National Grain and Feed Association

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NGFA Guidance on Animal Food Ingredients and Supplier Selection

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Approval/Recognition Processes for Animal Food Ingredients

The Federal Food, Drug, and Cosmetic Act (FFDCA)[1] gives the U.S. Food and Drug Administration (FDA) the authority to regulate ingredients and additives used in animal food. As defined by FDA, the term "animal food" means "food for animals other than man and includes pet food, animal feed, and raw materials and ingredients." As such, the term "animal food" encompasses animal feed and pet food, and components used to make such products, such as grains, oilseeds, animal- and plant-based ingredients, minerals, vitamins and other items.

In accordance with the 1958 Food Additives Amendment to the FFDCA, any substance that is reasonably expected to result, directly or indirectly, in becoming a component of or otherwise affecting the characteristics of animal food is a food additive that is subject to premarket approval by FDA, unless the 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, or meets one of the other exclusions from the food additive definition in section 201(s) of the FFDCA.

Thus, animal food ingredients and additives may gain federal approval and/or recognition in the United States for their intended use by premarket approval by FDA or a determination of GRAS status. Among other things, these methods focus on: 1) the safety of the ingredient, usually for a specific use; 2) ingredient effectiveness, if claimed for specific uses; 3) the manufacturing chemistry of the ingredient, if any; 4) manufacturing and/or extraction processes used to produce the ingredient; 5) use limitations; 6) potential toxicity associated with the ingredient; and 7) levels of known and/or potential contaminants.

Following is information about FDA's premarket approval process, GRAS determinations and other methods whereby an ingredient may be approved or recognized as acceptable for use in animal food.

- **FDA Food Additive Petition[2]:** Title 21, Code of Federal Regulations (CFR), Part 571 establishes FDA's food additive petition process through which ingredients may gain premarket approval. Animal food ingredients that are demonstrated to be safe and effective are approved by FDA as Animal Food Additive Petitions. 21 CFR Parts 573[3] and 579[4] list food additives currently permitted by FDA in the food or drinking water of animals. In addition, FDA-approved color additives for use in animal food are listed in 21 CFR Parts 73[5], 74[6] and 81[7]. These ingredients may be legally used only within the scope of their regulatory approval.

- **Generally Recognized as Safety (GRAS)[8]:** An ingredient can be GRAS for a specific use in animal food if there is consensus about its safety for that use among experts qualified by scientific training and experience to evaluate the ingredient. Significantly, an ingredient is not GRAS for all uses, but only for the use specifically identified in the GRAS determination.

A GRAS determination consists of two parts: 1) safety; and 2) common knowledge. Non-government qualified experts may make the safety determination based upon either: 1) scientific procedures that require the same quantity and quality of data/information necessary for approval of a food additive petition; or 2) common use of the ingredient in animal food prior to Jan. 1, 1958. The second part of a GRAS determination involves the general recognition element; such as whether there is common knowledge about the ingredient's use in animal food within the scientific community. The common knowledge elements require the information used as the basis of a GRAS determination be in the public domain. Private or proprietary information/data cannot be the sole basis used to determine an ingredient is GRAS.

FDA's regulations at 21 CFR Part 570.30 establish criteria for eligibility for classification of an animal food ingredient as GRAS.

After passage of the 1958 Food Additives Amendment which provided for GRAS determinations, FDA clarified the regulatory status of many food substances that were used in food prior to 1958 and amended its regulations to include a list of food substances that, when used for the purposes indicated and in accordance with current good manufacturing practices, are GRAS. The GRAS lists for animal food substances affirmed by FDA are found at 21 CFR Part 582[9] and 21 CFR Part 584[10]. Significantly, FDA states in its regulations that these parts do not include all substances that are generally recognized as safe for their intended use in animal food.

Currently, FDA no longer affirms the GRAS status of animal food ingredients. Instead, FDA in 2010 implemented a voluntary GRAS notification program through which a "GRAS notice" for an animal food ingredient may be voluntarily submitted to FDA for review. The GRAS notice is to summarize the data and information that the submitter relied upon to determine that the use of the ingredient in animal food is GRAS. Once received, FDA evaluates the submitted GRAS notice to determine if there is sufficient basis to support the submitter's claim. After the evaluation, the agency informs the submitter in writing either that the notice provides a sufficient basis for the GRAS determination – referred to as a "no-questions letter" – or that FDA has identified questions as to whether the intended use of the ingredient is GRAS. Such response letters are made available to the public on FDA's Current Animal Food GRAS Notices Inventory[11].

