



RE: Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records; Docket No. 2005D-0356

Executive Summary

Carolina Logistics Services, Inc. receives and manages the disposition of damaged and unsaleable merchandise inclusive of food products. Our clients include all major U.S. based grocery and general merchandise retailers and wholesalers. Our corporate offices are located in Winston-Salem, NC and we operate 35 returned goods facilities across the country, all of which are FDA registered pursuant to section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

- Industry statistics indicate that annually less than 1% of the U.S. grocery supply is deemed damaged or unsaleable. CLS transfers approximately 13% of this 1% received in our returned goods centers on to secondary market dealers and brokers. Stated differently, only 0.13% of all grocery items produced in the U.S. each year are ultimately sold by CLS to the secondary market for ultimate retail consumption.
- The nature of the reclamation industry places us very near the end of the food chain. The timeline from the point of manufacture to receipt and disposal of product would generally be no less than 109 days and as much as 195 days. More importantly, food items received by a CLS returned goods center are subsequently delivered to a secondary market dealer 21 to 52 days following receipt.
- The need to provide a per shipment accounting and description of each food item we transfer to a specific secondary market dealer (immediate subsequent recipient) at the time of the transaction will necessitate the reconfiguration of the business to accommodate extensive investments in technology, a change in the processing methods, and a perpetual increase in labor costs of at least 12-14%.
- CLS therefore proposes a modified ISR recordkeeping requirement for its reclamation business: With minimal changes to our current systems and processes, CLS can capture, track and report product information regarding each food item transferred to one of three or four secondary market dealers. This information would be retained and accessible for 2 years. Additionally, in the unlikely event of an incident involving a particular product, CLS would assume the responsibility for communicating with each potentially involved secondary market dealer to attempt to pinpoint the path of the product at issue and provide necessary direction.
- The field of reverse distribution relative to food items involves very few companies. In light of the small quantity of food product at issue this request would not affect FDA's ability to safeguard the U.S. food supply.