

# Guidance for Industry

## Human Food By-Products For Use As Animal Food

### DRAFT GUIDANCE

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For further information regarding this document, contact [Jeanette Murphy](#), Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246, email: [jenny.murphy@fda.hhs.gov](mailto:jenny.murphy@fda.hhs.gov).

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine  
August 2016**

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**Table of Contents**

|       |  |    |
|-------|--|----|
| I.    | Introduction.....  | 3  |
| II.   | Background.....  | 3  |
| III.  | Human food by-products for use as animal food.....   | 4  |
| A.    | Use of human food by-products for animal food.....   | 4  |
| B.    | Regulatory status of human food by-products used as animal food .....  | 5  |
| C.    | General considerations.....  | 6  |
| IV.   | Human food facilities exempt from food facility registration .....   | 6  |
| V.    | By-products from human food facilities that meet the requirements in § 507.12 are not subject to the full requirements of part 507 ..... | 7  |
| A.    | Meeting requirements of § 507.12 .....   | 7  |
| B.    | Holding requirements (§ 507.28(a)) .....   | 8  |
| C.    | Labeling (§ 507.28(b)).....  | 9  |
| D.    | Shipping containers and bulk vehicles (§ 507.28(c)).....   | 9  |
| VI.   | Human food facilities subject to the full requirements of part 507 for human food by-products for use as animal food .....               | 10 |
| VII.  | Human food and human food by-products with a food safety concern (Diversion to animal food use).....                                     | 12 |
| VIII. | Compliance dates .....   | 13 |
| IX.   | Appendix A: Definitions (§ 507.3).....   | 14 |

## Draft Guidance for Industry

### Human Food By-Products For Use As Animal Food

*This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.*

#### I. INTRODUCTION

This guidance is intended for domestic and foreign facilities that are required to register under section 415 the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and its implementing regulations because they manufacture, process, pack, or hold human food for consumption in the United States and their human food production also provides by-products for use as animal food in the US. This guidance contains information for these facilities to determine what requirements to follow for their human food by-products for use as animal food. The regulations applicable to human food by-product for use as animal food were established in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule published on September 17, 2015 (the final rule). (80 FR 56170).

This guidance applies only to by-products of human food processing and not to by-products from other types of processing. Examples of by-products of other types of processing that are sometimes used for animal food include spent grains from fuel ethanol production, glycerin from biodiesel production, lignin sulfonate and kraft lignin from wood pulp production or paper-making, or hemicellulose extracted from wood. Facilities that are not producing human food but are producing by-products for use as animal food are required to register and comply with all of 21 CFR part 507, unless they meet the criteria for an exemption. Resources on whether a facility is required to register and how to complete the registration process can be found online at: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>.

In general, FDA’s guidance documents 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. In this guidance, “Agency” and the pronouns “we” and “our” are used to refer to FDA.

#### II. BACKGROUND

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). This law enables FDA to better protect public health by helping to ensure the safety and security of the human and animal food supply by focusing on prevention of

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food safety problems rather than reacting to problems after they occur. As part of our implementation of FSMA, we established risk-based preventive control requirements for the production of animal food by food facilities required to register under section 415 of the FD&C Act. At the same time, we established Current Good Manufacturing Practice requirements (CGMPs) for the manufacturing, processing, packing, and holding of animal food.

On October 29, 2013, we issued a proposed rule for CGMPs and hazard analysis and risk-based preventive controls that would have applied to most facilities manufacturing, processing, packing, or holding animal food. (78 FR 64736). On September 29, 2014, we issued a supplemental notice of proposed rulemaking based on extensive stakeholder input on the proposed rule, which revised several key provisions of the proposed rule. (79 FR 58475). As part of this effort, we streamlined the proposed requirements for human food facilities that are also providing by-products for use as animal food, while ensuring the by-products would be safe for use as animal food.

On September 17, 2015, we issued a final rule that applies to establishments that are required to register with FDA as a food facility because they manufacture, process, pack, or hold animal food for consumption in the U.S. This final rule: (1) established CGMP regulations, and (2) required registered facilities to establish and implement hazard analysis and risk-based preventive controls for animal food. (80 FR 56170). The final rule provides flexibility so that facilities that are producing human and animal food can choose to comply with either the human food requirements in Title 21 of the Code of Federal Regulations, part 117 (21 CFR part 117),<sup>1</sup> or the animal food requirements in 21 CFR part 507, for the production of the animal food. The final rule also exempts some human food by-products for use as animal food from the requirements of part 507, except for limited holding and distribution CGMPs. These holding and distribution provisions are found in both the animal food CGMPs (21 CFR 507.28) and the human food CGMPs (21 CFR 117.95). The provisions are the same, but the agency decided to place them in both regulations for ease of finding for both human food and animal food manufacturers.

