Consumer Federation of America

March 1, 2010

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

Re: Docket No. FDA-2009-N-0523

To Whom It May Concern:

The Consumer Federation of America (CFA) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) Federal Register notice and request for comment on Product Tracing Systems for Food **(Docket No. FDA-2009-N-0523)**.

CFA is a non-profit association of some 280 organizations, with a combined membership of over 50 million Americans. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and anti-hunger and food safety organizations. Since its founding in 1968, CFA has worked to advance the interest of American consumers through research, education and advocacy. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food and agricultural policy, agricultural biotechnology, food safety and nutrition.

CFA believes that an effective product tracing system is a critical 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.

Consumers Support Traceability
Consumer polling data show strong public support for traceability. A 2009 poll conducted for the Pew Charitable Trusts found that 94 percent of consumers supported

requiring tracing systems that enable FDA to quickly trace food back to its source[1]. A 2008 Consumers Union poll found that 97 percent of consumers polled supported the government being able to trace food from production to sale if problems arise[2]. Additionally, a July 2008 AP/Ipsos poll found that 86 percent of consumers said produce should be labeled so it can be tracked through layers of processors, packers, and shippers, all the way back to the farm[3].

Elements of an Effective Product Tracing System

Current efforts to trace food products are often inadequate. FDA staff encountered significant difficulty in tracing tomatoes and peppers throughout the supply chain during the 2008 *Salmonella* Saintpaul outbreak investigation. The Office of Inspector General of the Department of Health and Human Services confirmed those difficulties in a 2009 report on traceability in which OIG investigators were only able to trace five of the 40 selected products through each stage of the food supply chain[4]. Investigators were unable to identify the facilities that handled four of the products. For the majority of the products, investigators were able to identify facilities that likely handled the products, but the information was insufficient to fully trace the products through each stage of the food supply chain. The OIG noted that a lack of lot-specific information and the mixing of products from various farms were key factors preventing investigators from conducting adequate traceback.

Additional important issues were raised at the joint FDA/FSIS public meeting on Improving Product Tracing in Foods, held December 9-10, 2009. Comments are provided on several of those issues below.

Effective tracing can be facilitated by the use of product lot or code numbers assigned to food products. Differentiating food production into lots establishes specific units of production that can be more easily identified during traceback activities. Properly conducted, this practice can help narrow the search for contaminated products to certain lots produced during certain times of the day and possibly limit implication of an entire day's production. It can also provide agencies the ability to more rapidly identify contaminated product. The OIG recommended that FDA seek statutory authority to require all processors, packers, manufacturers, distributors, storage facilities, and retailers to create and maintain lot-specific information for food products. CFA agrees with this recommendation. Lot or code numbers should be maintained throughout the supply chain. The numbers should be located on the food label and the shipping container and should be indicated in internal as well as external records. Agencies should specify appropriate lot sizes or timeframes of production.

At the December public meeting, several presenters noted that tracing records were often kept in different formats with differing information provided. This lack of standardization

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[1] Hart Research/Public Opinion Strategies, June-July 2009

[2] National Research Center, Consumers Union, Nov. 2008

[3] Ap/Ipsos poll, July 2008 http://meridianstar.com/national/x681114513/AP-Poll-Food-Safety

[4] Office of the Inspector General, Department of Health and Human Services, "Traceability in the Food Supply Chain." OEI-02-06-00210, March 2009, via http://oig.hhs.gov/oei/reports/oei-02-06-00210.pdf.

hinders agency efforts to conduct rapid and effective traceback and traceforward. Agencies should establish standardized record-keeping requirements which would identify key data elements necessary to facilitate traceability. These data elements should include such information as agencies find necessary to conduct effective traceability activities.

Proper documentation is insufficient, however, if agencies do not have ample access to facility records. FSIS requires certain firms and corporations "to maintain, retain and make available to FSIS records that fully and correctly disclose all transactions involved in their businesses subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act." These records, which include product tracing information, must be made available for examination and copying to a representative of the Secretary of Agriculture. FDA regulations, on the other hand, "require a firm to make certain information available to FDA, within 24 hours, when FDA has a *reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals*" (italics added). This standard of "reasonable belief" severely limits FDA access to facility records and impedes the agency's ability to act preventively. Rather, FDA should have routine access to facility records relating to the manufacture, processing, packing, transportation, distribution, receipt, holding and importation of food products.

Finally, several presenters at the December public meeting suggested that tracing requirements should be based on risk, with the implication that low-risk products should be exempt from traceability requirements. CFA disagrees with such a proposal. All food products should have adequate tracing systems in place. There have been too many recent examples of products implicated in foodborne illness outbreaks or contamination events that were previously assumed to be low-risk products. In addition, ingredients of processed products are increasing being implicated in foodborne illness outbreaks. Agencies need to be able to efficiently and accurately trace <u>all</u> products, including ingredients, through the supply chain.

FSIS Should Traceback Positive Findings to the Source

Traceback and trace forward activities are not just important in responding to outbreaks, these activities are also important for investigation of potential problems to prevent illnesses from occurring. In the event of a foodborne illness outbreak, FSIS conducts a full complement of steps to trace back to the source of raw materials when an outbreak indicates that *E. coli* O157:H7-adulterated product entered commerce. The agency does not take these same steps when its routine microbiological testing program for *E. coli* O157:H7 detects the pathogen in ground product at a federally-inspected facility or at retail.

