March 3, 2010

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

(Electronic copy submitted to http://www.regulations.gov)

> **Re:** **Docket No. FDA-2009-N-0523; Product Tracing Systems for Food;**
> **Public Meeting**

Dear Sir or Madam:

The Food Marketing Institute (FMI) appreciates this opportunity to respond to the joint request of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) for comments concerning steps the two agencies might take to enhance current food tracing systems. We appreciate the agencies' efforts to understand the complexities of this issue; and as explained below, we believe a full appreciation of these complexities and the challenges they present, particularly with regard to the retail sector, is crucial before making a determination as to if and how food tracing systems should be enhanced.

The Food Marketing Institute (FMI) conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Its international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

As discussed more fully below, FMI and its members have actively promoted improved food safety practices and tracing systems. As an industry, we begin all of our food safety efforts from the perspective that the single highest priority should be to *prevent* food adulteration from occurring. Only food that is safe for consumers should enter the food supply. Regardless of the strength of a traceability system - no matter how much time, money, and effort is invested in tracking programs and recordkeeping - hunting for adulterated food will never protect public health as well as preventing adulterated food from entering the food supply in the first place. The best way to protect the public health is to focus on preventing problems before they occur. FMI members are

acutely aware of this and have sound programs in place to prevent adulteration at store level and to work with their suppliers on producing safe food.

FMI and its members recognize, however, that no system is perfect, and therefore, FMI members have implemented effective systems to quickly *remove* adulterated food from the distribution system once the food has been identified. Suppliers notify retailers about products that have been recalled through a variety of means, including the newly-launched Rapid Recall Exchange (RRE). RRE was developed by FMI, GS1US, and the Grocery Manufacturers Association to provide quick and complete information on recalled products to retailers and distributors. Many retailers can even "lock out" the UPC code for a recalled food product so that a consumer who already has the product in his or her shopping basket will not be able to purchase it when he or she gets to the cash register.

FMI and its members are well aware that, in some cases, the first signs of a potential problem are the occurrences of food borne illness clusters, signaling that an as yet unidentified adulterated food product is somewhere in the food supply. Although retailers and wholesalers stand willing to help, they need clear information about which products are suspected of adulteration before they can get the products out of the system.

Over the past several years, we have experienced several prolonged investigations where the government struggled to solve the mystery of identifying the food that was making people sick. As a result, some have called for new mandatory traceability systems, and many of these recommendations would increase the granularity with which food is tracked through the supply chain.

FMI and its members agree that, no matter how strong our food safety system is or becomes, it can always be improved. Simply scrapping existing systems for newly-developed technologies, however, is not the answer. In addition to considering systemic enhancements, we recommend considering how to utilize existing information and systems more effectively, including how to improve communication and collaboration among all stakeholders.

Before addressing the specific information that travels through the food distribution system, however, it is paramount that the agencies understand how the system operates. Most people likely walk into a typical grocery store without realizing that it may have 75,000 different product types (or SKUs) on its shelves and without considering how all of those products arrived on the store shelves. These are products that have traveled from as far as Australia and as near as the farmer down the road. While there is no need for consumers to understand the complexity of the distribution and retail system, it is crucial for the agencies to appreciate this complexity before determining whether and how current systems should be enhanced.

Although the distribution system has some important variations, most food products travel from suppliers through a distribution center where they are sorted and reorganized before they are shipped out to individual grocery stores. According to a 2007 FMI survey, the median size of a United States food distribution center was more

than 583,000 square feet[1]. This is the equivalent of more than 13 acres. In Washington, D.C., many home lots are 1/4 of an acre, so a median sized distribution center could cover 52 homes and their yards. Put differently, a football field (including end zones) is 57,600 square feet, so the size of the median warehouse is more than 10 football fields combined. (The largest distribution center in our survey is nearly 6 million square feet, so these examples could be expanded by an order of magnitude.)

It is important to note that distribution centers do not operate on just one level. They typically have tall racks that create the equivalent of two or three additional levels of space above the ground level, significantly multiplying the amount of food that can be moved through a warehouse. Each of these levels is divided into large cubes of empty space that are called "slots." Ground level slots are called "pick slots" (because cases of food are picked from them), and upper levels are "reserve slots." The racks of slots are similar to a big skeletal hotel, and each slot is like a "hotel room" that is waiting for a delivery to occupy it on a temporary basis.