This guidance explains what requirements human food facilities must follow when they are providing by-products for use as animal food. It also explains what requirements facilities performing off-farm packing and holding of raw agricultural commodities (RACs) subject to the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (produce safety rule) in 21 CFR part 112 must follow when they are providing by-products for use as animal food.

### **III. HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD**

#### **A. Use of human food by-products for animal food**

By-products from human food facilities are commonly used as animal food, including as animal food ingredients. While these by-products may not be suitable or desirable for human consumption, they may be suitable as a source of energy and nutrition for certain species of

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<sup>1</sup> If the facility chooses to comply with subpart C of 21 CFR part 117 as to the manufacturing, processing, packing, and holding of animal food, then its food safety plan must address hazards for the animal food. (21 CFR 507.1(d)).

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animals. Animal producers and animal food manufacturers are able to use by-products from the production of human food as a beneficial and economical animal food that would otherwise be wasted. Using suitable human food by-products for animal food allows human food facilities to avoid using landfill or other means of disposal, which can have environmental and financial impacts.

Human food by-products used for animal food are typically: (1) distributed (sold or given away) to an animal producer to be fed directly to livestock, (2) distributed to another facility that will further process them for animal food use, or (3) further processed for animal food use at the human food facility.

Some examples of human food by-products used for animal food include:

- Wheat middlings generated while processing wheat for flour.
- Grain products (hulls, bran, germ, gluten meal, grits, and meals) from other grain processing operations.
- Peels, rinds, pomace, pulp, culls, or other similar material generated from processing fruits or vegetables for human consumption.
- Human food such as potato chips, cookies, bread, pastry products, and pasta that is not adulterated and is safe for use as animal food, but is not acceptable as human food for quality reasons such as the wrong size, shape, color, or texture.

**B. Regulatory status of human food by-products used as animal food**

It should be noted that food, including human food by-products, used for animal food must be safe for the intended use. Human food by-products used for animal food must be generally recognized as safe (GRAS) under the conditions of intended use as animal food, or must be the subject of a food additive approval for animal food, to prevent the food from being considered adulterated (sections 201(s) and 409 of the FD&C Act [21 U.S.C. 321(s) and 21 U.S.C. 348]). A substance with a use that is GRAS or approved as a food additive for use in human food may not always be suitable for use in animal food. For example, propylene glycol is considered GRAS as an anti-caking agent for human food when used as specified in the regulation (21 CFR 184.1666), but is prohibited in or on cat food (21 CFR 589.1001).

The Official Publication of the Association of American Feed Control Officials (AAFCO) contains feed (animal food) ingredients with their definitions, including the list of approved food additives found in 21 CFR part 573, as well as the list of GRAS substances found in 21 CFR part 584.<sup>2</sup> However, some of the ingredients in the AAFCO Official Publication are not approved food additives and may not meet the criteria needed to be recognized as GRAS (21 CFR 570.30). We have announced our intention to review the list of animal food ingredient definitions contained in the AAFCO Official Publication to align AAFCO ingredient listings with the Agency's regulatory process and the requirements of the FD&C Act.<sup>3</sup> Until this undertaking is completed, we intend to accept the listing of certain ingredients in the AAFCO Official

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<sup>2</sup>21 CFR part 582 lists additional substances that are GRAS for their intended uses.

<sup>3</sup> CVM Update "The FDA Announces Strategy to Create Definitions and Standards for Animal Food Ingredients" <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm440134.htm>.

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Publication for their marketing in interstate commerce, provided there are no food safety concerns about the use or composition of the ingredient that would render the food adulterated under section 402 of the FD&C Act.

**C. General considerations**

This guidance covers human food by-products for use as animal food. Human food facilities that are distributing a by-product should know whether their by-product can or will be used for animal food and whether it is suitable for use in animal food. Human food facilities that do not intend for their human food by-products to be used as animal food should make it clear during distribution that the by-products are not for use as animal food. For example, this can be done by stating that the by-product is "Not for Animal Food Use" on the invoice, bill of lading, or other documentation accompanying the by-product during distribution.

Regardless of whether a human food facility is required to comply with all, some, or none of the provisions in part 507, the human food by-products for use as animal food must not be adulterated or misbranded in violation of the FD&C Act.

