Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell
Leigh G. Barcham

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Re: FDA Issues Update to Facility Registration Guidance and New Supplemental Draft Guidance

The U.S. Food and Drug Administration (FDA) recently issued two guidance documents to assist establishments in determining whether they have an obligation to register as a food facility. The first document is the finalized seventh edition of FDA's *Questions and Answers Regarding Food Facility Registration* (Final Guidance). 1/ The second document is a supplemental draft guidance to the seventh edition (Supplemental Draft Guidance), which addresses which parties must register in situations where multiple entities share a physical space (e.g., a food manufacturer leases a building). 2/ The Supplemental Draft Guidance is open for comments through October 19, 2018. This memorandum summarizes the changes made in the Final Guidance since it was originally proposed in draft form in December 2016 and the new content in the Supplemental Draft Guidance.

Final Food Facility Registration Guidance

FDA released the draft version of the seventh edition facility registration guidance in December 2016 (Draft Guidance). Compared to the Draft Guidance, the Final Guidance includes additional questions and answers on the following two topics:

- **Meal-Kit Type Services:** If a meal-kit type service meets the definition of a retail food establishment, it is exempt from registration. In other words, the service is exempt if it sells food directly to consumers as its primary function, meaning the annual monetary value of its food sales directly to consumers exceeds that of food sales to all other buyers. Establishments that sell food directly to consumers via the Internet or mail order may be retail food establishments, provided they meet the other criteria of the retail food establishment definition.

1/ "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)," (August 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf.
2/ "Supplemental Questions and Answers Regarding Food Facility Registration," (August 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM615531.pdf.

- **Human and Animal Food Brokers:** The Final Guidance explains that human and animal food brokers that do not manufacture, process, pack, or hold human or animal food are not required to register with FDA.

In addition to this new material, the Final Guidance removes several questions and answers that appeared in the Draft Guidance. FDA did not provide any explanation as to why this guidance was deleted, nor has the agency advised whether their previous positions have changed. The deleted items addressed whether the following types of operations are required to register:

- An establishment that conditions and sells seed to farmers for cultivation where some of the seed is intended to be used as animal feed (formerly Question B.1.2);
- Packing sheds owned by a farm but located in a different general physical location (formerly Question B.1.8);
- A business that collects honeycombs or honey from multiple farms and then packs it in containers to be sent to a processing facility (formerly Question B.1.22);
- A farmer that makes silage and sells it to another farmer for use as animal food (formerly Question B.1.24);
- A local collecting facility for grains (formerly Question C.3.1);
- An establishment that only receives packaged produce raw agricultural commodities (RACs) for shipping and holds them in cold storage (formerly Question C.3.2);
- Receiving stations that are standalone operations and only collect and clean fruit prior to storage, including when there is a processing facility at the same location under separate ownership (formerly Question C.3.12); and
- A cotton gin that separates cotton fibers from cotton seeds and then sells the seeds to a manufacturer who processes the seeds into animal food for sale to livestock (formerly Question O.5).

The Final Guidance also no longer includes a discussion of who in a lessor-lessee relationship, such as a food producing business that rents space from a landlord, is legally obligated to register the facility (formerly Question C.3.4). This discussion presumably was removed because this issue is addressed in the separate Supplemental Draft Guidance, as discussed below.

FDA also notes in the Final Guidance that it intends to initiate a rulemaking that could change the definition of a "farm," which would have a bearing on which operations are required to register as facilities. Notably, FDA states that it does not anticipate the rulemaking would result in any entity that currently is a "farm" becoming a "facility."

Finally, as a reminder, the Final Guidance explains that beginning October 1, 2020, FDA will require facilities to provide a unique facility identifier (UFI) as part of facility registration. FDA has recognized the Data Universal Numbering System D-U-N-S (DUNS) number as the preferred UFI for food facility registration. Thus, companies should begin the process of obtaining DUNS numbers for each of their facilities so that they can provide them to FDA as part of their facility registration renewal submissions during the 2020 renewal cycle. 3/

3/ Information is available at https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006832.htm.

Supplemental Draft Food Facility Registration Guidance

FDA issued Draft Supplemental Guidance to respond to questions the agency has received about registration requirements in situations where multiple entities share the same physical space, such as when one entity owns a building and lessees manufacture/process, pack, or hold food in the building. Once finalized, the additional questions and answers in the Draft Supplemental Guidance will be incorporated into subsequent editions of the Final Guidance.

Previously, in the Draft Guidance, FDA had said that in a lessor-lessee relationship the owner, operator, or agent in charge of the facility each had an independent obligation to comply with the registration requirement, and that each of these individuals could satisfy the obligation for the other two. If the facility were not registered, the FDA could pursue enforcement action against any of these individuals.

In contrast, the Draft Supplemental Guidance explains that in some situations the lessor may not need to register with FDA:

1. **Food Manufacturer Leases a Building Where it Manufactures Food:** The food manufacturer is required to register the facility. If the building owner/lessor does not have physical control over the food, then it is not required to register the building as a facility.

2. **Food Manufacturer Stores Food in a Self-Storage Warehouse:** If the manufacturer keeps physical control over the food in the storage unit, it is holding food and is required to register the self-storage unit as a food facility. If the owner/lessor of the warehouse has no physical control over the food, it is not required to register the warehouse as a facility.

3. **Food Manufacturer Stores Food in a Third-Party Logistics Warehouse:** Typically, third-party logistics warehouses have sole physical control over the food stored in the warehouse, and therefore the owner, operator, or agent in charge of the warehouse must register it as a facility.

4. **Food Manufacturer Uses a Commercial Communal Kitchen:** In this situation, the commercial communal kitchen is used by multiple manufacturers that share responsibility with the landlord for maintenance of common facility infrastructure and equipment. Each manufacturer using the kitchen is a facility required to register. In addition, if the landlord/lessor has physical control over food at any time (e.g., responsibility for food in a common storage area in a communal kitchen), it is required to register.

The key theme in these situations is that when the owner/lessor of a building does not have physical control over the food, it is not required to register; however, whoever is operating the establishment and exercising physical control over the food held there must register their location as a facility.

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We will continue to monitor developments related to facility registration. Please contact us if you have any questions or would like to discuss how these guidance documents apply for your business.