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E-ALERT | Food & Drug

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SENATE LEADERS RELEASE AMENDED VERSION OF FOOD SAFETY BILL

Last week, the Senate Health, Education, Labor and Pensions (HELP) Committee released the Manager's amendment to the pending FDA Food Safety Modernization Act, S. 510.[1] The amendments reflect bipartisan revisions to the version of the bill that was cleared by the HELP committee in November of 2009.[2] This is the first significant action on the bill since November, as the bill was reportedly passed over during the spring to address the health care and financial reform bills, and then stalled earlier this summer due to controversial proposals to add amendments banning bisphenol-A and exempting small farmers from some provisions.[3] The Manager's amendment contains neither of these amendments, although it does introduce changes designed to lessen the regulatory burden on small businesses.

The FDA Food Safety Modernization Act represents a potential overhaul of the federal food safety laws. Among some of the more significant provisions, the Act would: (1) require facilities to adopt hazard analysis and critical control point plans; (2) require FDA to design food traceability programs; (3) overhaul FDA's import authority by creating a foreign supplier verification program that could require certification and testing; (4) expand FDA's access to records; (5) increase the frequency of inspections according to a facility's risk; and (6) enhance FDA's enforcement powers by, among other things, allowing the agency to suspend a facility's registration, providing whistleblower protections, and expanding FDA's administrative detention power.

The Manager's amendment does not change these key features, nor does it represent a significant policy change from the earlier version of S. 510. The amendment does, however, contain changes that would be of interest to the members of the food industry who will be expected to comply with the new regulatory scheme. Summarized below are the more significant revisions:

- Inspections. The Manager's amendment revises section 201 to significantly reduce the number of inspections FDA must conduct. The amendment does not change S. 510's risk-based classification system. In the earlier version of S. 510, high risk facilities were required to be inspected once during the first two years after enactment and once every year thereafter; the Manager's amendment changes this frequency to once during the first five years after enactment, and once every three years thereafter. Likewise, the earlier S. 510 required inspections once every four years for low-risk facilities; this frequency has been changed to once every seven years. The Manager's amendment also directs FDA to inspect no less than 600 foreign facilities within one year of the Act's passage, and it is directed to double this number during each of the next four years. The amendment also contains provisions permitting FDA to rely on state and local inspections and allowing the agency to enter into interagency agreements to improve seafood safety. Although these revisions represent a significant decrease in the

[1] The Manager's amendment is available at: http://help.senate.gov/imo/media/doc/WHI10337.pdf.
[2] For our client alert summarizing the version of S. 510 cleared by the HELP committee, click here.
[3] The House of Representatives has already passed a food safety bill, which significantly differs from the Senate bill in some respects. For our client alert summarizing H.R. 2749, click here.

number of inspections required for any one facility, S. 510, if enacted into law, would still result in a drastic increase in the overall number of inspections FDA conducts.

- Traceability provisions. Section 204 still requires FDA to establish traceability programs, but the provision has been substantially revised. Among other changes, the new section 204 contains more specific instructions on the look of these traceability provisions, directs FDA to create recordkeeping requirements for high risk foods, and specifies features FDA may not require. For instance, the new recordkeeping requirements cannot require specific technologies, and FDA is prohibited from requiring a full pedigree for foods. As revised, section 204 also reduces the effect of the programs on the agricultural industry. The traceability requirements will not apply to farm sales of food and commingled raw agricultural commodities, which the section defines as a commodity that is combined or mixed after harvesting but before processing. The provision also directs the Government Accountability Office to evaluate the new recordkeeping requirements, with specific attention to the program's compliance costs. On the whole, these new provisions may make the agency's task of creating tracing programs more difficult, and they could provide grounds for the industry to challenge the agency's final recordkeeping requirements.
- Flexibility for small businesses. Several provisions of S. 510, including those related to HACCP plans and tracing, have been revised to require regulatory flexibility for small farms and businesses, and include specific instructions to minimize the regulatory burden.
- Suspension of registration. The Manager's amendment revises S. 510's provisions allowing FDA to suspend a facility registration. Facilities are required by current law to be registered, and they must re-register every two years under S. 510. Under the Manager's amendment language, FDA may suspend the registration of a facility that knew or should have known that its food product posed a risk of causing serious adverse health consequences or death. The earlier version of the bill permitted FDA to suspend the registration of a facility that held food with a reasonable probability of posing such a risk.
- New dietary supplement ingredients. The Manager's amendment introduces a new section 113, which directs FDA to issue guidance on the safety of new dietary ingredients in dietary supplements. Specifically, FDA is directed to clarify when a dietary supplement ingredient is a new dietary ingredient and when the manufacturer should provide information on safety as required by Federal Food, Drug, and Cosmetic Act (FDCA) section 413(a)(2).
- Revisions to the reportable food registry requirements. The Manager's amendment also introduces new section 211, which amends section 417 of the FDCA. The new provisions would add a new subsection (f), entitled "Critical Information." That subsection would allow FDA to require responsible parties to submit "consumer-oriented information" such as descriptions of the food and affected product classification codes. It also adds a provision that requires grocery stores to notify consumers by posting recall information in a conspicuous area. A grocery store's failure to comply with the notification requirements would be considered a prohibited act under section 301 of the FDCA, permitting the government to seek criminal prosecution against the store. The term "grocery store" is not defined, raising the question of whether all stores that sell food must comply with the notification rules.
- Imports. The Manager's amendment requires FDA to exempt from the foreign supplier verification program articles of food imported in small quantities for research and evaluation purposes and food imported for personal consumption. It also clarifies sections relating to third party certification, making clear that certification can apply to a particular food or facility. The amendment also adds new section 115, which requires FDA to work with the Department of Homeland Security to deter "port shopping."
- HACCP plans: hazards intentionally introduced. The Manager's amendment contains language recognizing that intentionally introduced hazards may not be foreseeable.

- **Recalls.** The manager's amendment revises the provisions related to recall authority, requiring FDA to establish an "incident command operation" that would operate within 24 hours of a class I recall.

Despite the action by the HELP committee, the future of S. 510 remains unclear. Reports have indicated that its supporters are working with Senate leadership to put the bill on the calendar during September, although other reports have indicated that it is unlikely to receive floor time unless its supporters can assure that it will pass quickly. If the bill is passed, it will then need to be reconciled with the House's bill, which contains some significant policy differences. Most notably, the House bill contains per facility registration fees, which the neither the Manager's amendment nor the earlier version of S. 510 adopt. Covington & Burling LLP will closely monitor developments and is pleased to answer questions.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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