**IV. HUMAN FOOD FACILITIES EXEMPT FROM FOOD FACILITY REGISTRATION**

Establishments that are not required to register as food facilities are not required to follow the FSMA requirements for animal food found in part 507. (21 CFR 507.5(a)). Examples of such establishments include: establishments regulated solely by the United States Department of Agriculture's Food Safety and Inspection Service (USDA FSIS), restaurants, and retail food establishments, such as grocery stores. (21 CFR 1.226.) However, USDA FSIS establishments that are required to register with FDA because they also process FDA-regulated food must comply with part 507 for the manufacturing, processing, packing, or holding of any animal food. See section VI. *Human food facilities subject to the full requirements of part 507 for human food by-products for use as animal food; see also section V. By-products from human food facilities that meet the requirements in § 507.12 are not subject to the full requirements of part 507.*

Establishments that are exempt from registration do not have to meet the requirements in part 507 for the manufacturing, processing, packing, or holding of animal food. However, any animal food they manufacture, process, pack, or hold must not be adulterated or misbranded in violation of the FD&C Act. For example, a grocery store may have a bin of produce that is no longer desirable for human food and is waiting to be picked up by a food recycling or salvage company for animal food, or farmers who will feed the produce directly to their livestock. An employee who mistakes that bin of produce 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 FD&C Act even if a firm is not required to register as a food facility or comply with the regulations in part 507.

Regardless of whether a human food facility is required to register under section 415 of the FD&C Act, if the establishment rejects a human food for food safety reasons (i.e., because it has, or may have been, contaminated or adulterated), the human food facility may choose to divert

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that product for animal food use. If the facility wants to divert product with an animal food safety concern for animal food use, it should submit a request to the Center for Veterinary Medicine in accordance with Compliance Policy Guide Section 675.100 (for human food adulterated with rodent, roach, or bird excreta)<sup>4</sup> or the Director of the Compliance Branch in the local FDA district office in accordance with Compliance Policy Guide Section 675.200 (for other adulterated food)<sup>5</sup>. Contact information for FDA's district offices can be found at: <http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm>. Requests for diversion are reviewed on a case-by-case basis. See section *VII. Human food and human food by-products with a food safety concern (Diversion to animal food use)*.

**V. BY-PRODUCTS FROM HUMAN FOOD FACILITIES THAT MEET THE REQUIREMENTS IN § 507.12 ARE NOT SUBJECT TO THE FULL REQUIREMENTS OF PART 507**

**A. Meeting requirements of § 507.12**

Human food by-products for use as animal food may only be subject to limited holding and distribution CGMPs if the human food facility meets two conditions as specified in § 507.12. The by-products may be from human food production, or the off-farm packing and holding of raw agricultural commodities (RACs).

The first condition that must be met is that the human food facility must be subject to and in compliance with applicable human food safety regulations. Specifically, the human food facility must be: (1) subject to and in compliance with the CGMPs for human food (subpart B of part 117) and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations for human food, or (2) subject to and in compliance with the requirements of § 117.8 and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations for the off-farm packing and holding of produce (as defined in 21 CFR part 112). (§ 507.12(a)(1)). Section 117.8 states that the human food CGMP requirements apply to off-farm packaging, packing, and holding of RACs. It allows human food facilities conducting those activities on produce that is subject to part 112 to comply with either the human food CGMPs or the applicable packing and holding requirements of part 112.

The second condition that must be met is that the human food facility must not further manufacture or process the human food by-products for use as animal food (§ 507.12(a)(2)). 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, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding, formulating, freezing, grinding,

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<sup>4</sup> Compliance Policy Guidance (CPG) Sec. 675.100 Diversion of Contaminated Food for Animal Use, <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074693.htm>

<sup>5</sup> Compliance Policy Guidance (CPG) Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use, <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm>.

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homogenizing, irradiating, labeling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding (§ 507.3).

Drying is generally considered further manufacturing or processing; however, some passive activities such as dewatering by holding a by-product in a container with a screened bottom which allows water to escape, or holding in a perforated container which allows natural drying to occur are not considered further processing. Heat-treatment or freezing is generally considered further manufacturing or processing. Cooking or freezing a by-product to prevent deterioration or adulteration is considered further processing. However, holding by-products at a particular temperature to facilitate easier transportation of the by-products is not considered further processing.

