SCOPELITIS, GARVIN, LIGHT, HANSON & FEARY

FDA to Publish Sanitary Food Transportation Rule

The Food and Drug Administration (FDA) will issue its final rule on Sanitary Transportation of Human and Animal Food tomorrow, April 6. The following is a brief summary of the major provisions and changes from the proposed rule. The rule established differing compliance dates -- one year from publication for large businesses, and two years from publication for small businesses (assuming compliance is not delayed by court challenge). Small businesses are defined as entities employing fewer than 500 full-time equivalent employees; however, for carriers that are not also shippers and/or receivers, the threshold is set at less than $27,500,000 in annual receipts.

The final rule applies to both interstate and intrastate operations but does not cover transportation of: a) food transshipped through the United States to another country; b) food that is imported for future export and neither consumed nor distributed in the United States; or c) certain foods that are located in food facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture. The final rule does not apply to entities engaged in transportation operations that have less than $500,000 (as adjusted for inflation) in average annual revenues (calculated on a three-year rolling basis). Additionally, the final rule does not apply to "parcel delivery service," which term is undefined, but the intent appears to be to avoid regulation of transportation operations from licensed retail food establishments to consumers, including home grocery delivery operations from food distribution centers. The final rule is also inapplicable to food completely enclosed by a container that does not otherwise require temperature control for safety.

Clarifying an issue that generated numerous comments to the proposed rule, the final rule amends the definition of "shipper" to include property brokers or any other entities that arrange for transportation of food in the United States. Notably, the final rule also introduces "loaders," a new category of regulated entities defined as persons who load food onto a motor or rail vehicle

(which could include warehouse operations). Entities may be subject to the rule's requirements in multiple capacities depending on the function performed.

The final rule is less prescriptive than the proposed rule and does not, per force, require continuous temperature monitoring devices and reporting. However, transportation operations must utilize such conditions and controls to prevent food from becoming unsafe during transportation. That requirement is placed initially, and primarily, on the shipper, but a shipper that elects not to take on all responsibility can specify through instructions in writing to the carriers and, if necessary, the loader, certain obligations including equipment design specifications, cleaning procedures, pre-cooling requirements, and operating temperature requirements.

The loader, which may also be the carrier, must, before loading, determine that the equipment is in appropriate sanitary condition and that refrigerated compartments are adequately prepared to transport food, taking into account applicable shipper instructions. The carrier must ensure the vehicles and equipment meet the shipper's specifications and are otherwise appropriate to prevent food from becoming unsafe and must provide the operating temperature specified by the shipper. If requested by the shipper or receiver, the carrier must demonstrate that it maintained the operating temperature specified by the shipper by such means as agreed to by the shipper and the carrier. A receiver of food requiring temperature control must adequately assess the food to confirm it was not subjected to significant temperature abuse.

A carrier that has been assigned in a written contract responsibility for some element of sanitary transportation requirement under the final rule must provide adequate training in basic sanitary transportation practices to its personnel engaged in the relevant transportation operations.

Rather than impose detailed requirements, the rule effectively defers to contractual agreements between shippers and carriers (or loaders, including warehouse providers) for adopting appropriate standards and safeguards. This contracting freedom could potentially place carriers and warehouse providers at a disadvantage in negotiating customer contracts. Likewise, it will be interesting to see how these issues are addressed with respect to existing contracts (many of which will presumably already impose obligations on the carrier or warehouse provider with respect to food safety) and spot freight.

From the property broker's perspective, the rule is quite troubling in that the property broker is simply not in a position to fulfill many of the obligations of a shipper (such as imposing food safety obligations on carriers) because the property broker is not in a position to know what is required to maintain the safety of its customers' food products. Time will tell how the FDA pursues enforcement in situations where a property broker is involved.

To protect their interests with respect to services where there is no master contract in place, carriers, property brokers and warehouse providers would be well served to amend their standard conditions of service to account for these new regulations, including consideration of provisions that require notice prior to tender of any commodities subject to the rule, and adoption of minimum standards that apply in the absence of the shipper providing specific compliance instructions.

If you have questions regarding the rule, please contact Craig Helmreich (chelmreich@scopelitis.com), Prasad Sharma (psharma@scopelitis.com), or Nathaniel Saylor (nsaylor@scopelitis.com).