Because we have received a number of questions regarding FDA’s Sanitary Transportation waivers released earlier this week, we wanted to send out a quick note of clarification. Specifically, FDA’s notification is worded somewhat broadly, so it is important to read the full text of the waivers to understand which operations are exempt. The full text describing the relevant waiver is below:

“In accordance with the requirements of section 416 of the FD&C Act, by this notice we are waiving the following persons from the applicable requirements of the Sanitary Transportation rule:

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 establishments, and nonprofit food establishments as defined in 21 CFR 1.227), only when engaged in transportation operations as:

? 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;

? 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:
  • Delivery of the food directly to the consumer(s) by the authorized establishment or a third-party delivery service or;
  • 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).”
In summary, the waiver is only for operations that fall under other regulatory authorities (e.g., the Food Code). This means that retail stores are exempt from being receivers because that function falls under local and state authority. Shipments from store to store would similarly be exempt (except for loading) on the same basis. Likewise, home grocery delivery services would be exempt (except for loading) when food is delivered from a store directly to consumers.

However, shipments from distribution centers (DC) that are registered facilities (and other FDA registered food facilities) to retail locations are still covered by the rule, except that the retail food establishment where the food is received is exempt in its role as the receiver (as noted above). Food transported from a manufacturing facility to a DC is also covered under all parts of the rule. Additionally, food delivered to a consumer from a DC that is a registered facility (e.g., via a grocery delivery service) is not exempt under the waiver.

Finally, we have received some clarification from about what FDA means in the provision that exempts food establishment receivers when food is received “at a location where the authorized establishment receives and immediately transports the food to the food establishment.” This provision is unlikely to have application for most retail operations, as it is intended to cover transportation by a restaurant from a cash and carry operation.

For additional reference, you can review FDA’s analysis of comments submitted to the docket, and the published version of the waivers. Please let us know if you need further clarification.