CLIENT ALERT

Congress Moving Quickly On Food Safety Legislation

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On June 3, 2009, the House Energy and Commerce Subcommittee on Health held a hearing on the discussion draft of the Food Safety Enhancement Act of 2009, legislation that would grant the Food and Drug Administration ("FDA") new authority and resources to regulate the nation's food supply. Energy and Commerce Committee Chairman Henry A. Waxman (D-CA) released the draft measure in late May and the Subcommittee hearing included testimony from FDA Commissioner Margaret Hamburg and representatives from several stakeholder organizations.

In her testimony, Dr. Hamburg offered support for many of the bill's provisions, including the annual registration fee as a source of revenue for the FDA, the ability for the FDA to access company records for inspection, the increased frequency of inspections, and the mandatory recall provisions. However, she expressed concern about the legislation's timeframe for implementation of a more frequent inspection schedule, noting the lack of time and resources to hire and properly train new staff. She encouraged a modification of this provision.

Witnesses from industry and consumer protection groups supported the bill's focus on prevention, in particular the provisions regarding a risk-based inspection schedule, the hazard analysis, and the food safety plan. While industry and consumer protection groups were willing to support a fair registration fee, concerns were expressed regarding how the fees would be used. There was also concern about the traceability provisions, including an observation that efforts are already underway in some industries to set their own tracing methods and that too prescriptive legislative language could derail these industry-led efforts.

The draft legislation is the latest in a series of food safety measures introduced during the 111th Congress. Several provisions in Chairman Waxman's draft measure are similar to the food safety sections contained in H.R. 759, introduced by Representative John Dingell in January 2009 and in S. 510, introduced in March 2009 by Senator Dick Durbin.

Members of the Energy and Commerce Subcommittee on Health anticipate a mark-up of the draft legislation next week. Some of the proposed bill's major provisions are summarized below.

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As currently drafted, the Food Safety Enhancement Act of 2009 would require all facilities operating within the U.S. or importing food into the U.S. to register with the FDA annually and pay an annual registration fee of $1,000. The bill also provides for user fees associated with re-inspections and food recalls and allows FDA to charge a fee to domestic firms requesting export certificates for exported food.

The Food Safety Enhancement Act of 2009 would require food facilities to implement food safety plans. It would also provide the FDA with the authority to establish minimum safety plan requirements, as well as authority to audit individual plans. The draft legislation would increase inspections at all registered facilities, the frequency depending on a facility's risk level. High-risk

facilities would be inspected at least once every six to 18 months. Low-risk facilities would be inspected at least once every 18 months to three years. Warehouses that store food would be inspected at least once every three to four years.

The draft measure would also expand the FDA's authority to trace the origin of tainted food in the event of an outbreak of foodborne illness through regulations requiring food producers, manufacturers, processors, transporters, or holders to maintain information regarding the origin and previous distribution history of food. Additionally, the FDA must establish an interoperable record - a change from current law, which allows facilities to hold a record in paper or electronic format - with the goal of allowing rapid traceback.

The proposed bill would require the FDA to establish a program to recognize laboratory accreditation bodies. The FDA will only accept - and can also require - test results from accredited laboratories. The FDA may require certification that imported food meets all U.S. food safety requirements. The draft bill would authorize FDA to order mandatory recalls of food products, and would strengthen criminal penalties and establish civil penalties if facilities fail to comply with safety requirements. The legislation would also require country of origin information on processed food labels and for all produce, and country of origin information on food manufacturers' websites for all ingredients. It directs the FDA to issue regulations relating to safe production and harvesting of fruits and vegetables.

The draft legislation provides the FDA with new authority to subpoena records related to possible violations and establishes new whistleblower protections relating to food safety information.

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