If the facility meets those 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 the limited requirements found in § 507.28 for its holding and distribution. (§ 507.12(b)). (Identical provisions are found in § 117.95 for the convenience of the facilities to which the provisions apply.) The facility providing human food by-products for use as animal food is not subject to the other requirements of part 507, including the animal food-specific training requirements in § 507.4.

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 part 507. See section *VI. Human food facilities subject to the full requirements of part 507 for human food by-products for use as animal food.*

These provisions do not apply to a human food, or the by-product of a human food, that is rejected for food safety reasons (i.e., because it has, or potentially has, been contaminated or adulterated) (80 FR 56170 at 56222). See section *VII. Human food and human food by-products with a food safety concern (Diversion to animal food use).*

**B. Holding requirements (§ 507.28(a))**

When human food by-products for use as animal food are held for distribution, they must be held under conditions that will protect them from contamination. (§ 507.28(a)). Contamination may be caused by physical, chemical, or biological contaminants.

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 in a way that protects against the contamination of human food by-products for use as animal food. (§ 507.28(a)(1)). Containers and equipment that are commonly used include bulk tanks, bins, totes, drums, tubs, augers, conveyors, or holding vehicles. Methods and frequency of cleaning, repair, or replacement of containers or equipment will depend on what type of product is being held or conveyed and how the containers or equipment are being used. For some types of by-products it may not be necessary to clean the container



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after each use. The facility should consider the amount and type of by-products, the containers or equipment used, the frequency with which containers or equipment are used, as well as other factors when deciding what cleaning practices and cleaning frequency will protect the by-products from contamination.

In addition, human food by-products for use as animal food must be held in a way that protects against contamination from sources such as trash. (§ 507.28(a)(2)). Good practices to consider include: making it easy to distinguish animal food from trash; locating the by-products away from trash or waste containers; and providing readily accessible, clearly marked, separate receptacles for trash and waste.

Furthermore, human food by-products for use as animal food must be accurately identified during holding. (507.28(a)(3)). We recognize that a variety of systems are used by establishments to identify food within the plant, including labeling, computer systems, paper records, chalkboards, and other methods. Plant personnel should be able to accurately identify the human food by-products for use as animal food so that they are not contaminated, commingled, substituted, or incorrectly distributed in a manner that adulterates the animal food.

**C. Labeling (§ 507.28(b))**

When the human food by-products for use as animal food are distributed, labeling that identifies the product by the common or usual name must be affixed to or accompany it. (§ 507.28(b)). Labeling could be included on the invoice or bill of lading, for example. Our Compliance Policy Guide Sec. 665.100 discusses common or usual names for animal food ingredients, including the use of the ingredient definitions in the AAFCO Official Publication.<sup>6</sup> There are also industry and other regulatory resources that may assist facilities in determining the common or usual name of the animal food, such as the foods listed in the USDA National Nutrient Database for Standard Reference.<sup>7</sup>

**D. Shipping containers and bulk vehicles (§ 507.28(c))**

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 animal food, the shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute the animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle. (§ 507.28(c)).

When the facility is the shipper, we expect facility personnel involved in the process of loading the product into the shipping container or vehicle to be aware of the condition of the shipping container or vehicle, and consider whether its condition would contaminate the human food by-products for use as animal food. Depending on the circumstances, this examination could include looking at the shipping container or vehicle to observe whether there are any residues in it that may contaminate the human food by-product for use as animal food. When a visual

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<sup>6</sup> FDA, Compliance Policy Guide 665.100 Common or Usual Names for Animal Feed Ingredients, <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074687.htm>.

<sup>7</sup> USDA, National Nutrient Database for Standard Reference, <http://ndb.nal.usda.gov/>

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inspection is not practical, we would expect the facility to know what the shipping container or vehicle had previously been used for and because of that, whether the container needed to be cleaned prior to use to protect the human food by-product for use as animal food from contamination. This does not mean that the shipping container must be cleaned prior to each use in all situations.

The regulations do not require the facility to examine the shipping container or bulk vehicle when the customer arranges for the transportation of the animal food, including when the customer arranges for a third-party to pick up the animal food. However, if facility personnel are onsite and available, it would be good practice for the facility to examine the customer's shipping container or bulk vehicle to confirm that the shipping container or bulk vehicle will not lead to the contamination of the human food by-products for use as animal food.

We note that as part of FDA's implementation of FSMA, FDA issued a rule on the Sanitary Transportation of Human and Animal Food on April 6, 2016 (81 FR 20092). That rule establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. Human food facilities engaging in transport operations for human food by-products for use as animal food must be in compliance with applicable requirements in that rule. If human food by-products for use as animal food have not been further processed and are not being transported to another business for further processing (e.g., are being moved from the human food manufacturer to a farm to be fed directly to livestock), then the transportation of the human food by-products for use as animal food is not covered by the rule. Small businesses (as defined in the sanitary transportation rule) will have two years after the date the rule published to comply with the rule and other businesses will have one year to comply.

