

GUIDANCE FOR INDUSTRY #__ RECOMMENDATIONS FOR SELECTING SUPPLIERS OF SAFE INGREDIENTS FOR ANIMAL FOOD - - DRAFT GUIDANCE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

CONTAINS NON-BINDING RECOMMENDATIONS

Guidance for Industry

RECOMMENDATIONS FOR SELECTING SUPPLIERS OF SAFE INGREDIENTS FOR ANIMAL FOOD (CVM)

This guidance document represents the agency's current thinking on methods for selecting suppliers of safe ingredients to utilize in the manufacturing of animal feed and pet food.

It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

The federal Food, Drug and Cosmetic Act (FD&CA) prohibits the introduction into interstate commerce of adulterated animal food products. In recent years, the FDA has seen several instances of animal food product adulteration that were the direct result of using adulterated feed ingredients. This causes the products to be adulterated and may result in requests for recall and other sanctions provided for in the act.

Comments and suggestions regarding this guidance should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select "[XXD-XXXX][Recommendations for Selecting Suppliers of Safe Ingredients for Animal Food]" and follow the directions. All written comments should be identified with Docket No.XXD-XXX.

For questions regarding this guidance document, contact ----, Center for Veterinary Medicine (HFV- XX), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-XXX-XXX. Email: -----

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/cvm>. Paperwork Reduction Act (PRA) Public Burden Statement

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine

**CONTAINS NON-BINDING RECOMMENDATIONS
FOR SELECTING SUPPLIERS OF SAFE INGREDIENTS FOR
ANIMAL FOOD**

This guidance represents the Food and Drug Administration's current thinking on selecting suppliers of safe ingredients used in products regulated by CVM. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

The safety of feed ingredients may vary between suppliers, and even between different facilities of the same supplier, based on the scope and consistency of process controls implemented to protect against adulterants. Therefore, a critical part of the process of sourcing unadulterated feed ingredients involves having a sound business relationship with, and understanding of, ingredient suppliers, including their product safety procedures. The following Guidance provides recommendations for achieving this objective.

II. BACKGROUND

In the last five years, FDA has seen an increase in the number of animal food adulteration events reported to the agency that resulted in the recall of potentially adulterated products. Several of these adulteration incidents were subsequently determined to be caused by adulterated ingredients.

The firms involved and the agency spent countless hours recalling products, determining the causes and working with media and consumers to provide accurate information on the adulterated product(s) to ensure timely removal from the marketplace and prevention of untold loss of production and animal lives. FDA believes that industry preventive practices are necessary to minimize recurrences of these events and offers these recommendations for industry manufacturers.

III. FDA'S ANIMAL FEED SAFETY SYSTEM (AFSS)

FDA's Animal Feed Safety System or AFSS represents the collective regulatory documents, regulations and risk-ranking tools that the agency is or will be using to gauge the potential for harm from adulterants that may be present in animal food. The agency has placed a number of tools on the Center for Veterinary Medicine's website (www.fda.gov/cvm) for industry to utilize in determining the risks and hazards in animal food. This system is evolving and utilizes the tools of risk science, risk assessment, toxicology and other scientific disciplines to develop practical tools for assessing the safety of manufactured animal food.

Adulterants in the animal food supply can be introduced via manufacturing processes; contamination of ingredients or finished products; during transport; or through other means. The first steps in producing safe animal food products are identifying the common adulterants, assessing their relative risks, and reducing or eliminating the risks.

IV. INDUSTRY PROGRAMS

Several industry quality-assurance and third-party inspection programs have been created that generally take a risk assessment, product tracking and tracing, and hazard identification approach to manufacturing safe animal food. In the future, the agency will better define which programs can qualify for consideration under FDA's *Food Protection Plan*.

V. AGENCY RECOMMENDATIONS

A. Selecting Suppliers of Safe Ingredients

FDA recognizes that firms select specific ingredients for manufacture of animal food for a variety of reasons, including nutrient value, palatability, handling qualities, costs, effect on equipment and other reasons. Once an ingredient or several ingredients are selected, suppliers of the ingredient(s) must be selected either domestically or internationally.

