

Institute of Food Technologists 1025 Connecticut Ave., N.W., Suite 503 Washington, D.C. 20036-5422 USA

+1.202.466.5980 +1.202.466.5988 Fax iff.org

Frequently Asked Questions about the Product Tracing Pilots

How can individuals be involved and find out more about the pilots?

There are many variables with respect to conducting the pilots, and IFT hopes to gain stakeholder input during the process. There are several areas in which IFT is seeking specific input. After posting these questions, IFT hopes stakeholders will take advantage of opportunities to provide oral feedback (tentatively scheduled for October 3, 2011 in Seattle, WA, October 5 in Washington, DC, and November 2 in Chicago, IL; other locations TBD) and/or written feedback (by December 1; input on product selection should be received by October 10). Exact dates and locations, and additional information, will be available at www.ift.org/traceability shortly. Caitlin Hickey is the IFT point of contact for inquiries (chickey@ift.org).

Why was IFT chosen by the FDA to lead these pilots?

IFT was competitively awarded a 5-year contract with FDA in 2009. This was IFT's third competitively awarded contract. Within the five year period, FDA asks IFT to perform specific "tasks". In the last contract, tasks focused on issues such as food defense, allergen labeling, and product tracing. Results from the most recent product tracing tasks can be found at www.ift.org/traceability under '2009 IFT Report Findings and Recommendations to FDA: Traceability (Product Tracing) in Food Systems'. The most recent task requires IFT to execute the product tracing pilots that FDA is required to perform as part of the Food Safety Modernization Act.

How will this all come together?

Three IFT food scientists (one Ph.D, and 2 MS), along with support staff, will work with a group of 8 "core expert panelists". Although the pilot tests are the main component of the task, IFT staff must also conduct related work to inform the final report to FDA. Core expert panelists have been invited. They include Douglas Bailey from the USDA Agricultural Marketing Service, Benjamin Miller from the MN Department of Agriculture, Bruce Welt from the University of Florida, Brenda Lloyd from UFPC/Yum! Brands, Jack Guzewich, IFT's Food Safety Strategist, Thomas Breuer from Deloitte Consulting, and Caroline Smith DeWaal from the Center for Science in the Public Interest. In addition, IFT expects to enlist a number of participants, potentially including state traceback investigators, food industry members, and others, for actual pilot tests. Both the produce and processed food studies will consist of at least two tests. Finally, IFT is charged with evaluating the costs and benefits associated with the pilots and other tracing technologies. IFT expects to issue a subcontract to Auburn University to support their cost- benefit research efforts on this task. Stakeholder input sessions, described below, will also take place.

Is IFT accepting additional sources of funding to complete the work?

No. Although IFT has recently launched a Traceability Improvement Initiative which is privately funded, that Initiative is not supporting the pilots (the Initiative is augmenting an award from the National Center for Food Protection and Defense to study interoperability of traceability technology providers). IFT will not accept additional funds to support the pilots. However, IFT has been encouraged by the inkind support offered by technology providers, food industry members and others. IFT does not expect that the budget will allow IFT to reimburse all participants for all time expended on this task, and is appreciative of the effort that may be volunteered. A team from Deloitte Consulting will be leading the cost- benefit evaluation (with Auburn University) pro bono.

How will the pilots be conducted?

First, gaining stakeholder input is critical and will help shape details around how the pilots are conducted. Second, it is important to clarify that Congress required pilots to evaluate product tracing, not recalls. A traceback investigation seeks to identify points of convergence, beginning with many downstream points in a supply chain and potentially including a number of different types of products. IFT will work with a group of state traceback investigators to evaluate some historical data to determine a "baseline" for the time and effort involved in various investigations (including produce and processed food(s)), as well as the factors that seem to influence the ability to trace products.

IFT does not expect that the first pilot test will use any kind of technology solution. Rather, IFT will evaluate industry practices and will test how these processes, practices, and systems can be modified to improve the speed and accuracy of a traceback investigation. This might include testing Critical Tracking Events, Key Data Elements, standardization, and data formats.

Once the data requirements and food industry practices have been evaluated, IFT will explore how collaboration platforms (likely third party technology solutions) can be used to further enhance traceback capabilities.

Is IFT going to create a new traceability solution to test in the pilots?

No. Over the past several years IFT has learned about so many commercially available technologies, as well as those in development, that it did not seem economical or efficient to develop a new system for this task.

If the pilots are supposed to test technology providers, how will they be selected?

As stated above, examining the effect of using a technology platform is only one aspect of the task. Given the scores of technology providers in existence, many of whom have already contacted IFT requesting to be involved, how participants will be selected is a very difficult question to answer. IFT seeks considerable input regarding the characteristics of the platform(s) that should be involved, and how to fairly select participants. IFT does not expect that all technology providers who wish to be involved will serve as "the" collaboration platform or have ready access to the data used in the pilots. Consistent with FSMA provisions, FDA will be engaged in rulemaking with regard to product tracing. Consequently, all data and documents used or generated as part of this task order will be provided to FDA and may become part of a public record in the rule making process. Data and documents may also

become public if a request is made under the Freedom of Information Act. IFT **will not** remove any company-identifying information. FDA will redact any documents or data that are to be made public, in keeping with the applicable laws and regulations governing disclosure.

If only a few technology providers will be involved in the pilots, how can other providers let FDA know of their capabilities?

FDA must hold 3 public meetings (separate from IFT's stakeholder input sessions) as they proceed in rule making related to product tracing. In addition to providing input directly to FDA, individuals and companies are also encouraged to provide input directly to IFT for consideration by the core expert panel. This information may be evaluated and compiled for inclusion in IFT's report to FDA.

How will food industry participants be selected and what is expected of them?

IFT is interested in input regarding the food products to be evaluated. Once selected, IFT will seek participants. Consistent with FSMA provisions, FDA will be engaged in rulemaking with regard to product tracing. Consequently, all data and documents used or generated as part of this task order will be provided to FDA and may become part of a public record in the rule making process. Data and documents may also become public if a request is made under the Freedom of Information Act. IFT will not remove any company-identifying information. FDA will redact any documents or data that are to be made public, in keeping with the applicable laws and regulations governing disclosure.

How will the stakeholder input meetings be run?

At the meetings, there will be a 15 minute overview by IFT on the task. There will be no other formal presentations. The rest of the time will be divided based on the number of stakeholders requesting time. Each person will get at least 5 minutes, depending on the number of individuals requesting time to speak. We will schedule people in the order that they register until all spots are full. Because of space limitations, preference will be given to those wishing to speak versus attend or listen. We expect an audio recording will be available for a limited time after the meetings.

Can an individual speak at more than one stakeholder input meeting?

Individuals may speak at more than one session, pending space. Priority will be given to those who are not speaking at another input session. IFT will be giving the same presentation at all input meetings.