Animal food GRAS determinations also may legally be made by qualified experts without notification to FDA. Such determinations commonly are referred to as "independent GRAS conclusions." Although allowed by federal law, FDA strongly encourages persons who intend to market an animal food ingredient on the basis of a GRAS determination to submit a GRAS notice to FDA. In addition, state regulatory officials who have local jurisdiction for the manufacture and distribution of commercial animal food may not accept animal food ingredients within their state that have not been approved and/or recognized through a process involving FDA review.

- **AAFCO Ingredient Definition Process:** The Association of American Feed Control Officials (AAFCO)[12] – the professional organization of state and federal feed regulatory officials – administers an "Informal Review Sanctioned" ingredient definition process whereby animal food ingredients may be recognized by FDA and states as acceptable for use. Within this process, the ingredient sponsor works with the designated AAFCO representative assigned to the relevant ingredient product category to submit a package of information about the proposed ingredient to AAFCO and to FDA for a review of safety and efficacy. AAFCO and FDA have entered into a Memorandum of Understanding (MOU)[13] that describes the roles of both organizations in creating or modifying animal food AAFCO ingredient definitions.

  The AAFCO *Official Publication* contains the most complete list of ingredients with their definitions that are approved or recognized as acceptable for use in animal food. The *Official Publication* includes the list of approved animal food additives as well as a list of substances that are GRAS for an intended use. Although many of the ingredients in the *Official Publication* are not approved food additives and may not meet the criteria needed to be recognized as GRAS for a specific use, FDA has accepted the listing of such ingredients in the *Official Publication* for their marketing in interstate commerce, provided there were no apparent safety concerns about the use or composition of the ingredient. FDA also accepts the names of the animal food ingredients as defined in the *Official Publication* as the common or usual names of the ingredients (FDA Compliance Policy Guide 665.100)[14]. In addition, state feed regulators recognize the ingredients listed in the *Official Publication* as being acceptable for use. AAFCO has made Chapter 6 of the *Official Publication* that includes feed terms, names, and definitions available to the public free of charge on its website[15].

- **Common or Usual Name:** In accordance with commercial feed law provisions in many states, some ingredients are so commonly used in animal food and are ordinarily understood that they do not require a definition, as provided by Regulation 6(a) of the Model Regulations found in the AAFCO *Official Publication*. Salt, sugar, water, corn, oats and barley are good examples of ingredients described by common and usual names. Materials that are uncommon or not well understood by individuals involved in animal feeding may not meet this common-knowledge threshold.

- **Approved by the State Secretary of Agriculture:** If a state has adopted Regulation 6(a) of the AAFCO Model Regulations, the state's secretary or commissioner of agriculture has the authority to approve feed ingredients and their names. This regulation permits state authorities to allow the use of products locally available that are suitable for use in animal food.

- **Other Possibilities:** There are other possible options for recognizing the use of a substance as an animal food ingredient, including: 1) pesticides approved by the U.S. Environmental Protection Agency for use in animal food; and 2) biologic products approved by U.S. Department of Agriculture.

Other Regulatory Considerations for Animal Food Ingredients

The Food Safety Modernization Act (FSMA)[16] – signed into law on Jan. 4, 2011 – mandated that FDA issue significant regulatory requirements for human and animal food facilities. In several cases, the regulations establish requirements related to the safety of ingredients used in animal food. Following is a summary of FSMA-related regulations that address the safety of animal food ingredients.

- **Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications[17]:** On Nov. 27, 2015, FDA published a final rule that provides for FDA accreditation of third-party certification bodies to conduct food safety audits of foreign human and animal food entities and to issue food and facility certifications under FSMA. These certifications are required for participation in the voluntary qualified importer program (VQIP) – a voluntary, fee-based program mandated by FSMA to allow the expedited review and importation of foods into the United States from importers who achieve and maintain a high level of control over the safety and security of their food supply chains. In addition, when FDA has determined that an imported food is subject to certification under FSMA because of the risk it poses to public and/or animal health, the agency may require a certification under this rule as a condition for admitting the human or animal food into the United States.

- **Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP)[18]**: FDA on Nov. 27, 2015 published its final rule to establish FSVP requirements for importers of food for humans and animals to ensure the safety of imported food. The regulation requires importers to verify that food they import into the United States is: 1) produced in compliance with the hazard analysis and risk-based preventive controls requirements established under other FSMA-related rules; 2) not adulterated; and 3) not misbranded.

