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FDA Releases Draft Guidance on Human Food By-Products For Use As Animal Food

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Animal Food and Drug

Earlier this week, the Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA) published Draft Guidance for Industry No. 239, "Human Food By-Products for Use as Animal Food" as part of the agency's implementation of the Food Safety Modernization Act (FSMA). The draft guidance describes the regulatory requirements — including the provisions of FDA's new food safety rule for animal food in 21 C.F.R. part 507 — that apply to human food by-products intended for use as animal food.[1] Part 507, which applies to animal food establishments required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FDCA), contains current good manufacturing practices (CGMPs) and requirements for hazard analysis and risk-based preventive controls for animal food. As discussed below, certain human food by-products intended for use as animal food are exempt from the requirements of part 507, except for limited CGMPs relating to holding and distribution.[2] This alert highlights key aspects of the draft guidance and discusses points of interest to industry stakeholders.

Scope of the Draft Guidance

The draft guidance applies to by-products of human food processing[3] for use as animal food[4], such as:

- 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.

[1] The final rule that added Part 507 to FDA's regulations was published on September 17, 2015, *see* 80 Fed. Reg. 56170 (Sept. 17, 2015), and was the subject of a separate Covington Alert.

[2] *See* 21 C.F.R. §§ 117.95, 507.12, & 507.28.

[3] The draft guidance does not apply to by-products from other types of processing for use as animal food.

[4] CVM recommends human food facilities that do not intend for their human food by-products to be used as animal food make it clear during distribution that the by-products are not for use as animal food, for example, by printing "Not for Animal Food Use" on documentation accompanying the by-product during distribution.

- 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.

Compliance with the Limited CGMPs Applicable to Certain Human Food By-Products for Use as Animal Food

To be exempt from animal food CGMPs other than those relating to holding and distribution, a human food by-product for use as animal food must meet both of the following conditions:

1. The human food facility is subject to and complies with applicable human food safety requirements, including the human food CGMP requirements in subpart B of part 117 or, with respect to off-farm packing and holding of produce, with section 117.8; and
2. The human food facility does not further manufacture or process the human food by-products for use as animal food.[5]

The applicable regulations contain a number of examples of activities that constitute manufacture or processing[6] as referred to in the second condition,[7] above, and the draft guidance provides additional examples:

- Drying, with the exception of some passive activities like holding the by-product in a container with a screened bottom that allows water to escape, or allowing natural drying to occur through a perforated container;
- Heat-treatment or freezing; and
- Cooking or freezing to prevent deterioration or adulteration.

The draft guidance additionally includes specific recommendations about compliance with the holding and distribution CGMPs.

Compliance with the Full Requirements of Part 507

If the conditions discussed above are not satisfied, a human food facility that additionally makes animal food may either comply with part 507 with respect to animal food, or may opt to apply part 117 human food CGMPs for the manufacturing, processing, packing, or holding of animal food. If a facility chooses the former option, it must comply with part 507 beginning when the by-product is separated from the human food.

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[5] *See* 21 C.F.R. § 507.12(a); *see also* 21 C.F.R. §§ 117.95 & 507.28.

[6] FDA does not consider as further processing holding by-products at a particular temperature to facilitate easier transportation.

[7] 21 C.F.R. § 507.3.

Diversion for Animal Food Use of Human Food for which there is a Food Safety Concern

The draft guidance additionally recommends that human food rejected because of human food safety concerns be assessed for its suitability for animal food before it is diverted to that use, including consideration of:

- whether the human food safety concern is also an animal food safety concern,
- the type of animal food for which the rejected human food will be used or the animal species to which it will be fed,
- the level of the food safety concern, and
- FDA's guidance on the diversion of contaminated or adulterated food for use as animal food.

Importantly, FDA does not expect a diversion request to be submitted to the local FDA district office when management has determined that the human food safety concern is not an animal food safety concern.[8]

Comment Period

Although FDA accepts public comments on guidance documents at any time, you should submit comments on the draft guidance **by November 23, 2016**, to ensure that the agency considers those comments before it issues the final version of the guidance.

Covington continues to monitor FDA's implementation of FSMA and will keep its clients apprised of significant developments.

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[8] FDA Compliance Policy Guide § 675.200, *Diversion of Adulterated Food to Acceptable Animal Feed Use*, describes the procedure for submitting a diversion request to FDA.