Consumer Federation of America

June 7, 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

To Whom It May Concern:

Consumer Federation of America[1] is pleased to comment on the Food and Drug Administration notice concerning Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food (Docket No. FDA-2012-N-1153).

Traceability is an important component of a modern food safety system. Tracing systems can be used both in responding to foodborne illness outbreaks and in preventing them. When an outbreak occurs, it is essential that the government be able to efficiently and accurately trace contaminated product through the supply chain in order to remove it from commerce and reduce the risk to the public. Product tracing systems can also help prevent illnesses from occurring if a food is found to be contaminated but has not yet been distributed in commerce. While there are unquestionably costs associated with product tracing systems, the benefits are significant. Effective product tracing can reduce recall costs to both industry and consumers, prevent additional consumers from becoming ill from contaminated food, improve consumer confidence in the food supply, and enhance industry supply chain management.

The Institute of Food Technologists (IFT) report on Product Tracing is a very thorough documentation of the pilot programs IFT conducted, as well as an analysis of opportunities and challenges to effective product tracing. For the purposes of this notice, CFA will comment on several discrete areas raised in the IFT report.

[1] CFA is an association of nearly 300 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food safety, agricultural biotechnology, food and agricultural policy, and nutrition.

Product tracing requirements should apply to all foods

CFA agrees with IFT's recommendation that FDA should establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not only high-risk foods. FDA needs to be able to efficiently and accurately trace all products, including ingredients, through the supply chain. While the statutory language in the Food Safety Modernization Act refers only to high-risk foods, CFA does not believe that such an approach is sufficient to protect the public.

We have seen several incidents in recent years where previously "low-risk" foods became associated with nationwide foodborne illness outbreaks, sickening consumers. Several years ago, most stakeholders would have identified peanut butter as a "low-risk" food. After multiple contamination events that sickened numerous consumers, peanut butter can no longer be considered "low-risk." Further, ingredients of processed products, such as spices, are increasingly being implicated in foodborne illness outbreaks. If FDA is investigating an outbreak linked to a non high-risk food or a food with multiple ingredients with inadequate product tracing records, the investigation could be slowed and hindered, placing additional consumers at risk.

In addition, it is likely that the definition of "high-risk" will change over time as FDA gathers new data and information and adjusts the agency's "high-risk" foods list. Some companies may be producing both "high-risk" and non-high risk foods at the same time and would be following two separate recordkeeping requirements. Having to continually update or expand product tracing information based on FDA's "high-risk" list would confuse food companies as well as FDA and could lead to delays in outbreak investigations if information is not available. Both FDA and the food industry should consider the consequences of having separate product tracing requirements for "high-risk" and non high-risk foods.

CFA urges FDA to develop a standard set of product tracing requirements that can be applied to all FDA-regulated food products. FDA should pursue efforts to require all food producers to comply with those product tracing requirements. If, due to statutory restraints, FDA is unable to legally apply those requirements to all food products, the agency should use guidance and communication opportunities to encourage all food producers to comply voluntarily.

FDA should clearly articulate product tracing information needs

The IFT report makes clear the need for FDA to identify the specific information the agency needs to effectively conduct a product trace. IFT identifies Key Data Elements and Critical Tracing Events as essential pieces of data. FDA should require food firms all along the supply chain to identify and maintain this information as part of its product tracing requirements.

In addition to this information, FDA should identify the specific type and format of information that FDA finds most useful. FDA should also express the reason for requesting certain information so that the food industry can better understand the importance of that data to FDA's investigations. FDA should include this information in any guidance the agency develops on product tracing. The agency should also consider articulating how product tracing information was used in any final outbreak investigations reports in order to provide real-world examples of how the agency uses the information.

All food companies should develop and execute a product tracing plan

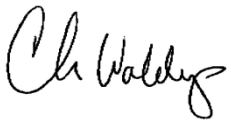
IFT notes that many of the firms participating in the pilot program were surprised by the product tracing process and "had never considered how their records would need to be pieced together with those of their supply chain partners to facilitate an effective traceback." The pilot process allowed these firms to

better understand how a product trace might work and provided them the opportunity to improve their internal processes. CFA believes that all firms might benefit from thinking through a product tracing scenario similar to the benefits that can be derived from a mock recall exercise.

The Food Safety Modernization Act requires companies to develop a recall plan. Similarly, FDA should require all food firms to develop, maintain, document and execute a product tracing plan. By developing and testing such a plan, firms will be in a better position to provide product tracing records to FDA during an investigation. As with the pilot firms, companies may enhance their internal processes as a result of such an exercise. FDA inspectors should review these plans and documentation that the plans were tested when they visit food facilities.

CFA appreciates the opportunity to provide comments on this notice.

Sincerely,



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