Comments to FDA in Response to IFT Traceability Recommendations in Support of the Food Safety Modernization Act
Docket No.FDA-2012-N-1153

On behalf of the Canadian Produce Marketing Association (CPMA), GS1 US, Produce Marketing Association (PMA) and United Fresh Produce Association (UFPA), we are pleased to submit comments on the technical aspects of the IFT Traceability Recommendations.

What is the Produce Traceability Initiative (PTI)?

The Produce Traceability Initiative is a voluntary, industry-wide effort designed to help the industry maximize the effectiveness of current track and trace procedures, while developing a standardized industry approach to enhance the speed and efficiency of traceability systems for the future. Industry participants cover every segment of the produce supply chain. The PTI is an industry-led, supply chain wide Initiative governed by a 34 member Leadership Council. The work is carried out by volunteer-led working groups in the areas of Implementation, Master Data, Technology, and Communications and is administered by CPMA, GS1 US, PMA and UFPA.

Background information: The Institute of Food Technologists (IFT) announced the public release of its report for the U.S. Food and Drug Administration (FDA) focused on the outcomes of two pilot projects designed to test and study various product tracing practices for fresh produce and processed foods. This report on the pilots, which were required by the Food Safety Modernization Act (FSMA), offers recommendations to the FDA on how to improve product tracing in a way that benefits all stakeholders: for regulators to resolve foodborne illness outbreaks earlier and the food industry to respond to them quicker.

Download full Report: www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM341810.pdf

General Comments: On behalf of the four associations supporting the PTI, we appreciated the opportunity to work with IFT on the traceability pilot projects, demonstrating a variety of advances within the produce industry. We believe that whole-chain traceability is an important step for our industry, and have worked hard with our member companies to develop best practices to enhance traceability in their operations.

We believe that specific company decisions and choices for traceability practices, beyond the current law's requirement to be able to track one-step-up and one-step-back, should be a company decision in the marketplace. We recognize that different companies and business trading partners may have choices as to how they ensure traceability in their supply chains. In addition, the marketplace is extremely efficient at continual development of technologies and processes to enhance business operations that could change traceability systems over time. Therefore, we do not support further mandatory traceability requirements, but stand ready to work with FDA to facilitate market-based solutions to enhance overall tracking efficiency and speed within our industry.

For additional information, please contact Jane Proctor at CPMA (jproctor@cpma.ca), Angela Fernandez at GS1 US (afernandez@gs1us.org), Ed Treacy at PMA (etreacy@pma.com) and Dan Vache at UFPA (dvache@unitedfresh.org)

IFT Recommendation 1: From an overarching perspective, IFT recommends that FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification.	***Comment:*** We agree with the IFT recommendation that FDA should approach traceability implementation for all foods, rather than singling out different categories of foods. This approach has proven efficient for the PTI in encouraging all industry segments in improving traceability processes. This all-inclusive philosophy has also been effective in facilitating collaboration and the sharing of best practices among different companies working with different products. Having PTI focused on a uniform set of record-keeping practices for all of the produce industry has been a contributing factor to the successful growth of companies representing a wide range of products. PTI working groups have developed guidance documents (www.producetraceability.org/resources/) based on a uniform set of practices and the industry is encouraged to further refine these best practice guidelines as business needs and supply chain efficiencies require.
IFT Recommendation 2: FDA should require firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of CTEs and KDEs as determined by FDA.	***Comment:*** Since PTI has been focused on recordkeeping needs to document Critical Tracking Events (CTEs) for Transport Events (receiving and shipping), Transformation Events (input and output), Depletions Events (consumption and disposal) with the Key Data Elements (KDEs) of Global Trade Item Numbers (GTINs) and Batch/Lot numbers, it is in alignment with IFT's recommendations in this regard. We agree with the recommendation on page 208 of the report that capturing Batch/Lot numbers along the supply chain would be a best practice to allow quick access to the lot numbers assigned at the most recent CTE in order to identify products in the supply chain with minimal financial impact to companies and the industry as a whole. The produce industry has had wide-reaching education through PTI webinars, best practice documents, presentations and discussion groups, and many companies are implementing Batch/Lot numbers for traceability.
IFT Recommendation 3: Each member of the food supply chain should be required to develop, document, and exercise a product tracing plan.	***Comment:*** The mission of the PTI from the outset of the initiative in 2008 has been focused on helping "the industry maximize the effectiveness of current track and trace procedures, while developing a standardized industry approach to enhance the speed and efficiency of traceability systems for the future" for every segment of the produce supply chain, from packing to distribution to retail stores and distribution to foodservice establishments. As evidenced by the continued activities of the PTI working groups, we support the active engagement of all industry members in ensuring effective traceability.

