

FSMA FACT SHEET

What do I Need to Do if I Send Human Food By-Products for Use as Animal Food?

Overview

By-products from human food facilities are commonly used as animal food, including as animal food ingredients. This FSMA fact sheet summarizes the requirements for such by-products. Below, is an overview of how a “facility” should determine which rules apply for its by-products, followed by an explanation of the set of limited holding and distribution requirements that apply to “facilities” in some situations. Additionally, the fact sheet explains the requirements for farms.

Determining Which Rules Apply for a Facility

Regardless of whether human food by-products for animal consumption are from a facility that produces food for human consumption or from an off-farm packing and holding operation (e.g., brown skin facility), these materials may only be subject to limited holding and distribution Current Good Manufacturing Practice (CGMP) requirements if the human food facility meets the following two conditions (as specified in 21 CFR § 507.12):

1) The human food facility must be subject to and in compliance with applicable human food safety regulations.

Specifically, the human food facility must be in compliance with all applicable human food safety requirements under the Federal Food, Drug and Cosmetic Act (FFDCA) and either: (1) subject to and in compliance with the CGMPs for human food (subpart B of part 117), or (2) subject to and in compliance with the applicable packing and holding requirements for off-farm packing and holding of produce (under 21 CFR § 117.8).

2) The human food facility must not further manufacture or process the human food by-products for use as animal food. Manufacturing/processing is defined as making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities include: baking, canning, cooking, grinding and mixing.

If the facility meets these two conditions, then once the by-product for use as animal food is separated from the human food, the human food by-product for use as animal food is only subject to limited requirements (found in both § 507.28 and § 117.95, and explained in the section below) for its holding and distribution. Accordingly, the facility providing human food by-products for use as animal food is not subject to the complete animal food-specific CGMP or Preventive Controls regulations in 21 CFR Part 507.

If the facility does not meet both of these conditions, it must manufacture, process, pack or hold its by-product for use as animal food in compliance with the complete Animal Food CGMPs and Preventive Controls for Animal Food regulations in 21 CFR Part 507. Among other things, this requires developing a Food Safety Plan and implementing Preventive Controls. The specific requirements under those regulations are not explained in this fact sheet.

Limited Holding and Distribution Requirements for Eligible Facilities

When a by-product for use as animal food is eligible for the limited holding and distribution CGMP regulation, the following requirements apply:

1) The human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

- Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
- Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
- During holding, human food by-products for use as animal food must be accurately identified.

2) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.

3) Shipping containers (e.g., totes, drums and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

Requirements for Farms

Because farms are exempt from facility registration, they do not have to meet the specific CGMP or Preventive Controls requirements for animal food. (Bear in mind, though, that a farm would be required to register and meet such requirements if it manufactures or processes animal food for consumption off-farm.) However, any animal food farms that manufacture, process, pack or hold must not be adulterated or misbranded in violation of the FFDCA. For example, a farm may have a bin of produce that is not desirable for human food and is waiting to be picked up by farmers who will feed the produce directly to their livestock. An employee who mistakes that bin for a trash receptacle may unintentionally cause the bin of food to become adulterated. Distribution of adulterated animal food in interstate commerce is a violation the FFDCA even if a firm is not required to register as a food facility or comply with the Animal Food CGMPs or Preventive Controls for Animal Food regulations.