



THE VOICE OF FOOD RETAIL

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July 3, 2013

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

RE: Docket No. FDA-2012-N-1153

On March 5, 2013 the Food and Drug Administration (FDA) published notice of the availability of a report from IFT *"Pilot Projects for Improving Product Tracing along the Food Supply System."* The report is the result of pilot projects required by the Food Safety Modernization Act (FSMA), and FDA is now requesting comment on the report before FDA reports to Congress and contemplates rulemaking.

Food Marketing Institute proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost \$770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

FMI and several retail companies participated in the pilot projects organized by the Institute of Food Technologists. Product tracing is very important to retailers in terms of being able to identify where products are from and where products have moved to in the supply chain. Foodborne illness investigations often start with retailers since we are only one step removed from consumers, so we are very familiar with traceback investigations and the need for accurate information to be available quickly.

FMI generally agrees with and supports the recommendations in the report. FMI will support FDA in its implementation of the recommendations consistent with its authorities pursuant to FSMA.

FDA asked several questions in the *Federal Register* publication on March 5, 2013. FMI would like to provide the following information in response to those questions:

1. FMI is supportive of the industry use of key data elements (KDE) and critical tracking events (CTE). These concepts and subsequently defined terms have been vetted with multiple segments of the food industry and provide a strong framework for product tracing. The retail industry faces challenges with product tracing currently, as is the case with many other segments of the food industry. Tracking depletion would be a

significant challenge and workable solutions must be identified to make this a practical step for retail.

2. For product tracing to be effective, critical mass is needed in the food industry. If only certain foods are traced, there will be too many holes in the records that the system will not be effective and more time will be spent tracking down missing information. If systems are in place and employees are trained, it is easy to capture more information. The process of identifying a list of high risk foods has not been an easy one for FDA. FMI proposes that FDA incentivize the industry to have voluntary product tracing for all foods.
3. Product tracing can be trace back or trace forward. There are some elements that overlap with product recalls but FMI believes they are different events.
4. The economics of product tracing are very likely to change over the next few years. FMI recommends that FDA reevaluate the economics as product tracing evolves.
5. The more information as FDA can provide about product tracing investigations, the better. The majority of the industry does not know what to expect and companies in different districts or different states can have very different experiences with investigations. FDA should be as transparent as possible with the industry about what the agency needs and what the industry should expect.
6. Knowing what information to send in what format would help the retail industry. FMI recommends that FDA remain flexible to advances in technology and not lock the industry into one format that will become outdated. Many investigations and the pilots have demonstrated that paper is too slow. The industry recognizes the need to move to electronic product tracing with interoperable systems to make sharing data a simpler process.
7. FDA should carefully consider industry initiatives and business processes that are in place when looking at improving product tracing.

FMI also offers the following comments:

Although the IFT Report recommends that lot/batch numbers be collected during transport CTEs and consumption CTEs as a best practice, FMI notes that Congress in section 204 of FSMA explicitly prohibited FDA from requiring product tracking to the case. Section 204 also explicitly prohibited the agency from requiring a full pedigree for foods, or a record of the complete previous distribution history of the food from the point of origin of such food. Congress included these limitations because of concerns related to the burdens of collecting and maintaining such information.

The IFT Report also explores the use of shopper card data in traceback investigations. FMI members voluntarily cooperate with public health officials to share information and provide data on consumer purchases to assist with investigations. Where privacy barriers are not an issue, FMI supports retailers openly sharing information with public health officials in order to protect public health in identifying the contaminated products and assisting with the speed of investigations.

The definitions and language used for product tracing are relatively new for the food industry and have the potential to cause some confusion. One such term is "standard." The retail industry has a long history of working with supply chain partners on standards. Many standards exist in the industry and are in place between supply chain partners. We encourage FDA to work with the industry on appropriate terminology and definitions as you move forward with product tracing initiatives.

Thank you for the opportunity to comment on this report. We look forward to working with FDA as the agency moves forward with its report to Congress and rulemaking on this topic.

Sincerely,

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