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MEMORANDUM

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Re: FDA Issues Proposed Rule on Preventive Controls for Animal Food Under FSMA

The Food and Drug Administration (FDA) has issued its proposed rule on Current Good Manufacturing Practice (CGMPs) and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals under the FDA Food Safety Modernization Act (FSMA). This memorandum provides an overview of the proposal, with a focus on the impact for facilities that divert human food or supply "waste" from human food production (e.g., by-products that may not be edible for humans or lack nutritional value for humans) for use in animal food.

The proposed rule would apply broadly to any facility that manufactures, processes, packs, or holds animal food. "Animal food" is defined to include pet food, animal feed, and raw materials and ingredients that will be used in food for animals. The proposed rule specifically addresses "waste" diverted from human food facilities for use in animal food. Facilities in compliance with FDA's preventive controls for human food regulation (proposed 21 CFR Part 117) are deemed in compliance with the animal food proposed rule, so long as their hazard analysis also addresses hazards reasonably likely to occur in the animal food. Facilities owned by food companies that only have small annual sales of waste for animal food may be subject to a partial exemption from compliance with the animal food proposed rule as a "qualified facility."

In this memorandum, we provide an overview of the proposed rule, address the proposed requirements for facilities that process both human food and animal food, and then discuss the proposed exemption for qualified facilities. Our primary focus is the effect of this proposed rule on human food companies.

Overview of the Proposed Rule

The proposed rule would require animal food facilities to implement (1) CGMPs and (2) preventive controls. The proposal is closely aligned with FDA's proposed rule addressing CGMPs and preventive controls for human food. 1/ The structure of the proposed rule largely tracks the statute, establishing requirements for: a written food safety plan; hazard analysis; preventive controls; monitoring; corrective actions; verification; and creation and maintenance of associated records.

1/ 78 Fed. Reg. 3646 (Jan. 16, 2013). For an overview of the CGMP and preventive controls for human food proposed rule, *see* Hogan Lovells memorandum dated January 9, 2013, *FDA Proposes Extensive New Food Safety Regulations Under FSMA*. Both proposed rules are issued under section 103 of FSMA, which requires FDA to minimize, as appropriate, the number of separate standards that apply to separate foods.

There are a few modifications from the human food rule, such as no allergen controls and no references to ready-to-eat foods. 2/

As with the human food proposed rule, the agency has not proposed specific codified language on supplier verification and testing, but is requesting comment on these issues. To the extent the final rule on animal food includes a supplier verification requirement, human food facilities that supply food or waste for use in animal food would be subject to supplier verification by their customers.

Additionally, this proposed rule represents the first time that CGMPs would be required for the animal food industry. The proposed CGMPs for animal food are largely similar to those for human food, with several exceptions, including that they do not address allergen cross contact and do require labeling controls.

Proposed Requirements for Human Food Facilities That Divert Human Food or Waste for Animal Food

Under the proposed rule, human food processors that divert human food or waste for animal food can choose between complying with human or animal food preventive controls and CGMP regulations, so long as the food safety plan also addresses hazards that are reasonably likely to occur in the animal food. There are several unique considerations to account for when addressing hazards for animal food:

- Nutrient Imbalances: In the preamble, FDA explains that nutrient imbalance hazards can result from excessive levels of a nutrient in animal food leading to toxicity; from a nutrient deficiency in the food that can compromise the health of animals; or from diets containing essential nutrients in inappropriate proportions of essential nutrients.

- Intended Use: FDA states that if a facility manufactures food for multiple animal species, the agency would consider the animal food intended for each animal species to be a separate type of animal food requiring its own hazard analysis. For example, if Salmonella were a hazard, the facility would need to identify Salmonella serotypes to which each pet/animal for which the food is intended is susceptible.

- Human Health: The hazard analysis must consider potential hazards related to the health of the human handlers (e.g., pet owners) who are likely to come in contact with the finished food.

In order to conduct an analysis of these potential hazards, therefore, the supplier of the human food or waste would need to understand the downstream use of the food or waste, including the further processing that will occur and the specific animals for which the finished animal food is intended. It may make a significant difference if the human food or waste is being diverted for use in pet food as opposed to use in livestock feed. This proposed requirement for an expanded hazard analysis is the single most important aspect of this proposed rule as applied to human food facilities.

FDA also requests comment on whether and/or how the proposed rule should apply to Food Safety Inspection Service (FSIS) official establishments that manufacture, process, pack, or hold food for animals (or food and/or waste that may be diverted from these facilities to food for animals).

2/ This is a reflection of the requirement in the statute that the regulations must acknowledge differences in risk for different types of food.

