



Docket No. 2005D-0356

The purpose of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) is to enhance the security of the United States food supply. This comment requests that the Food and Drug Administration (FDA) exercise its enforcement discretion and permit CLS to comply with a modified immediate subsequent recipient (ISR) requirement because of the burdens that would be imposed by strict compliance with the requirement. Such an exercise of enforcement discretion would only affect the small handful of companies involved in reverse distribution and would not interfere with the purpose of the Bioterrorism Act.

Business Overview

Carolina Logistics Services, Inc. ("CLS") processes damaged and otherwise unsaleable merchandise for major wholesale and retail companies. Our corporate offices are located in Winston Salem, NC and we operate returned goods centers in 35 locations throughout the continental United States.

By way of definition; reclamation addresses the process of removing and disposing of unsaleable merchandise from the supply chain. Returned goods are goods that have been deemed unsaleable for whatever reason and have been removed from conventional retail and wholesale channels. Finally, reverse distribution, nearly synonymous with reclamation, identifies the physical process of removing unsaleable product from the supply chain and routing same back through distribution channels to the merchandise' designated disposition; return to vendor, sold to a secondary market dealer or destroy.

The two primary services CLS provides its retail and wholesale clients include: facilitating financial reimbursement for the cost of unsaleable merchandise from the responsible manufacturer or vendor; and assistance with the disposal of damaged and unsaleable merchandise.

According to the Grocery Manufacturers Association and the Food Marketing Institute, damaged and unsaleable merchandise represents approximately 1% of all grocery items produced and distributed in the U.S. annually. It should be noted that the products received and processed by CLS are either at the end of their life cycle (in such cases the product is generally destroyed) or very near the end of their life cycle. A small percent of the grocery products processed at a CLS returned goods center will be re-sold to secondary market brokers for later consumption. This represents on average 12.5 % of the total product processed in a returns center, or slightly more than 1/10th of the 1% of all grocery items produced and distributed in the U.S.

Identification of Unsaleable Product

A product is typically identified as unsaleable after a retail store receives the product and places it on shelves or it becomes unsaleable by the nature of the handling process (e.g., dented cans). Additionally, products remaining from seasonal promotions (e.g., Easter candy) are typically considered unsaleable after the promotion has ended.



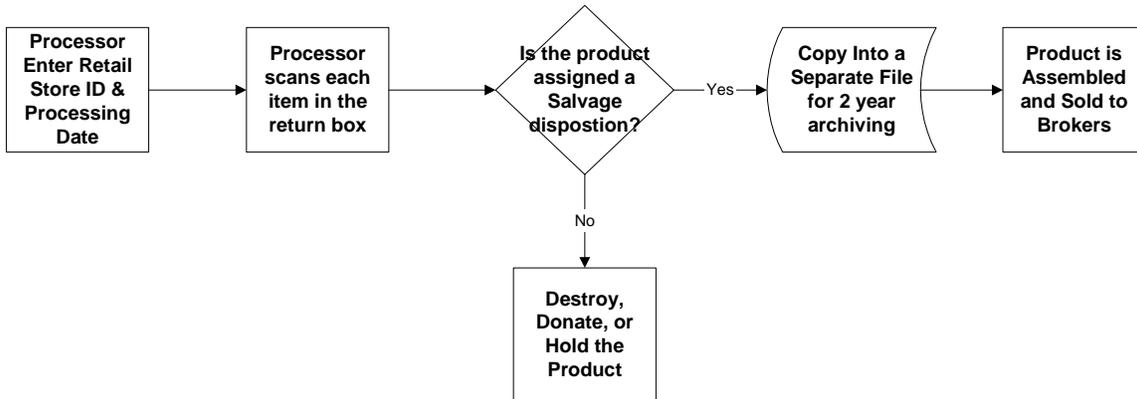
Post Unsaleable Product Path

Once identified as Unsaleable, the product is consolidated in the store’s back room and returned to the distribution center on the next truck coming with new products. The returns are then consolidated to a single truck and, when filled, sent to the returns center for processing.