The average distribution center receives 500 food deliveries per week[2]—everything from the products you find in the produce, meat and seafood department to the individually wrapped packs of gum at the checkout lines. Individual consumer units of food are generally packed in cases or boxes that are stacked and shrink-wrapped onto pallets. Multiple pallets make up each of the 500 average deliveries. This process delivers more than half a million cases of food each and every week. After receiving, the pallets of cases are put away into the distribution center's cubes or slots—one pallet for each slot.

The next step is order selection. Each store serviced by the distribution center places an order with the warehouse almost like a shopping list: two cases of green beans, one case of chicken breasts, six cases of pasta, and so on. Warehouse order selectors then fill each store's order by traveling throughout the large distribution center on motorized carts, stopping at each relevant floor level pick slot to collect the requisite number of cases of the specific foods on the list and adding them to the motorized cart. When all of the cases requested have been selected, the order is repalletized and shrink wrapped so that it can be delivered to the store. Using this process, the median distribution center ships more than 617 million pounds of food every year[3]. This is more than 300,000 tons of food. Multiplying this by the number of warehouses and distribution centers throughout the country gives a sense of the truly enormous magnitude of the system.

Efficiency is the most important hallmark of a distribution center. Food is not manufactured or processed in a warehouse. There is no change or "value added" to the food itself. The safety and quality of the food is not improved at a distribution center.

The sole purpose of distribution is to get the right mix of foods from hundreds of suppliers to hundreds of stores so that, when each consumer walks into his or her grocery

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[1] FMI Distribution Center Benchmarks 2007: pg. 13
[2] FMI Distribution Center Benchmarks 2007: pg. 5
[3] FMI Distribution Center Benchmarks 2007: pg. 27

store this afternoon, he or she will find a full assortment of the 75,000 SKUs of products that he or she has come to expect every time he or she walks in the door. The cost of that convenience is directly proportional to the degree of efficiency that can be achieved at the warehouse that sorts and distributes the food.

Given the importance of efficiency and the massive volumes that move through the system, warehouse performance is measured in pennies and seconds per case. The average cost to handle all cases through the distribution center was $0.39 per case in 2007[4]. Although the 2007 FMI study did not measure time, one company reported that its time to handle outbound cases averages 20.57 seconds per case, and we consider this company to be representative, with statistics comparable to many other companies. After considering the volume of cases handled by the typical distribution center—more than 500,000 inbound and another 500,000 outbound at each distribution center every week—it becomes apparent that what might seem like a minor shift in process, requiring a few additional seconds to handle each case is capable of causing significant disruptions.

Despite this complexity, unique information systems have been developed to track food products. Typically, a wholesaler places an order with a supplier and assigns a Purchase Order (PO) number to the order. The PO number is captured on the invoice that is sent from the supplier to the wholesaler for payment, as well as on the manifest or shipping documents that accompany the shipment, which is delivered in pallets or stacks of individual cases. When a pallet is received, most warehouses add a "license plate" or internal tracking information to the pallet as a whole. The license plate, PO, and invoice can all be connected, so information that the supplier sends on the invoice (such as lot information when available) can be connected to the pallet.

Cases can only be selected from a ground level "pick slot" so they are stored in higher level "reserve slots" until they are "let down" to a pick slot. Time of let down is recorded, so the warehouse knows the time period during which a particular pallet is in a pick slot, as well as which stores' orders are being selected during that time period. Distribution centers can use this information to connect the information provided by a supplier on an invoice or an advance ship notice with a store or group of stores that were likely to receive the product.

Case-specific information is not routinely captured at the warehouse today. Breaking down pallets upon receipt so that warehouse personnel could examine and capture information from each case, only to reconstitute the pallet before slotting, would add an extraordinary amount of time and no commensurate food safety benefit to a process that is measured in fractions of a second. Similarly, requiring a selector to record case-specific information for each case at the time that a store order is being fulfilled would add a significant amount time to the process. In broad terms, adding as few as four seconds of handling time to a process that currently takes 20.57 seconds would decrease productivity by 20%.

