



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
ift.org

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RE: Docket Number FDA-2011-N-0016

To Whom it May Concern:

The Institute of Food Technologists IFT, the Society for Food Science and Technology, appreciates the opportunity to comment on Docket No. FDA-2011-N-0016 on record keeping and records access requests. Founded in 1939, IFT is a nonprofit scientific society with more than 18,000 members working in food science, food technology, and related professions in industry, academia, and government. IFT's long-range vision is to ensure a safe and abundant food supply contributing to healthier people everywhere.

IFT, under contract with the U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN), convened a panel of diverse experts to examine available technologies and current product tracing practices in food and other industries. Accurate record keeping is integral to the effective and timely tracing of food products through the supply chain. In November, 2009, IFT released a technical research report that provides recommendations for improved product tracing, which is freely available at www.ift.org/traceability. The comments below are based on this report.

The Federal Register notice asked four questions:(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

In response, IFT feels that:

- 1) Yes, the proposed collection of information is necessary for the proper performance of FDA's functions. This information does have practical utility, but information pertaining to product transformations also needs to be considered to ensure comprehensive internal traceability.
- 2) Based on the variation in practices used to capture information, it is difficult to comment on the accuracy of FDA's estimate of the burden of the proposed collection of information. As the adoption of electronic technologies by the food industry increases over time, the burden associated with data collection should decrease.
- 3) To enhance the quality, utility, and clarity of the information to be collected, FDA should encourage the adoption of standard ways to express this information (for example, encouraging a uniform way of expressing date and time) without prescribing the exact standard, which should be selected by industry. However, IFT believes that the food industry must first determine the Critical Tracking Events (CTEs) and the Key Data Elements (KDEs) necessary for product tracing. Through this exploration, IFT expects that certain standards will be recognized.
- 4) To minimize the burden of the collection of information on respondents and FDA in a time of investigation of a food outbreak, FDA should encourage the food industry to capture these

records in an electronic format in the interest of accuracy and efficiency of analysis, including through the use of automated collection techniques, when appropriate, and other forms of information technology. FDA should also have systems and mechanisms in place to accept electronic records. While electronic data capture minimizes the burden of collecting information on the part of the industry, it is inefficient, counterproductive, and serves as a disincentive to the industry when FDA will only accept “hard copies” of records, especially if they are simply printouts of electronic records.

IFT believes accurate tracing will play an integral role in helping FDA achieve its mission of ensuring that the nation's commercial supply food (other than meat, poultry, and egg products) is safe, wholesome, and correctly labeled and packaged. Proper record keeping serves as the foundation of a prompt response to public health incidents. Specifically, IFT recommends the following as best practices for effective product tracing:

Record Keeping

Each facility handling a product must record key data elements, such as lot numbers, dates/times, etc., for each Critical Tracking Event (CTE). CTEs are those instances when product or ingredient is moved between premises, is transformed, or is determined to be a point where data capture is necessary for effective tracing. The Bioterrorism Act of 2002 includes some, but not all, CTEs, focusing primarily on the transactional events between trading partners. Records of these elements allow product and component linkages to be maintained throughout the supply chain. Accurate internal product tracing must also be maintained by all supply chain partners, including point of service. For products that do not undergo further processing or transformation (e.g., the case is not opened) a one-to-one relationship between incoming and outgoing lots must be maintained, even when repacking occurs. Maintaining the correct information elements is essential to a complete product tracing system, whether records are kept in paper or electronic format. The way in which each firm captures and records data internally should not be prescribed. However, for product tracing to occur rapidly, each entity must provide key data elements (KDEs) for CTEs to the appropriate agency within 24 hours of a request, in an electronic format.

Data in Electronic Format

Timely communication of requested information is best facilitated by data in an electronic format. When requested, the submission of data to FDA should be in an electronic format. For firms that lack the resources to convert their operations from paper-based systems, data transfer may be done by third parties, but must be done regularly and kept current.

Approved Standardized Formats

For each key data element, a limited, select set of standard nomenclature must be identified. The exploration of CTEs and KDEs should precede the selection of standards, and will likely inform the selection of standards. IFT believes that industry should work collaboratively to determine the standards for KDEs and information transfer; the government should not prescribe specific standards. Any progress made toward identifying and specifying content standards for product tracing will benefit all record keepers. IFT believes that current or newly developed standards for the content and format of electronic systems have practical utility for companies who continue to use paper-based records, as human-readable data that supports standardized electronic data can be useful.

Required Audit

The ability to trace product should be part of any standard third party audit. Appropriate identification of CTEs, adherence to one-to-one internal product tracing, and correct capture of key data elements should be included as part of audit procedures.

Training

Guidance should be developed to detail the identification of CTEs and define relevant terms such as "lot". Educational modules on product tracing compliance should be developed, and all segments of the food industry and regulatory community should be jointly trained in their use.

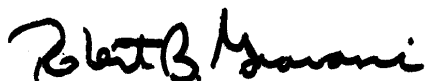
IFT believes that setting clear objectives for those in the food supply chain, and leveraging existing technologies and industry systems to meet those objectives, is the most appropriate approach to effective product tracing. Any product tracing system implemented should be simple, user friendly, and globally accepted. IFT's Core Recommendations on product tracing are that:

1. Standardized expressions of key data elements should be agreed upon.
2. Education on Critical Tracking Events (CTE) and key data elements (KDEs) should be developed.
3. Evidence of appropriate implementation should be part of standard audits.
4. Each supply chain partner must:
 - Identify their CTE(s) in order to trace product.
 - Record standardized key data elements for each CTE that links incoming with outgoing product, whether product is transformed (internal tracing) or changes location (external tracing).
 - Provide appropriate agency with relevant key data elements for each CTE, in an electronic format and within 24 hours of any request.

With the new requirements of the Food Safety Modernization Act, including the mandate that FDA conduct product tracing pilots, IFT hopes that FDA will offer an opportunity to a limited number of industry players to participate in a collaborative period in which CTE-Analysis is performed, CTEs and KDEs defined and plans are reviewed by FDA or their designated representative. Results of these interactions could be used to further develop the regulations and better understand the burden of current record keeping requirements.

Thank you for the opportunity to provide comments. Please contact Jennifer McEntire, Senior Staff Scientist and Director, Science and Technology Projects, if IFT may provide further assistance. She can be reached at 1025 Connecticut Avenue, NW, Suite 503, Washington, DC 20036; telephone number: 202-330-4984; or email address: jcmcentire@ift.org.

Sincerely,



Robert Gravani, Ph.D.
IFT President