  Covered importers are responsible for developing and implementing a written FSVP that includes analysis of hazards and implementation of risk-based controls. To do so, a qualified individual, as defined within the rule, is required to develop, implement and oversee the plan.

  The importer's FSVP is to include:

  - **Hazard Analysis**: A written hazard analysis is to be conducted by the importer's qualified individual to identify and evaluate "known or reasonably foreseeable hazards" associated with the food and its foreign supplier. The hazard analysis is to include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of controls.

- **Foreign Supplier Approval and Verification:** If an importer conducts a hazard analysis and appropriately determines the foreign food has no hazards requiring a control, then the importer does not need to conduct supplier approval and verification activities. This exemption from further supplier approval and verification activities does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined by FDA's produce safety rule.

  If the hazard analysis does establish there is a hazard requiring a control, then the hazard must be controlled by either: 1) the foreign supplier; or 2) the importer (when the importer is subject to FDA's preventive controls rules); or 3) the importer's customer.

  In cases when the importer controls the hazard, importers subject to and in compliance with FDA's final rules that established preventive controls requirements for human and animal food are deemed to be in compliance with the FSVP requirements if the importer, in accordance with the preventive controls rules, has implemented preventive controls to address the hazard(s) in the food.

  In cases when the importer relies on the foreign supplier to control the hazard in the food, the rule establishes that the importer is required to:

  - Approve the foreign supplier based on an evaluation of the foreign supplier's performance and the risk posed by the food.

  - Establish and follow written procedures to ensure foods are imported only from foreign suppliers that have been approved based on the evaluation conducted under the rule's requirements (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods are subject to adequate verification activities before importing the food). The importer is required to document the use of the written procedures.

  - Develop written supplier verification activities and conduct such activities to provide assurance the hazard requiring a control has been significantly minimized or prevented. The rule specifies that such supplier verification activities may include:

    - On-site audits of the foreign supplier's facility. Significantly, the rule requires an annual on-site audit when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a "SAHCODHA" hazard), unless there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance the hazard is controlled. When conducted, audits are to be performed by a "qualified auditor" as defined by the rule.

- Sampling and testing.

- A review of the supplier's relevant food safety records.

- Other appropriate supplier verification activities, as provided by the rule.

- **Sanitary Transportation of Human and Animal Food**[19]. FDA on April 6, 2016 published final regulations for the sanitary transportation of human and animal food that establish requirements for shippers, loaders, carriers, and receivers to use sanitary transportation practices to ensure the safety of food and feed when shipped by truck or rail.

  Under the rule, vehicles and equipment used in food transportation operations are to be designed of such material and workmanship so as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe. In addition, the sanitary condition of vehicles and transportation equipment is to be maintained to prevent food from becoming unsafe during transportation operations. Further, vehicles and transportation equipment are to be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in unsafe food.

  General requirements of the rule require that: 1) competent supervisory personnel be assigned to ensure transportation operations are carried out in compliance with all requirements of the rule; 2) all transportation operations be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations (e.g., taking effective measures, such as segregation, isolation or other protective measures to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination); and 3) not selling or further distributing food if an entity covered by the rule becomes aware of an indication of conditions that may render the food unsafe during transportation until a qualified individual accesses the situation.

  The rule also establishes specific requirements that procedures be implemented to ensure a previous cargo does not make food unsafe during transportation, and that vehicles and transportation equipment are in a suitable condition prior to loading bulk food.

- **Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Preventive Controls Rule for Animal Food)**[20]**:** FDA on Sept. 17, 2015 published a final rule establishing current good manufacturing practice and preventive controls requirements for animal food, including animal food ingredients.

The Preventive Controls Rule for Animal Food has three distinct subparts that establish requirements for covered facilities to: 1) adhere to specified current good manufacturing practice (CGMPs); 2) conduct a hazard analysis of ingredients and processes associated with their operations and implement risk-based preventive controls, as needed; and 3) implement a supply-chain program to verify that its supplier of an ingredient controls a hazard requiring a preventive control if the facility relies on the supplier to control such a hazard.

- **CGMP Requirements:** Provisions within the CGMP regulations related to ingredients include:

  - Animal food ingredients are to be examined to ensure they are suitable for manufacturing and processing into animal food. An examination of raw materials or other ingredients may, among other things, include: 1) reviewing specifications, guarantees, or other associated information received by the facility; 2) performing a visual check of the animal food and/or its packaging; 3) performing relevant sampling and testing; and 4) getting information from the transporter about shipping conditions (e.g., transport time, weather).