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[4] FMI Distribution Center Benchmarks 2007: pg. 72

In an industry that measures profit in terms of a penny on the dollar, these costs would necessarily be passed on to consumers in terms of higher food prices; yet the consumer would receive no additional measure of food safety in exchange. In these times of economic crisis, with unemployment hovering in double digits in many states, too many home foreclosures, and 36 million people receiving federal food assistance, we cannot lose track of what adding cost means to real consumers every time they shop for food.

Of course, FMI and its members believe that affordability need not be sacrificed for safety. But we already capture significant amounts of information. We should look for better ways to use and share this information, in addition to considering new systems and technologies.

Some have suggested ever increasing levels of granularity to address the food traceability issue. As highlighted several times in the agencies' December public meeting, traceback efforts are not straight line processes; they are iterative. Improving existing methods of sharing information with the agencies – such as through the Reportable Food Registry – or ways of collaborating about available information – such as through a "war room" approach, where people from different disciplines, including industry, are brought together to collaborate in solving the mystery posed by a food borne illness outbreak – might help in ways that additional layers of data can not.

In addition to a focus on better utilizing existing data, new technologies and systems and the possibilities that they hold should be considered. FMI has endorsed the Produce Traceability Initiative, and some of our members are actively working to meet the milestones for implementing it, including case level tracking utilizing increased voice-directed selection or outbound case scanning. Not all of our members, however, have concluded that this is the appropriate business model for them.

Any new systems or technologies must be "interoperable." From the discussion above about the hundreds of thousands of products that move through a distribution center, it becomes obvious that any information that needs to be captured at the warehouse must be in a language that can be commonly understood. Although uniform systems are not necessary, each system does need to be able to "talk to others" and exchange information.

FMI would like to take this opportunity to specifically address two issues often included in the food traceback debate that have particular importance for its members— customer loyalty cards and meat grinding logs.

There has been discussion of enhanced use of retailers' customer loyalty card programs. It is important to recognize that both retailers and consumers have varying philosophies about loyalty card programs. Some retailers make them an essential component of their "go to market" strategy. Consumers who value that approach participate. Other consumers truly do not want to give their personal information to any retailers, explaining why some of our members' loyalty card databases have a disproportionate number of customers named after cartoon characters or other false

aliases. And some retailers are likewise philosophically opposed to loyalty card programs. Nearly 60 percent of food retailers do not utilize any type of loyalty card program.[5]

With regard to grinding logs, we must make two points. First and again, *E. coli* O157:H7 does not originate in grocery stores; it comes into the store on product that is already contaminated with this pathogen. All meat that is sold in grocery stores comes from federally inspected (or equivalent state inspected) plants that are under continuous USDA inspection. No meat leaves these plants unless it has been approved by the USDA inspector and bears the mark of federal inspection. If *E. coli* O157:H7 is in meat ground at a grocery store, it is because meat that entered the store carried *E. coli* O157:H7. We believe that all participants in the process – processors, government and retail – are working hard to solve this difficult problem, but solving it will require collaboration and communication.

Second, in terms of grinding logs themselves, we would like to work with USDA to articulate more clearly the problem that USDA is trying to solve. USDA officials suggested in the December public meeting that poor store-level records meant that the specific source of supply could not be identified, specifically that they could only narrow down to six or nine suppliers. But if the issue is narrowing down suppliers, grinding logs are not the answer. For better or for worse, commingling is a fact of life in today's food chain – from milk, to wheat, to ground beef. Recording the six or nine suppliers that were used to produce a given day's ground beef will not change the fact that six or nine suppliers were used. Retailers know who their suppliers are. If the issue is narrowing the scope, this focus should be clear. Supplier groups have voiced concern with the quality of retail grinding logs, but these groups have not always been willing to assist their customers by providing mechanisms such as peel-off labels or labels on cry-o-vac bags. Again, the best way to address these issues is to work together.

In conclusion, FMI and FMI's members support enhancements of the food safety system. We are continually looking for new ways to help in this effort and stand ready, willing, and able to work with state, local and federal government officials, as well as our partners across the food supply chain. Before imposing new traceability requirements, however, it is important that the agencies consider the complexities of the food supply chain and how existing programs might be better utilized. Thank you for this opportunity to comment.

Sincerely,

Leslie G. Sarasin, Esq., CAE
President and Chief Executive Officer

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[5] The Food Retailing Industry Speaks 2009: Annual State of the Industry Review, p. 32.

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