use.

Algae

FDA Food Safety Modernization Act (FSMA) was passed and shifts the focus for food safety from responding to contamination to preventing it. FSMA includes animal foods.

Where to Find More Information

- FDA Regulation of Animal Foods (http://www.fda.gov/SafetyFood)
- CVM GRAS Notification Program (http://www.fda.gov/AnimalVeterinary/Products/AnimalFeed/GRAS/GRASSubstances/GRASNotifications/default.htm)
- CFSAN Color Additive Program (http://www.cvm.fda.gov/coloradditives)
- FDA Food Safety Modernization Act (FSMA) (http://www.fda.gov/ForIndustry/ColorAdditives/)
- AAFCO Ingredient Definition Process (http://www.aaftc.org/Directory/CommitteePages/GreenerDefinitions.aspx)

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Regulatory Processes for Using Algae Biomass or Algae Products in Animal Food

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