Proposed Scope of the Qualified Facility Exemption

Some companies that divert human food or waste for animal food may be subject to modified requirements as "qualified facilities." 3/ Qualified facilities would be exempt from the hazard analysis and preventive controls requirements (Proposed 21 CFR § 507, Subpart C), but are still subject to FDA's CGMP and facility registration requirements.

"Qualified facilities" include "very small businesses," as defined through this rulemaking. 4/ FDA is co-proposing three alternative definitions for "very small business," based on total annual sales of animal food: $500,000, $1,000,000, or $2,500,000. 5/

Notably, eligibility as a very small business depends on the company's total dollar value of sales of animal food – not their sales of human food. However, FDA requests comment on whether food for animals and humans should be aggregated in determining whether a facility that sells food for both purposes meets the statutory criteria of a qualified facility.

Additionally, the total sales used to determine eligibility as a "very small business" apply on a company-wide – not facility-specific – basis. The determination includes animal food sales by subsidiaries or affiliates. Thus, whether a facility can be considered a "qualified facility" will depend on annual company-wide sales.

Proposed Modified Requirements for Qualified Facilities

Qualified facilities are exempt from the preventive controls requirements for animal food, but would still be subject to CGMP requirements. Facilities that process both human food and animal food could choose between complying with the CGMP requirements for animal food or human food, which are similar.

Additionally, qualified facilities must submit two types of documentation to FDA. The first type of required documentation would establish that the facility meets the definition of "qualified facility." The second type of required documentation relates to food safety practices at the facility. There are two options for satisfying this second documentation requirement:

(1) The facility may choose to submit documentation that demonstrates it has conducted a hazard analysis, is implementing preventive controls, and is monitoring the performance of the preventive controls to ensure the controls are effective; or

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3/ This exemption is commonly referred to as the "Tester Amendment" in FSMA, named after Senator Jon Tester (D-Mont.) who introduced this part of the legislation.

4/ A facility also can meet the "qualified facility" definition if it had annual average animal food sales of less than $500,000 during the preceding 3-year period and primarily sells animal food directly to "qualified end-users." A "qualified end-user" is a consumer of the food, or a restaurant or retail food establishment, that is (a) located in the same state as the qualified facility or no more than 275 miles from such facility and (b) purchases the food for sale directly to consumers at such restaurant or retail food establishment. With respect to animal food, FDA explains in the preamble that it considers the term "consumer" to refer to the purchaser of the animal food and the animal(s) consuming the food, and the term "restaurants" to include pet shelters, kennels, and veterinary facilities in which food is provided to animals.

5/ These co-proposed definitions are higher than the co-proposed "very small business" definitions in the preventive controls for human food proposed rule (where FDA proposed to define "very small business" as meaning total annual sales of $250,000, $500,000, or $1,000,000). In the preamble, FDA explains that the proposed alternative definitions are higher for animal food than for human food because there are more medium and large businesses in the animal food industry.

(2) The facility may choose to submit documentation that demonstrates it is in compliance with state, local, county, or other applicable non-federal food safety laws, including foreign laws and regulations (e.g., licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a state department of agriculture)).

FDA proposes allowing use of FDA's existing facility registration portal to self-certify that a facility has appropriate information demonstrating that the facility is a "qualified facility." FDA proposes that self-certification must be submitted initially within 90 days of the applicable compliance date of the final rule and at least every 2 years thereafter, or whenever there is a material change in the information (i.e., a change that affects whether or not a facility is a qualified facility). A qualified facility must maintain the records relied on to support these documentation requirements for at least 2 years.

Consumer Notification

The proposed rule also contains a provision requiring consumer notification in certain circumstances if the food comes from a qualified facility. Under the proposed rule, if a qualified facility follows the second documentation option (i.e., a non-federal governmental certification of compliance), it must notify consumers of its name and business address. 6/ Because this provision is required by the statute and was drafted with the intent of functioning in the context of human food, it is unclear how this would apply to a human food company diverting food or waste for further processing. Companies may wish to submit comments to FDA on this point.

Compliance Timeline

FDA proposes that covered facilities would be required to come into compliance with the proposed rule one year after publication of the final rule in the *Federal Register.* Small businesses, defined as those with fewer than 500 employees, would be required to comply with the requirements two years after the publication date. Very small businesses would be given two extra years (3 years total) to come into compliance after the date of publication of the final rule.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.

6/ If labeling is required for the food, the label must include a prominent and conspicuous statement of the name and "business address" of the facility where the food was manufactured or processed. If a food packaging label visible to the consumer is not required for a food (e.g., the food is sold for further processing), the name and business address of the facility where the food was manufactured or processed must be prominently and conspicuously displayed at the point of purchase on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business.