Small grinding facilities may purchase and re-grind a small portion of a given slaughterhouse's product lot of beef while the rest is purchased by other facilities. If FSIS testing reveals adulteration at that single grinding facility, current agency policy is to prohibit the tested grinder from selling any of the product. However, since that product was only a portion of the slaughterhouse's product lot, there is likely other meat from that

same lot in commerce. Yet FSIS does not attempt to identify any other firms that received portions of the original product or to inform those firms that they may have received adulterated product. Without notification from FSIS, the other grinding establishments will continue to use and sell ground beef made from the same production lot as the tested, adulterated material, needlessly exposing consumers to illness and death.

On average, FSIS' routine testing program for *E. coli* O157:H7-adulterated product in federally-inspected or retail facilities finds the pathogen 40 times every year. Current policy means the USDA is passing up 40 opportunities each year to prevent foodborne illness tragedies. This failure to act is not consistent with a preventive, public health-based program and threatens consumers on a daily basis.

There is no scientific basis for following one policy when *E. coli* O157:H7 adulteration results in an illness and another when FSIS testing finds *E. coli* O157:H7 adulteration before it has had the opportunity to cause an illness. FSIS should follow the same procedure when it learns from its routine testing program that *E. coli* O157:H7-adulterated product entered the production or distribution chain as it does in response to *E. coli* O157:H7-related illness.

Recall Communication Should be Enhanced

Part of an effective traceability policy is effective communication with consumers during an outbreak investigation and food recall. FDA and FSIS should seek and Congress should provide both agencies with the authority to mandate a recall. While it is typically in the best interest of companies to voluntarily recall a product that has been found to be contaminated, there have been occasions when companies have refused to do so. For those instances, the agencies need the authority to require the company to conduct a recall to assure that contaminated product is quickly removed from commerce.

In the event of a recall, both agencies issue press releases alerting the public to the recall. These communications typically include the name of the company conducting the recall, the appropriate contact information, identifying information about the recalled product(s) often including pictures of the product labels, the risk to consumers from the contaminated product, and what actions consumers should take to protect themselves. These are all important elements to include in the recall notice.

However, three elements included in FSIS recall notices are not included in FDA notices. First, FSIS press releases provide a clear indication at the top of the notice of the classification of the recall (Class I, Class II, or Class III). This immediately alerts the public and the media to the public health importance of the recall. Second, FSIS has stopped using the term "voluntary recall" in its notices and now simply indicates that a company is conducting a recall of a product. While technically all food recalls are currently voluntary (exception: recalls of infant formula are mandatory), the use of the term "voluntary" can lessen the importance of the recall in the minds of the media and the public. Finally, FSIS posts a retail distribution list for all Class I recalls for products sold at retail. This information can help consumers properly identify recalled products that may be in their possession because it provides the name of the store at which the recalled

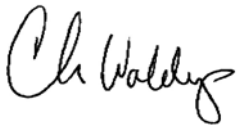
product may have been sold. FDA should incorporate each of these elements into its recall communication policies; in fact, the agency should go further than FSIS in developing a retail distribution list policy and include Class II recalls as well.

Use of Retail Consumer Loyalty Cards Should be Encouraged

Many retailers use consumer loyalty cards to track retail purchases and provide consumers with special discounts on food products. The Food Marketing Institute estimates that about 45 percent of food retailers offer loyalty programs and approximately 35 percent of shoppers use their loyalty cards every time they shop[5]. Some retailers such as Costco, Wegmans[6] and Giant Eagle[7], have begun using those same programs to contact consumers in the event of a recall. The loyalty card databases allow retailers to specifically target consumers who have purchased a recalled product with emails, phone calls and letters alerting them to the recall. Shoppers have generally responded positively to notification from the retailer that they may have purchased a recalled product. This pro-active communication with consumers is commendable and should be encouraged.

In addition, the Centers for Disease Control noted in its recent investigation of the *Salmonella* Montevideo outbreak linked to pepper-coated salami and sausage products that investigators successfully used loyalty card information to determine the specific brands of product suspected to cause illness[8]. Consumers who were sickened gave public health officials permission to retrieve purchase information based on their loyalty card numbers. Agencies should continue to explore this type of information gathering in conducting traceback activities provided they obtain consumer permission to access the information.

Sincerely,



Chris Waldrop
Director, Food Policy Institute

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[5] Food Marketing Institute, *U.S. Grocery Shopper Trends 2007.*

[6] Aleccia J, "Dial-a-recall? Stores use cards to warn buyers." *MSNBC.com,* January 23, 2009, via http://www.msnbc.msn.com/id/28802536/.

[7] Lindeman T, "Giant Eagle lauded for recall efforts." *Pittsburgh Post-Gazette,* January 21, 2010, via http://www.post-gazette.com/pg/10021/1029898-28.stm.

[8] Centers for Disease Control and Prevention, "Investigation Update: Multistate Outbreak of Human *Salmonella* Montevideo Infections, February 24, 2010, via http://www.cdc.gov/salmonella/montevideo/index.html.