  - If animal food ingredients are susceptible to contamination with mycotoxins or other natural toxins, they are to be evaluated and used in a way that does not result in an animal food that can cause injury or illness to animals or humans.

- **Hazard Analysis and Risk-Based Preventive Controls Requirements:** A written hazard analysis is to be conducted and/or overseen by a preventive controls qualified individual, as defined within the rule, to identify and evaluate "known or reasonably foreseeable hazards" within the animal food facility's operations. The hazard analysis is to include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. Determinations made during the hazard analysis are to be justified. Further, this analysis is to consider the effect of specified factors on the safety of the animal food distributed by the facility, including raw materials and ingredients received by the facility; transportation practices, and other relevant factors (e.g., levels of natural toxins).

  The rule requires preventive controls to be implemented for those identified hazards the preventive controls qualified individual determines require one or more preventive control(s) to be significantly minimized or prevented. As with the FSVP regulations, the rule specifies that if the hazard analysis does establish there is a hazard requiring a preventive control in a raw material or ingredient received by the facility, then the hazard is to be controlled by either: 1) the supplier of the raw material or ingredient; or 2) the animal food facility itself; or 3) the animal food facility's customer.

- **Supply-Chain Program:** The final rule requires an animal food facility to have a risk-based supply-chain program for those raw materials or other ingredients for which the facility has identified a hazard requiring a preventive control that will be controlled by the supplier of the raw material or ingredient. Animal food facilities that control such a hazard requiring a preventive control within their own operations, or who follow requirements applicable when relying on a customer to control such a hazard, are not required to have a supply-chain program for ingredients with the identified hazard.

  Importantly, the final rule's definition for "supplier" plays a key role in how and whether a facility may use a supply-chain-applied preventive control to significantly minimize or prevent a hazard in a raw material or ingredient that it receives. The definition for "supplier" is "the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature."

  Therefore, an establishment that provides a raw material or other ingredient to a receiving facility is a "supplier" only if it manufactures/processes the raw material or ingredient, raises the animal, or grows the raw material or ingredient that is provided to a receiving facility without further manufacturing/processing by another establishment.

  As an example of how the "supplier" definition works in practice, consider the supply chain for corn used by a feed mill that consists of many farmers delivering corn to a country grain elevator, then the country grain elevator delivering corn to a terminal grain elevator, and then the terminal grain elevator delivering corn to the feed mill.

  In this supply-chain scenario, the country grain elevator and terminal grain elevator are not "suppliers" because these establishments only held (stored) the corn and did not grow or manufacture/process the corn. So, for this supply chain, the farmers are the "suppliers," since the farmers are the establishments that grew the corn and no further manufacturing/processing of the corn occurred prior to receipt by the feed mill. Further, the suppliers of the corn to the feed mill likely are not only the farmers who delivered corn to the country elevator, but also the farmers whose corn was stored at the terminal elevator and which was commingled with corn received from the country elevator.

  The practical application of the definition for "supplier" is important because if a facility chooses to rely on a supply-chain program as a preventive control, the facility must approve the supplier of the raw material or ingredient according to the preventive controls rule. As illustrated by the supply chain example above,

within a complex supply chain where raw materials or ingredients are obtained from multiple sources, handled in a commingled nature and stored by one or more entities, it may be difficult, if not impossible, to identify the "supplier" of the raw material or ingredient.

If there is a hazard requiring a preventive control associated with a supplier's raw material or ingredient and the facility relies on the supplier to control the hazard, the rule requires that the facility:

- Receive that raw material or ingredient only from approved suppliers, or on a temporary basis from unapproved suppliers whose raw materials or ingredients are subject to verification activities before being accepted for use. The facility must approve the supplier of the raw material or ingredient and cannot rely on another entity to perform this approval. In addition, the facility is to develop and implement written procedures to ensure the raw material or ingredient is received only from approved suppliers.

- Perform activities to verify the supplier or other designated entity is adequately controlling the hazard, including, as appropriate to the raw material or ingredient and its supplier:

  - Conducting annual onsite audits of the supplier's operations. Significantly, for a raw material or ingredient with a hazard requiring a preventive control and for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA hazard), the supply-chain program requires an annual onsite audit be conducted of the supplier unless there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance the hazard is controlled. The onsite audit is to be conducted by a qualified auditor that is an employee of the receiving facility or a separate third-party organization.

  - Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.

  - Reviewing the supplier's relevant animal food safety records.

  - Other appropriate supplier verification activities based upon the risk associated with the ingredient and the supplier.