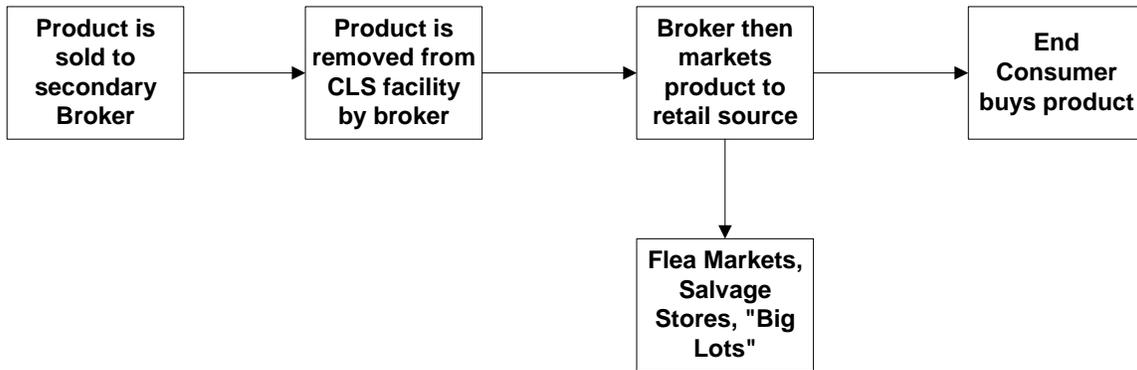
Returns Center Process Model

CLS facilities remove the product from the trucks by company until processing occurs. The inventory and processing order is the standard FIFO method. The facilities are equipped with PC’s to access and collect client specific information with scanning equipment similar to point-of-sale stations in retail stores. The processor first enters the retail store ID (or scans a bar coded label with this information included) and the processing date and then begins to scan each item in the box sent by the retail store. When an item is scanned, the system will find the item in the client’s Master file and will find the associated manufacturer of the product. The manufacturer stipulates the disposition of their product and the system reflects this disposition to the processor who in turn moves the product to the disposition area. The product disposition typically involves one of four channels: it can be destroyed, returned to the manufacturer, donated to a food bank, or sold to a secondary market broker. All products assigned to secondary brokers will be copied to a separate file by UPC, store ID, processing date, and quantity processed. This file can be developed to hold and access information for 2 years after the date the item was processed.



Secondary Market Process Model

CLS forwards all revenue resulting from secondary sales to our clients. They require we sell the product at market competitive prices. This requires that CLS deal with multiple secondary brokers when selling products to ensure pricing leverage is available and the volume can be removed from our facilities in a quick time frame. The number of secondary brokers is typically 3 to 4 for each returns facility. CLS currently maintains records of all sale transactions referencing the secondary broker. The broker acts as a wholesaler who then markets the product to a retail outlet such as flea markets, “Crushed n’ Dent stores”, or even large retail networks such as “Big Lots”.



FDA View of Recordkeeping Obligations of Reclamation Centers

In its guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records," a question was asked about reclamation centers and their recordkeeping obligations. Q&A Guidance (2d ed.), Question 36.1. FDA stated, "[I]f the food is returned to the manufacturer or sold to another nonconsumer, the reclamation center must establish and maintain records identifying the immediate subsequent recipient of the food, to the extent this information is reasonably available." Answer 36.1; see also 69 Fed. Reg. 71562, 71579 (Dec. 9, 2004). In the preamble to the final rule, FDA stated its view that, in the context of the retail food exclusion, information is "reasonably available" "if you have a system in place to capture the information. FDA does not intend to require the reconfiguration of business operations." 69 Fed. Reg. at 71575. However, in the Q&A Guidance, FDA further refined its answer about what is reasonably available: "FDA considers the information that must be 'reasonably available' in this subsection [§ 1.345] to refer to the retailer's knowledge as to whether the recipient of the food is a consumer or a business; it does not exempt the retailer from keeping required records when the retailer knows the recipient is a business and is able to capture this information." Q&A Guidance, Answer 6.6. Because FDA's interpretations as to what is "reasonably available" were provided in the context of the retail food establishment ISR exclusion, it is unclear whether these same interpretations apply to reclamation center ISR recordkeeping obligations. As discussed below, we believe that they should not.