**VI. HUMAN FOOD FACILITIES SUBJECT TO THE FULL REQUIREMENTS OF PART 507 FOR HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD**

Human food facilities that are required to register under section 415 of the FD&C Act must manufacture, process, pack or hold their animal food in compliance with part 507 if they do not meet the requirements of § 507.12 because (1) they are not subject to human food CGMPs (part 117) and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations for human food, or they are not subject to and in compliance with the requirements of § 117.8 and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations for the off-farm packing and holding of produce (as defined in 21 CFR part 112), or (2) they further manufacture or process their human food by-products for use as animal food.

If a human food facility is subject to the human food CGMPs in subpart B of part 117 and the animal food CGMPs in subpart B of part 507, the facility may choose to follow either the human food CGMPs in part 117, or the animal food CGMPs in part 507 for the manufacturing, processing, packing, or holding of animal food, including the further manufacturing or processing of human food by-products for use as animal food. (§ 507.1(d)).

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Similarly, human food facilities that are subject to the hazard analysis and risk based preventive controls for human food in subpart C of part 117 and for animal food in subpart C of part 507 may choose to follow either subpart C of part 117 or subpart C of part 507 for the manufacturing, processing, packing, or holding of animal food. The food safety plan must address the hazards associated with the animal food. (§ 507.1(d)). The human food facility may choose to have two separate food safety plans (one for animal food and one for human food), or the facility may choose to have one food safety plan that addresses both the animal food and human food being manufactured, processed, packed, or held at the facility.

The hazard analysis and risk-based preventive controls requirements in subpart C of part 117 might not apply to certain activities in a human food facility (e.g., seafood processing subject to 21 CFR part 123). (§ 117.5) However, these facilities could still be subject to subpart C of part 507 for their animal food. If so, then the facility must follow the requirements in subpart C of part 507 for the manufacturing, processing, packing, or holding of its animal food.

For those facilities that choose to follow part 507 for their human food by-product for use as animal food, compliance with part 507 must begin when the by-product is separated from the human food. From that point forward, any further manufacturing, processing, packing, or holding of the animal food would need to be done in compliance with part 507.

Unless the facility is exempt from the requirements for hazard analysis and risk-based preventive controls in subpart C of part 507 (for exemptions, see § 507.5), the facility must have a food safety plan that addresses any hazards for the animal food, including human food by-products for use as animal food, that require a preventive control. (§§ 507.1(d) and 507.31) The food safety plan for human food by-products for use as animal food must be prepared by or under the oversight of a preventive controls qualified individual(s) and must address the hazards associated with the animal food after the by-product has been separated from the human food. (see § 507.31(a)-(c)). The food safety plan must include a written hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of animal food to determine whether there are any hazards requiring a preventive control. The hazard analysis must be based on experience, illness data, scientific reports, and other information. (§ 507.33(a)(1) and (a)(2)).

If the facility determines that there are no hazards requiring a preventive control, it must document the analysis in the written food safety plan. (see § 507.33(a)(2)). The facility must also reanalyze the food safety plan as required (at least once every three years) and update it as necessary. (see § 507.50). If the facility determines that a hazard requires a preventive control, it must identify and implement the preventive control to significantly minimize or prevent the hazard and assure that the food is not adulterated. (§ 507.34(a)(1)). The hazard analysis and risk-based preventive control requirements are found in 21 CFR part 507, subparts C and E. We intend to issue a guidance providing more detail on how to conduct a hazard analysis and implement preventive controls.

## VII. HUMAN FOOD AND HUMAN FOOD BY-PRODUCTS WITH A FOOD SAFETY CONCERN (DIVERSION TO ANIMAL FOOD USE)

Human food that has been rejected for human food safety reasons should be evaluated by establishment management to determine whether it is appropriate to divert to animal food. In addition, a human food by-product for use as animal food that may have an animal food safety concern, for example because it resulted from production of a human food that was rejected for food safety reasons, should be evaluated by establishment management to determine whether it is appropriate to divert to animal food. Food with animal food safety concerns includes situations where the food has been, or potentially has been contaminated or adulterated.

