AMERICAN SPICE TRADE ASSOCIATION, INC.

1620 I Street, N.W. • Suite 925
Washington, DC 20006 USA
Tel: 202-331-2460 • Fax: 202-463-8998
E-mail: info@astaspice.org
Web: www.astaspice.org

July 3, 2013

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

Re: Food and Drug Administration, HHS
Docket No. FDA-2012-N-1153
78 *Federal Register* 14309 March 5, 2013)

To Whom It May Concern:

On behalf of the American Spice Trade Association, we appreciate the opportunity to submit comments under the "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; Request for Comments and for Information", 78 *Fed. Reg*. 14309 (March 5, 2013). The notice was issued to obtain comments on the Institute of Food Technologists' report "Pilot Projects for Improving Product Tracing along the Food Supply System" and to help the Agency as it implements FSMA provisions relating to the tracking and tracing of food.

American Spice Trade Association

The American Spice Trade Association (ASTA) was established in 1907 to provide representation for the American spice trade. Its members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the industrial, food service, and consumer levels. On behalf of its members, ASTA works with federal and state regulators and legislators and assists its members in addressing a variety of technical issues to help members provide an adequate supply of safe and wholesome spices for their industrial, food service and consumer customers.

Food Safety - A Priority

ASTA shares FDA's commitment to safety. The highest priority of ASTA and its members is providing clean, safe spices to their customers: food manufacturers, food service and consumers.

IFT Traceability Pilot

ASTA appreciates the opportunity to provide comments on the IFT report "Pilot Projects for Improving Product Tracing along the Food Supply System". An ASTA member participated in the pilot project focusing on the tracing of chicken, peanuts, and spices in processed foods in order to share our unique perspective on food safety tracking and tracing. ASTA commends IFT for the work on this important process and the opportunity to be able to offer insight during the pilot and offers the following input on the recommendations outlined within the document.

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. Further, FDA should issue guidance documents defining these requirements.*

ASTA believes that all FDA-regulated foods should be subject to food tracing requirements that are thoughtful and carefully developed. Although it may seem logical to categorize foods as either high risk or low risk, it is not an easy determination and a myriad of circumstances can dictate changes in a risk assessment, and those circumstances can change quickly. An item that is categorized as low risk today could be high risk tomorrow due to an event such as unsanitary practices, unintentional or intentional contamination, etc. Food safety does not discriminate between product categories. Traceability should be uniformly required across all foods. Furthermore, differentiating between traceability requirements for high risk and low risk foods would be difficult to comply with in instances where a product may contain both low risk and high risk items as ingredients.

ASTA supports requiring one step forward and one step back for all food to insure that FDA and industry stakeholders have the necessary information required to trace the source of an outbreak without being overly prescriptive and demanding traceability further along the supply chain.

Recommendation 2 - *With regard to future rulemaking, IFT recommends that FDA require firms who manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain critical tracking events (CTE) and corresponding key data elements (KDE)-related records as defined by FDA based on input from the food industry.*

ASTA acknowledges that KDEs and CTEs are necessary elements that are routinely captured as part of business. Although we support the capture of KDEs and CTEs, we caution that the process of doing so should not be overly prescriptive and a burden to business. FDA should not dictate the format of these elements and should allow companies the flexibility to capture this information as best needed for their business.

Recommendation 3 - *Also in regards to rulemaking, IFT recommends that FDA require each member of the food supply chain to develop, document, and exercise a product tracing plan.*

ASTA agrees that a product tracing plan should be required for each member of the food supply chain. A company needs to know what to do before an issue arises. FDA should encourage companies to test their product tracing plans.

Recommendation 4 - *FDA should encourage and support existing industry-led initiatives for the development of implementation guidelines and should seek stakeholder input by issuing an Advance Notice of Proposed Rulemaking (ANPR) or using other input mechanisms.*

ASTA agrees that FDA should encourage and support existing industry-led initiatives and seek stakeholder input. We further encourage FDA to look to ASTA to collaborate on initiatives when possible and utilize ASTA guidance when it is available. ASTA offers to assist FDA by defining elements and assisting in the development of any such documents.

Recommendation 5 - *FDA should clearly and more consistently articulate and communicate to industry the information needed during a product tracing investigation.*

ASTA agrees that consistent, articulate communication between FDA and industry would be beneficial in efficient and effective work during a product tracing investigation. ASTA urges FDA to ask for the specific information they are seeking during an investigation as opposed to asking for a particular document. A clear understanding of the information the Agency is seeking would help companies identify and produce the needed information in a more timely manner.

Recommendation 6 - *FDA should develop standardized, structured, and electronic mechanisms for industry to provide the Agency CTE and KDE product tracing data when requested during a specific food safety investigation.*

ASTA concurs with IFT that a standard template or spreadsheet for input in the event of a food emergency could be beneficial to expedite the initial assessment. Providing companies with the information that would be requested ahead of time would assist in better preparation in the event of a food tracing event.

Recommendation 7 - FDA should accept CTE and KDE data sent in summary form through standardized and structured reporting mechanisms and initiate investigations based on this data.

ASTA agrees with IFT's recommendation that FDA asking for a summary of CTE and KDE data when necessary could help identify links quickly and allow time for companies to gather the supporting documents without delaying initial assessment.

Recommendation 8 - *If available, FDA should request CTE and KDE data for more than one up - one back in the supply chain.*

Although some firms may be able to provide this data due to joint ventures and/or supply agreements, ASTA urges that only data collection to support a one up/one back traceability be required. As mentioned previously, a one up/one back traceability system required of all product (as opposed to differentiation between low risk and high risk) would result in the necessary tools to trace food without being overly prescriptive.

Recommendation 9 - *FDA should pursue the adoption of a technology platform to allow the Agency to efficiently aggregate and analyze data reported in response to a specific request from regulatory officials. The technology platform should also be available to regulatory counterparts.*

ASTA believes that FDA can best determine which technology platform would be best for the Agency to efficiently aggregate and analyze data. Although this is a good practice, we caution that mandating industry to use a particular platform would be overly prescriptive and potentially damaging to businesses that may not be able to afford the costs. Businesses should be able to determine which system works best for their unique circumstances just as FDA should be given the flexibility to determine which technology platform works best for its needs.

Recommendation 10 - *FDA should coordinate traceback investigations and develop response protocols between and among state and local health and regulatory agencies using existing commissioning and credentialing processes. Further, FDA should formalize the use of industry Subject Matter Experts (SMEs) to address FDA's general questions about the characteristics of a particular supply chain at the outset of an investigation.*

ASTA fully supports coordinated efforts to maximize efficiencies and avoid duplication of efforts. We support ongoing FDA collaboration with industry associations such as ASTA to provide industry or sector insight and guidance.

ASTA understands that product traceability is clearly one tool that can be used to assist in the identification of and to gather information to assist in determining the source of contamination in foods implicated in foodborne illness outbreaks. In many cases traceability is straight forward, however in certain instances tracing beyond one step forward and one step back can be an insurmountable challenge. And with implementation of an integrated solid traceability system that does not discriminate between product risk or type, the need to track beyond the immediate steps would be unnecessary. ASTA supports the approach of one step forward and one back traceability.

ASTA and its members are committed to ensuring the safety of spices. We thank you for the opportunity to comment on the IFT report.

Sincerely,

Cheryl Deem
Executive Director