IFT Recommendation 4: FDA should encourage current industry-led initiatives and issue an Advance Notice of Proposed Rulemaking or use other similar mechanisms to seek stakeholder input.	***Comment:*** We agree that FDA should encourage industry-led initiatives such as the PTI to continue with the work of embedding traceability requirements within business operations in the food industry. PTI volunteers within their working groups have developed 25 best practice and guidance documents (www.producetraceability.org/resources/) with stakeholder input and continue to seek out ways to communicate business challenges and solutions that produce industry members bring to the attention of not only the working groups, but an active PTI Leadership Council representing both supply and buy side of the supply chain. As the four administering organizations of the PTI include the Canadian Produce Marketing Association (in addition to GS1 US, Produce Marketing Associations, United Fresh Produce Association), it is important to note that continued coordination and alignment with Canadian produce traceability practices will be important to the North American produce industry. Additionally, given the importance of bilateral trade with Canada, and the focus on food safety, including traceability, as part of the Canadian government's Safe Food for Canadians Act, it is important for both efforts to attempt, wherever possible, to align government policy. Since the last public meetings on traceability held by FDA in 2009, PTI has created an industry-driven approach to collaborate on developing best practices and assisted the produce industry toward traceability implementation. FDA can leverage these PTI best practice documents, educational materials and industry expertise in developing traceability guidance for the food industry (www.producetraceability.org/resources/#3).
IFT Recommendation 5: FDA should clearly and more consistently articulate and communicate to industry the information it needs to conduct product tracing investigations.	***Comment:*** Based on the concerns expressed by the produce industry, we see a great value in FDA developing more precise information the agency may find valuable when conducting a traceback investigation. The use of a uniform traceback/recall template would help industry focus on fine-tuning traceability processes to be able to provide the information that FDA would need. Aligning best practices for trading partners in North America is another important consideration for the use of such template. We are eager to learn what specific Critical Tracking Events and Key Data Elements FDA would find most valuable in a traceback investigation.

IFT Recommendation 6: FDA should develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations.	***Comment:*** We agree with this recommendation as a way in which government and industry can work together to enhance tracing investigations. Both the PTI vision (electronic storage and retrieval of traceability information for every case of produce, www.producetraceability.org/documents/PTI%20Flyer_FNL_v2%202011-10-20.pdf) and the PTI action plan (traceability implementation based on standardized product identification, data capture and data sharing, www.producetraceability.org/documents/PTI%20Action%20Plan%20final%2061810.pdf) are aimed at helping the produce industry come together to define the most important CTEs and KDEs necessary for effective and efficient product tracing and recalls if needed. Companies that have piloted or fully implemented traceability processes have documented the benefits of having standardized, structured, and electronic mechanisms in place to be able to trace product through the supply chain. These benefits include limiting the scope and cost of recalls, quicker and more accurate product withdrawals, and business efficiency improvements for the analysis of traceability data for a variety of reporting needs (www.producetraceability.org/resources/casestudies-pilot/#5).
IFT Recommendation 7: FDA should accept summarized CTE and KDE data that are submitted through standardized reporting mechanisms and initiate investigations based on such data.	***Comment:*** We are in agreement with this recommendation and also recommend that this information be accepted electronically. We have seen the evidence in pilot programs that it is more efficient to obtain and disseminate information electronically. When CTEs and KDEs are recorded with standardized and structured data, companies are able to provide summary information quickly to respond to information requests from FDA. When in-depth information is needed in an investigation, the detail of the data can be shared efficiently.
IFT Recommendation 8: If available, FDA should request more than one level of tracing data.	***Comment:*** If industry members are able to provide additional traceability data beyond one-step-up and one-step-down, on a volunteer basis, we encourage FDA to accept and use such data in its tracing investigations.

IFT Recommendation 9: FDA should consider adopting a technology platform that would allow efficient aggregation and analysis of data submitted in response to a request from regulatory officials. The technology platform should be accessible to other regulatory entities.	***Comment:*** We believe that PTI has been successful because it relies on standardized product identifications with GS1 Standards, not a centralized database. Whatever technologies FDA pursues to aggregate and analyze, data should be compatible with current data exchange scenarios. The produce industry does not support a centralized model of data collection in which industry is required to populate with all traceability data, due to the complexity and cost of such an effort. The produce industry is eager to continue with implementations based on unique identification of products and standardized data capture and data sharing protocols.
IFT Recommendation 10: FDA should coordinate traceback investigations and develop response protocols between state and local health and regulatory agencies, using existing commissioning and credentialing processes. In addition, FDA should formalize the use of industry subject matter experts in product tracing investigations.	***Comment:*** We support this recommendation. Coordination of traceback investigations between all public and private stakeholders will go a long way in ensuring effective traceability. The formalized use of industry subject matter experts would help ensure that traceback investigations are coordinated and planned based on both focused and broad knowledge about the nuances in how different fresh food supply chains operate. We have seen the value of this collaborative approach as the initiative has developed a review process for creating best practice documents with the input of not only industry representatives (focused expertise), but also with the coordination of four industry associations (broad expertise). We support the formalized integration of SMEs into the process of understanding a particular supply chain's unique challenges. Collaboration with key industry groups, like the PTI, is likely to help facilitate solutions and answers related to traceback investigations. It is also important to note that an established protocol to coordinate with Canadian authorities and experts would also benefit the industry and is aligned with the efforts of President Obama's and Prime Minister Harper's Regulatory Cooperation Council effort to achieve a common approach to food safety.