Strict Compliance with the Act Would be Unduly Burdensome

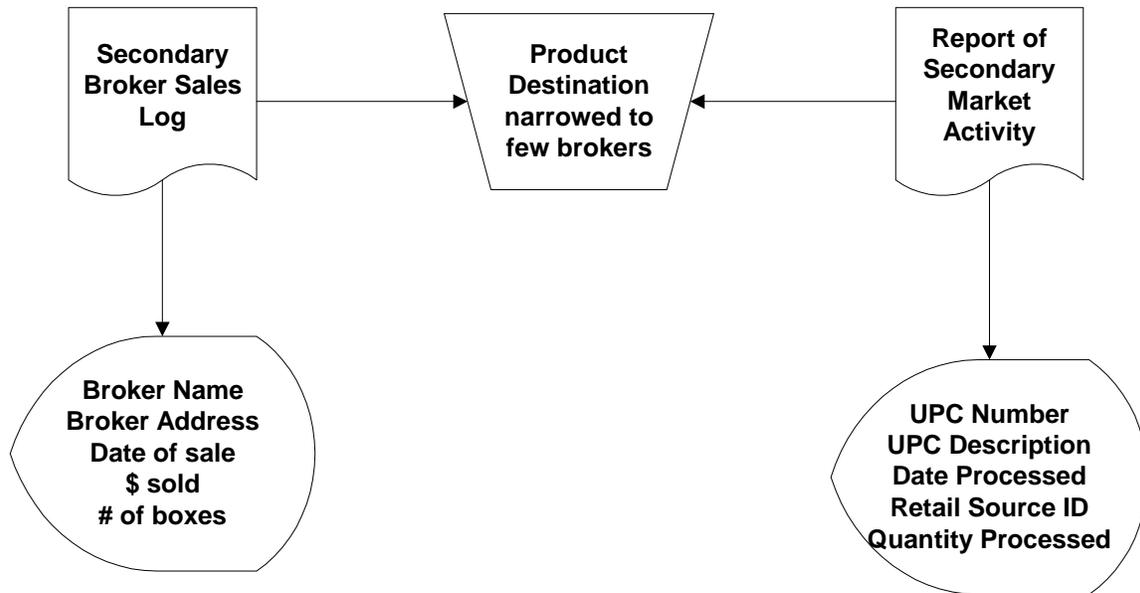
Under the current system, each pallet destined for a secondary broker contains a wide variety of goods and is filled by weight. Rigid application of the regulation on nontransporter ISR records, 21 C.F.R. § 1.345, would require each item transferred to a secondary market broker to be accounted for separately. To fulfill this obligation, CLS would have to track every item moving to a secondary broker pallet and then develop methods to group multiple pallets into a single shipment. This would amount to a major reconfiguration of our current business operations.

The impact of these necessary modifications would result in significant systems development effort, an extensive investment in technology and most importantly an ongoing increase in labor costs. The overriding concern is that the recordkeeping regulations will add enough cost to the returns process that retail clients, with traditionally thin margins, will reconsider using return centers as a viable option. If CLS is forced to assume the entire cost increase independently, then the company's ability to continue to offer products to our secondary market client base will be placed in significant jeopardy.

Proposed Modified Recordkeeping Solution

CLS believes the purpose of the Bioterrorism Act and regulations can be fulfilled if it is permitted to comply with a slightly modified ISR recordkeeping requirement: CLS proposes that, consistent with its current practices, it will keep all secondary broker sales in a formal log book referencing

the date of sale and the broker purchasing the product. Secondary market transaction activity can be requested by a selected date range. The log, in conjunction with the detailed transaction activity, will enable the product to be traced to one of three to four secondary brokers during the time in question. Were there to be an event necessitating the tracing of product from a CLS facility – i.e., a reasonable belief on the part of FDA that a food product is adulterated and such adulteration may lead to serious adverse health consequences in man or animal – CLS would take the initiative in ascertaining which of its secondary brokers actually received the product in question and would accomplish this task within 24 hours of notification.



Conclusion

The field of reverse distribution, as outlined in the above business overview, is a very narrow business. Because the scope of applicability of this modification would be so narrow, permitting it would not frustrate the overriding purpose of the Act to enhance the security of the United States food supply. CLS’ proposal would enable the FDA to fulfill its objective of traceability with respect to the food that CLS processes, with CLS’ proactive participation in pinpointing the downstream path of its products. Because CLS will continue to keep all secondary broker sales in a formal log book referencing the date of the sale and the broker purchasing the product, and because the secondary brokers will also maintain records of where they got their food supply, the chain of distribution will be ascertainable in the event such information is requested.

Exercise of FDA’s enforcement discretion to permit such a modified requirement will enable CLS to continue its reverse distribution business with minimal disruption and capital investment, which might otherwise lead to the cessation of business operations due to the burdensome costs of compliance with the Act. CLS believes the requested proposal is appropriate in light of the small quantity of product at issue – roughly 0.13% of the nation’s annual grocery supply – and its ability to effectively trace its own product.