Global Expert in New Food Ingredient Registration

Guide to U.S. Animal Food Ingredient Regulatory Submissions: ——Animal Food GRAS Notices, Food Additive Petitions, FDA AFIC, and AAFCO SRIS

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U.S. Local Team: Based in Virginia, our U.S. team includes full-time food regulatory and toxicology experts, including 2 DABTs, 1 ERT, and 24 DCSTs. We support clients with U.S. compliance services covering FDA GRAS, NDI, CAP, Animal Food GRAS, FDA AFIC, and AAFCO SRIS.

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Chapter 1: U.S. Animal Food Regulatory Access Framework

1.1 Scope of the U.S. Definition of Animal Food

In the United States, animal feed is regulated under the broader category of food. From the outset, U.S. laws and regulations governing feed have been built on the principle that "animal food is food".

- **Statutory definition:** Under Section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), "food" means "articles used for food or drink for man or other animals …." Consequently, **animal food**—defined as food intended for consumption by animals other than humans, including pet food, other animal food, and their raw materials and ingredients—falls squarely within this statutory definition. This is the basis for the principle that "animal food is food."
- **Scope of regulation:** Any substance intended for use as an ingredient in animal food, to become a component of animal food, or to be added to animal drinking water is categorized as "food" and must comply with the applicable regulations. Additives used in animal food are generally regulated under the food additive framework; accordingly, the term "**feed additive**" is used interchangeably with "food additive" in this context. That said, the food additive definition does not extend to the following, which are subject to separate statutory authorities: color additives, ingredients used in dietary supplements, new animal drugs, pesticide residues in agricultural products or processed foods, chemical pesticides, and other such components.

**Note: In this guide, "animal food" refers to feed.*

1.2 The U.S. Animal Food Regulatory System

✧ Dual federal-state regulation

As a federal republic, the United States allows individual state governments—while complying with federal law—to enact their own commercial feed statutes reflecting local industry conditions (for example, the Kansas Commercial Feeding Stuffs Act and the Washington Commercial Feed Law). These state laws typically prescribe detailed requirements on product labeling, sales licensing, on-site inspection, registration, administrative fees, nutrient analysis, and recordkeeping. Consequently, feed products are subject not only to federal FDA oversight but also to state-level requirements in every state where they are marketed.

Chapter 2: Food Additive Petition (FAP)

2.1 What Is a Food Additive Petition (FAP)?

Under Sections 201(s) and 409 of the U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act) , any substance intended to be added to food is considered **a food additive** and must undergo premarket review and approval by the U.S. Food and Drug Administration (FDA).Unless qualified experts unanimously agree that the substance is generally recognized as safe (GRAS) under its intended conditions of use, or the substance's use does not fall under the definition of a food additive (for example, substances that meet the definition of a pesticide, dietary ingredients in dietary supplements, color additives, new animal drugs, or substances authorized or approved for use prior to September 6, 1958, are excluded from the definition of a food additive).

If a manufacturer intends to introduce a completely new feed additive, or to apply for an additional use or animal species for an already approved additive, it must submit a FAP application to the FDA. The FDA will add or amend the relevant entry in the Code of Federal Regulations (CFR) only after determining that the safety and efficacy of the additive have been sufficiently substantiated by scientific evidence. All food additives approved through the FAP process and permitted for addition to animal feed and drinking water are listed in Title 21, Part 573 (21 CFR Part 573). Once an additive is approved, manufacturers must strictly limit its commercial use to the specifications set forth in the 21 CFR Part 573 regulatory entry. Any action that exceeds the provisions of this entry is considered a violation of the law.

Figure 2-1 List of Approved Feed Additives

Chapter 3: Generally Recognized as Safe (GRAS)

3.1 Definition and Classification of GRAS

GRAS, an acronym for “Generally Recognized as Safe,” is a very important category within the U.S. food regulatory system. A substance is considered GRAS if a panel of scientifically trained, experienced, and qualified experts determines, through scientific procedures or a sufficient history of use prior to 1985, that it is safe under its intended conditions of use. In the United States, GRAS certification is a flexible and expedited means of market entry that exempts food additives from premarket approval.

Currently, GRAS certification in the United States can be divided into two categories:

- **Self-GRAS**

Any individual or organization may make a Self-GRAS determination, based on a qualified expert panel's conclusion that the substance is safe under its intended conditions of use. This type of GRAS determination is not submitted to FDA, is not reviewed by FDA, and generally is not disclosed publicly.

- **FDA GRAS Notification (GRAS Notice)**

Any individual or organization may submit a completed Self-GRAS determination to FDA as a GRAS Notice, and FDA will review that GRAS determination.

There is no legal difference between a Self-GRAS determination and an FDA GRAS Notification. However, because an FDA GRAS Notice is filed with the agency, this type of GRAS is generally considered more "authoritative".

CIRS Note:

The FDA published a proposed rule on GRAS reform on August 11, 2026. The core change of this new regulation is the requirement that substances in human and animal foods claimed to be GRAS must submit a GRAS notification. Therefore, companies whose feed ingredients have obtained U.S. marketing authorization solely through the Self-GRAS pathway are advised to monitor regulatory developments and promptly prepare for FDA GRAS notifications.

Chapter 4: Animal Food Ingredient Consultation (AFIC)

4.1 What Is AFIC

In October 2024, when the 17-year Memorandum of Understanding (MOU) between AAFCO and FDA officially expired and was not renewed, the traditional joint-review mechanism for ingredient definition applications was terminated. At the same time, FDA is evaluating its Food Additive Petition (FAP) and GRAS notification programs to determine whether adjustments are needed to support the efficient development and review of new feed additives.

Against this backdrop, FDA established an interim transitional measure—the Animal Food Ingredient Consultation (AFIC) program — for voluntary consultation with companies developing feed ingredients. AFIC is designed to offer a new, streamlined review route for companies that might otherwise have relied on the AAFCO ingredient-definition process.

Under FDA Guidance for Industry #294, "Animal Food Ingredient Consultation (AFIC)," a company may submit an animal food ingredient consultation to FDA. The applicant must prepare a detailed dossier covering the manufacturing process, target animal species, and safety evaluation. Once the submission clears FDA's initial screening, it is posted on FDA's website. For the first 90 days, interested stakeholders may submit supplemental information—for example, on the safety of the product—while FDA conducts its technical review in parallel. If FDA identifies no safety concerns after its evaluation, it will issue a "consultation completion letter."

Characteristics of AFIC

- **FDA Consultation Completion ≠ FDA Approval**

AFIC does not constitute food additive approval, nor does it constitute a GRAS determination. Once an AFIC is complete, the concluding letter FDA issues is fundamentally an exercise of enforcement discretion. The letter typically includes language such as: " At this time, we have no questions or concerns about the safety of this ingredient when used in accordance with the conditions of intended use described in this letter. FDA generally does not anticipate initiating enforcement action with respect to the food additive approval requirements of the Federal Food, Drug and Cosmetic Act for this ingredient or animal food containing this ingredient as long as