Suggestions for Selection of Animal Food Ingredient Suppliers

The quality and safety of animal food ingredients may vary between suppliers, and even between different facilities of the same supplier, based on the scope and consistency of the operational procedures, quality assurance practices and safety systems in use. Therefore, a critical part of the process of sourcing ingredients that meet necessary quality and safety parameters involves having a sound business relationship with, and understanding of, ingredient suppliers, including their product quality and safety procedures.

Animal food manufacturers/distributors are to comply with applicable regulatory requirements, which may include following CGMPs, conducting an analysis that involves evaluating known and reasonably foreseeable hazards associated with ingredients, and implementing risk-based preventive controls, including a supply-chain program, as necessary. In all cases, ingredients used and/or distributed are to be approved/recognized for their intended use.

The following sample checklist provides steps that animal food manufacturers/distributors may wish to consider when selecting suppliers of ingredients. The sample checklist includes examples of risk-based practices to assist animal food facilities evaluate the quality and safety of ingredients. However, since each operation is unique, all of the steps outlined within the sample checklist may not be relevant for a specific facility or for specific suppliers of certain ingredients. Further, additional steps, not listed in the sample checklist, may need to be performed for appropriate supplier selection. Animal food manufacturers/distributors should consider implementing those practices to select ingredient suppliers that will be effective in identifying suppliers who can consistently provide ingredients of necessary quality and safety specifications. Importantly, for those animal food facilities that are required to approve suppliers under FDA's FSVP rule or Preventive Controls Rule for Animal Food, this sample checklist is not intended to be a substitute for supplier verification activities required by those regulations.

Animal Food Ingredient Supplier Sample Checklist

Supplier Information

Name: _____

Address: _____

Phone number: _____

Email address: _____

FDA Bioterrorism food facility registration number(s): _____

Ingredient(s) provided:

_____

_____

Name of supplier representative(s):

_____

_____

Ingredient Information		Date	Comments
□ Yes □ No	Specification sheet approved		
□ Yes □ No	Material safety data sheet (MSDS) approved		
□ Yes □ No	Labeling approved		
□ Yes □ No	List of potential contaminants evaluated		
□ Yes □ No	Historical nutrient and contaminant analytical data approved		
□ Yes □ No	Certificate of Analysis approved		
□ Yes □ No	Country of origin for components of ingredient provided		

Supplier Quality Assurance and Animal Food Safety Practices		Date	Comments
□ Yes □ No	Supplier facility/operations observed and evaluated, as appropriate		
□ Yes □ No	Procedures provide for routine testing of nutrients/contaminants, with analytical testing results available		
□ Yes □ No	Procedures implemented to address relevant biosecurity concerns		
□ Yes □ No	Procedures include sample retention procedures by lot number		
□ Yes □ No	Procedures implemented for disposition of non-conforming products		
□ Yes □ No	Procedures implemented to address customer complaints		

Supplier Quality Assurance and Animal Food Safety Practices (cont.)		Date	Comments
□ Yes □ No	Procedures implemented for product recalls		
□ Yes □ No	Supplier practices conform with applicable federal and state regulatory requirements		
• FDA Current Good Manufacturing Practices for medicated feeds *(21 CFR 225.10 – 225.115, 21 CFR 225.120 – 225.202)*			
• FDA BSE-prevention feed regulations *(21 CFR 589.2000 and 21 CFR 589. 2001)*			
• FDA Bioterrorism Recordkeeping requirements *(69 FR 71561)*			
• FDA FSVP regulations *(21 CFR 1, Subpart L)*			
• FDA CGMP and Preventive Controls for Food for Animals *(21 CFR Part 507)*			
• FDA Sanitary Transportation for Human and Animal Food *(21 CFR Part 1, Subpart O)*			
□ Yes □ No	Audit results conducted by qualified auditor are available that demonstrate compliance to quality/safety systems		

Supplier Terms		Date	Comments
□ Yes □ No	Supplier has agreed in writing to meet all specified requirements		
□ Yes □ No	Product warranty received, which indicates regulatory approval/recognition and suitability for use in animal food		
□ Yes □ No	Certificate of product liability insurance approved		

This supplier is approved to supply the listed ingredient(s). A review of this supplier's approval is to occur by this date: _____

Approved by: _____ Date: _____

(Authorized Quality Assurance/Regulatory Representative)

Approved by: _____ Date: _____

(Authorized Nutrition Representative)

Approved by: _____ Date: _____

(Authorized Purchasing Representative)

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