When selecting ingredient suppliers, FDA encourages manufacturers to consider whether the ingredient, if adulterated, could pose a risk to human or animal health. Other considerations should include the process controls and reliability of the supplier for product safety. Although it may not be feasible, firms should consider visiting one or more of a potential supplier's facilities to assess its process controls and product safety. A review of the supplier's standard operating procedures for controlling adulterants should be considered. If a supplier is visited, the animal food manufacturer may consider procuring straight-run or representative samples to assay and determine the levels of adulterants, if present.

If the supplier is not visited, the purchaser should request a representative sample to use for future comparison. Alternatively, the manufacturer may compare the incoming ingredient to a sample of a previous load or lot the purchaser deemed acceptable. The purchaser should note the visual and other characteristics from the supplier's product and how it would affect product safety. The use of knowledgeable, trained personnel will increase the likelihood of understanding the ingredient characteristics important to finished product safety.

The purchaser may consider requesting that one or more shipments have certified certificates of analyses from reputable and agreed-upon laboratories, where appropriate. Some purchasing agreements may specify analyses to be performed in advance of shipment, certificates of analyses that should accompany the shipments or an agreement that the purchaser may, at its option, take samples by an agreed-upon method and send the samples to an outside laboratory for analysis. Some purchasing agreements also may require the supplier to agree to purchaser sampling and analyses by the purchaser's laboratory or sampling and testing kits used to analyze samples during receiving.

Other items for consideration may include a review of the supplier's certificate of insurance, as well as references from past purchasers of the supplier's products. A detailed discussion with past suppliers can assist the purchaser in deciding sampling frequency of shipments, adulterants and nutrients to analyze, as well as other factors on the safety of the supplier's products.

B. Laboratory Selection

When selecting a laboratory to check an ingredient for potential adulterants, an assessment should be made of the methodology utilized, laboratory quality programs, repeatability of results and other issues that may impact the accuracy of results.

Since an adulterant may not be identified until weeks after the unloading and use of an ingredient, samples of each receipt should be retained for subsequent assay in the event adulteration is suspected. In these cases, more emphasis should be placed on the visual inspection and comparison to an expected standard, as detailed in section V. C. Ingredient Receiving below.

C. Ingredient Receiving

Once an agreement is made with a supplier either via a broker or directly with the ingredient manufacturer, the next step – ingredient receiving – is critical to the safety of the final products. Manufacturers need to determine, to the extent practicable, that the product a supplier has shipped does, in fact, meet the safety and other specifications to which the purchaser and supplier agreed. There are several tools to assist in that determination. First, the receiving firm should verify the accuracy and completeness of the shipping documents and label that accompany the product. Then, after sampling the product and before unloading, the firm should ensure the product meets the firm's expectations regarding color, texture, uniformity, odor, foreign material, temperature, moisture and other product safety factors. This can be done by visual and other inspection by trained unloading personnel. Trained unloading personnel are critical positions in the manufacturing of animal food. These personnel should be knowledgeable of the ingredients used, be able to compare them to the facility's criteria for acceptance, and be able to use deductive reasoning to determine whether the incoming ingredient meets the expected specifications or may significantly deviate from them.

FDA believes that ingredient sampling and visual inspection are key components of any animal food safety program. If possible, the incoming product should be compared to the ingredient standard samples received from the supplier of that ingredient. Representative reserve sample(s) should be collected and stored in a remote location (away from the unloading area) for future reference. Each manufacturer or facility should determine a suitable sample-retention period.

The unloading personnel should refer to the facility's established standard operating procedures for regular or interval testing of a sample for adulterants based on the firm's sampling and analytical protocols. Plant personnel should be wary of ingredients that signal significant concerns, including but not limited to differing color, odor, texture, extraneous material, consistency and handling properties that may be an indicator of potential adulterants. Firms should consider impounding or placing under quarantine products that significantly deviate from expected characteristics until further testing can be conducted and

results reviewed. Alternatively, the firm should consider rejecting such loads and returning them to the supplier.

D. Rejection of Ingredients

If a firm rejects an ingredient for its intended purpose due to potential adulteration, the purchaser should notify the supplier, and either the supplier or the purchaser should recondition the product, such that it is no longer an adulterated product for its intended use, or dispose of the product in an acceptable manner.

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