Obama's Food Safety Working Group Announces Recommendations Including Creation Of A “Unified Incident Command System,” While FDA Plans Public Workshops To Discuss Reportable Food Registry Requirements

July 10, 2009

Still no sign that adequate procedural safeguards will be in place on time

On July 7, 2009, President Obama's Food Safety Working Group ("Working Group") announced its key findings and recommendations regarding a "public health-focused approach" to strengthening the nation's food safety policies through programs that expand surveillance and data collection activities concerning food safety incidents, increase law enforcement, and improve response and recovery of products implicated in food safety incidents[1]. The Working Group's report includes the following action steps:

- ***Preventing Salmonella Contamination.*** The Food and Drug Administration ("FDA") is issuing a final rule to control *Salmonella* contamination of eggs during production[2]. In addition, *by the end of the year*, the Food Safety and Inspection Service ("FSIS") will develop new standards to reduce the prevalence of *Salmonella* in turkeys and poultry.
- ***Reducing the Threat of E. coli 0157:H7.*** *By the end of the month*, FSIS will issue improved instructions to its workforce on how to verify that establishments handling beef are acting to reduce the presence of *E. coli*. Also by that time, FDA will issue commodity-specific draft guidance on preventative controls to reduce the risk of microbial contamination in production and distribution of tomatoes, melons, and leafy greens.
- ***Building a National Traceback and Response System.*** *Within three months*: (1) FDA will issue draft guidance on steps the food industry can take to establish product tracing systems to detect origins of foodborne illness; and (2) federal agencies will implement a new "Unified Incident Command System" to address outbreaks of foodborne illness.
- ***Strengthening the Public Health Epidemiology Program.*** *Within six to twelve months*, FSIS will improve collaboration with states by increasing the capacity of its public health epidemiology liaison program to State Public Health Departments through additional hires and

expanded outreach.

- ***Updating Emergency Operations Procedures.*** *Within one month,*federal food safety agencies will ask state and local agencies to update their emergency operations procedures to be consistent with the new "Guidelines for Foodborne Disease Outbreak Response" soon to be issued by the Council to Improve Foodborne Outbreak Response.

- ***Improving State Capacity.*** The Centers for Disease Control will work with collaborating states to evaluate and optimize best practices for aggressive and rapid outbreak investigation, and will launch a new system to facilitate information-sharing and adoption of best practices *within twelve months*.

- ***Using New Technologies to Communicate Critical Food Safety Information by Creating an Improved Individual Alert System.***The federal government will enhance http://www.foodsafety.gov/ to better communicate information to the public and include an improved individual alert system allowing consumers to receive food safety information, such as notification of recalls. Agencies also will use social media to expand public communications. The first stage of this process will be completed *in ninety days*.

- ***Improving Organization of Federal Food Safety Responsibilities.*** The Working Group will serve as a mechanism to "break down stovepipes, address cross-cutting issues and increase coordination of food safety activities across the U.S. government." The Department of Health and Human Services and the U.S. Department of Agriculture will continue to serve as the Working Group's leadership. FDA also is creating a new position, Deputy of Commissioner for Foods, to oversee and coordinate its efforts on food, including food safety.

One of the Working Group's key findings and recommendations above, scheduled to take place within just three months, is the creation and implementation of a government-wide "Unified Incident Command System." This system is designed to coordinate information, decision-making, and response activities relating to potential food safety incidents, including with respect to product recalls and incident reports submitted to FDA's Reportable Food Registry, which is scheduled to launch in September 2009. Particularly in the absence of procedural safeguards necessary to ensure the integrity of the system in accordance with constitutional and administrative law standards, the new Unified Incident Command System is likely to amplify the already significant legal and business risks associated with unverified and unfounded food safety incident reports that potentially may be submitted to FDA's Reportable Food Registry and similar systems that apply to dietary supplement products[3]. Notably, although the President's Food Safety Working Group includes broad representation from federal agencies, there is no evidence the Working Group's findings and recommendations either recognize the need for procedural safeguards to be established before a new Unified Incident Command System is launched, or consider the risks the system is likely to present to the public and responsible companies in the absence of appropriate procedural safeguards.

While public comments on the Working Group report and other food safety policy issues may be submitted by e-mail, twitter, or Facebook (all accessible from the Working Group website), companies that are engaged in the production of food, food ingredients, or packaging materials are advised to submit comments urging the establishment of appropriate procedural safeguards in connection with the Unified Incident Command System and Reportable Food Registry to the following two FDA dockets, also: Docket No. FDA-2009-D-0260 ("Draft Guidance for Industry: Questions and

Answers Regarding the Reportable Food Registry") by *July 27, 2009* and Docket No. FDA-2009-N-0247 ("FDA Transparency Task Force; Public Meeting") by *August 7, 2009*[4].In addition, companies may present public testimony addressing the need for procedural safeguards in any of the three currently scheduled public workshops designed to address issues presented by FDA's current draft guidance on the Reportable Food Registry, which was issued on June 11, 2009[5].

The Reportable Food Registry implements section 417 of the Federal Food Drug & Cosmetic Act ("FFDCA"), which was adopted under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). The Registry will become operational on the FDA website on September 8, 2009. The guidance to be discussed at the public meetings, titled "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007," provides information on who must submit a report and how, when, and where to submit reports, as well as answers to questions regarding the information that companies must submit to FDA as part of the required reports, the circumstances under which companies must notify other companies in the supply chain that a reportable food submission to FDA has been made, and other requirements concerning the operation of the electronic portal and the Reportable Food Registry electronic database[6]. FDA has stated that the purpose of the upcoming public workshops is to discuss the agency's draft guidance on the Reportable Food Registry, including the purpose of the Registry, how it will work, the responsibilities of persons required to submit reports, and the role of Federal, State, and local public health officials in voluntarily reporting instances of reportable food.

Public Workshop Dates And Registration

Companies wishing to participate should register for the public meeting of their choice as soon as possible by contacting FDA via mail, email, or fax at the contact information below or by registering online here (click on the link to the Reportable Food Registry Public Workshops). All registrations should include name, title, firm name, address, phone, and fax number. On-site registration also is available.

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Tel: (240) 221-4326
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First Workshop

When:	Thursday, July, 23, 2009, 9 a.m. to Noon
Where:	Harvey W. Wiley Federal Building FDA, Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway College Park, MD 20740
Advance Registration:	By July 17, 2009

Second Workshop

When:	Wednesday, August 5, 2009, 9 a.m. to Noon
Where:	Hyatt Regency Chicago 151 East Wacker Dr. Chicago, IL 60601
Advance Registration:	By July 27, 2009

Third Workshop

When:	Tuesday, August 25, 2009, 9 a.m. to Noon
Where:	Ronald V. Dellums Federal Building Edward Roybal Auditorium 1301 Clay Street, 3rd Floor Oakland, CA 94612
Advance Registration:	By August 14, 2009

Kelley Drye & Warren LLP

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[1] *See* "Food Safety Working Group: Key Findings," available online here

[2] *See* 74 Fed. Reg. 33030 (July 9, 2009).

[3] *See* Federal Food Drug and Cosmetic Act section 761, requiring manufacturers, packers, and distributors of dietary supplement products to submit to FDA any report of a serious adverse event associated with a dietary supplement used in the United States through the submission of a "MedWatch form" containing prescribed information.

[4] *See also* June 24, 2009 client advisory titled "Increasing Transparency & The Reportable Food Registry"

[5] *See* 74 Fed. Reg. 30603.

[6] *See* 74 Fed. Reg. 27803 (June 11,2009).