If the establishment management decides not to divert the contaminated or adulterated food to acceptable animal food use and chooses to dispose of it, then management should make it clear during disposal that the rejected food is not for use as animal food. If the facility itself is not transporting the food for disposal, the facility should include the statement "Not for Animal Food Use" on the invoice, bill of lading, container, or other documentation accompanying the disposal so that the food is not used for animal food.

When evaluating whether a rejected human food or a by-product with a food safety concern is suitable for use as animal food, at a minimum establishment management should consider: (1) whether any human food safety concern is an animal food safety concern; (2) the type of animal food the food will be used for, or the animal species to which it will be fed; (3) the level of the food safety concern, considering the animal species to which it will be fed; and (4) FDA's guidance on the diversion of contaminated<sup>8</sup> or adulterated<sup>9</sup> food for use as animal food. The management should use this and any other relevant information to make a determination whether the food is safe to use as an animal food prior to marketing or distributing the food for use as animal food.

In some situations, the establishment management may be aware from past practice, experience, publications, or papers (e.g., from extension services) that the human food safety concern is not a food safety concern for animals. In other situations, management may choose to use an animal food expert to review the food safety concern and determine whether it is an animal food safety concern. Management should be aware that some food safety concerns may be an animal food safety concern for some species, but not other species. When management has made a determination that the human food safety concern is not an animal food safety concern, we do not expect a diversion request to be submitted to the local FDA district office. Examples of food rejected for human food safety concerns that may not present animal food safety concerns are: food that contains human allergens, meat that was produced without the benefit of USDA or equivalent state inspection, and certain returned products. If management cannot determine whether the human food safety concern is an animal food safety concern, the establishment should submit a diversion request to the local FDA district office, following the procedure outlined in CPG 675.200.

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<sup>8</sup> Compliance Policy Guidance (CPG) Sec. 675.100 Diversion of Contaminated Food for Animal Use, <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074693.htm>.

<sup>9</sup> Compliance Policy Guidance (CPG) Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use, <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm>.

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In some situations, the establishment management may be able to rework or reprocess the human food or human food by-product to eliminate the animal food safety concern. For example, if a human food or human food by-product is contaminated with an undesirable microorganism that may also be pathogenic to animals, the establishment may heat treat, or use other processing methods to reduce or eliminate the contamination so that it is no longer an animal food safety concern. Alternatively, the establishment may distribute the product to another establishment that will process the human food or human food by-product so that there is no longer an animal food safety concern. In these cases, we would not expect a diversion request. However, if management cannot determine whether the food can be safely reworked or reprocessed to eliminate the animal food safety concern, the establishment should submit a diversion request to the local FDA district office, following the procedure outlined in CPG 675.200.

The local district office will contact CVM, which will help determine on a case-by-case basis whether the contaminated or adulterated food may be suitable for use as animal food, or whether any proposal to rework or recondition the food would result in a food suitable for use as animal food. As a reminder, it is prohibited under the FD&C Act to distribute adulterated animal food.

**VIII. COMPLIANCE DATES**

We recognize that food facilities may need time to comply with the subject CGMP requirements and if applicable, the risk-based hazard analysis and preventive control requirements in subpart C. In addition, smaller businesses may need more time than larger businesses to comply with the CGMP requirements because they generally have less income and fewer available resources than larger businesses. Therefore, the compliance dates issued in the final rule were staggered based on business size. Table 1 gives the staggered dates for a business to comply with the CGMP requirements in subpart B and the related requirements, based on the size of a business.

**Table 1. Dates for businesses to comply with part 507.**

| Size of Business     | Definition  | Compliance date for subpart B (CGMPs) and related requirements | Compliance date for subpart C and § 507.7  |
|----------------------|---|--|--|
| Very small business  | A business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale). | September 17, 2018   | September 17, 2019, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. |
| Small business       | A business employing fewer than 500 full-time equivalent employees.   | September 18, 2017   | September 17, 2018   |
| All other businesses | A business that does not meet the definition of a small business, or a very small business.   | September 19, 2016   | September 18, 2017   |

IX. **APPENDIX A: DEFINITIONS (§ 507.3)**

Adequate means that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in § 1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.

Holding means storage of animal food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

Manufacturing/processing means 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, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extrusion, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmospheric packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

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Packing means placing animal food into a container other than packaging the animal food and also includes activities performed incidental to packing an animal food (e.g., activities performed for the safe or effective packing of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Plant means the building or structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Rework means clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business employing fewer than 500 full-time equivalent employees.

Very small business means, for purposes of this part, a business (including any subsidiaries or affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).