

Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule: Guidance for Industry

*Additional copies are available from:
Office of Food Safety HFS-300
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2166
<http://www.fda.gov/FoodGuidances>*

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
August 2017**

Table of Contents

I. Introduction

II. Background

III. Discussion

IV. References

Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA, that Agency, or we) on this topic. 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 those persons who are subject to the Sanitary Transportation of Human and Animal Food Rule (81 FR 20091), published on April 6, 2016. Specifically, this guidance provides clarification on the scope of the waiver for food establishments that provide food directly to consumers from the requirements of the Sanitary Transportation of Human and Animal Food Rule (the food establishment waiver) in response to questions the Agency has received since publication of the final rule.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our 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 FDA guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition.

II. Background

In a proposed rule published on February 5, 2014 (79 FR 7006), entitled “Sanitary Transportation of Human and Animal Food,” the Agency announced that it had tentatively determined that, in accordance with the provisions of Section 416 [21 U.S.C § 305e] of the Federal Food, Drug & Cosmetics Act (FD&C Act), it would be appropriate to waive the applicable provisions of the rule under specific circumstances. The final rule was published on April 6, 2016 (81 FR 20091) with an effective date of June 6, 2016, and an initial compliance date of April 6, 2017. FDA published three waivers from the requirements of the Sanitary Transportation of Human and Animal Food Rule in the Federal Register on April 6, 2017 (82 FR 16733). Following publication of the waivers, FDA received questions regarding the scope of the food establishment waiver, which waives the requirements of the rule for:

1. Businesses subject to the requirements of part 1, subpart O, that are permitted or otherwise authorized by the regulatory authority to operate a food establishment that provides food directly to consumers (i.e., restaurants, retail food establishments², and nonprofit food establishments as defined in 21 CFR 1.227), only when engaged in transportation operations as:
 - a. Receivers, whether the food is received at the establishment itself or at a location where the authorized establishment receives and immediately transports the food to the food establishment;
 - b. shippers and carriers in operations in which food is transported from the establishment as part of the normal business operations of a retail establishment, such as:
 - i. Delivery of the food directly to the consumer(s) by the authorized establishment or a third-party delivery service, or
 - ii. Delivery of the food to another location operated by the authorized establishment or an affiliated establishment where the food is to be sold or served directly to the consumer(s).

Specifically, the Agency received questions asking if the term “retail food establishment” applies to businesses that only sell animal food, because retail food establishments, as defined by 21 CFR 1.227, can encompass establishments that sell human food as well as establishments that sell food for animals. We are issuing this guidance to clarify that the retail food establishment waiver applies to establishments that are permitted or otherwise authorized by the regulatory authority to sell human food. We are also clarifying that these establishments, that are permitted or otherwise authorized by the regulatory authority to sell human food, that sell both human and animal food also fall under the retail food establishment waiver. The retail food establishment

² For more information on the types of animal food establishments that may meet the definition of a retail food establishment, please see Draft Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition) at B.2.16, available at: <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/fooddefense/ucm331959.htm>

Contains Nonbinding Recommendations

waiver does not extend to establishments that sell food for animals and do not sell food for humans.

III. Discussion

The purpose of this guidance is to clarify what is meant by the term "permitted or otherwise authorized" and "retail food establishment" as used in the waiver, in light of questions that have arisen since the publication of the final waiver about whether this waiver extends to establishments that only sell animal food.

When the waivers were published on April 6, 2017 (82 FR 16733), FDA clarified that the term "food establishment" collectively represents specific types of establishments subject to the waiver, which are defined in 21 CFR 1.227, including restaurants, retail food establishments and non-profit food establishments, that hold valid permits as initially described in the proposed rule published on February 5, 2014 (79 FR 7006). Using the term "food establishment" in this manner does not broaden the scope of this waiver to include establishments that only provide food for animals directly to consumers. This is because the agency's intent in granting this waiver is that it only be applicable to establishments that are permitted or otherwise authorized by regulatory authorities under each regulatory authority's adoption of requirements that are based on FDA's Food Code. These regulatory authorities are already performing food safety and regulatory oversight and inspection activities for their permitted or otherwise authorized retail food establishments through state and local regulations modeled after the FDA's Food Code. This intent was expressed in the preamble of the proposed rule in which FDA discussed the reasons why it intended to grant the food establishment waiver. FDA stated that for the purpose of establishing the scope of this waiver, we intend to define "food establishment" using the definition set forth in the 2009 edition of the FDA's Food Code, which includes only operations that provide food for human consumption (79 FR 7030). In this regard, in both the 2009 and the current (2013) editions of the FDA's Food Code, "*food establishment*" means an operation that:

- Stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for **human** consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and
- Relinquishes possession of food to a consumer directly or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Therefore, consistent with the discussion of the scope of the food establishment waiver in the proposed rule, the waiver only applies to establishments that are permitted or otherwise authorized by the regulatory authority to sell human food.

With regard to such retail food establishments that also sell food for animal consumption, the waiver would also cover any animal food that they handle. For any animal food that is covered under the rule, the same public health practices that they are implementing to ensure the safety of human food at their establishments (e.g., temperature controls) would also apply to their

Contains Nonbinding Recommendations

handling of animal food. As a result, we do not think that this waiver will result in the transportation of food under conditions that will be unsafe for human or animal health or that will be contrary to the public interest.

IV. References

The following references are on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. FDA, "Food Code 2009," 2009, available at: <https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm2019396.htm>
2. FDA, "Food Code 2013," 2013, available at: <https://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm>