

June 29, 2009



**MEMORANDUM**

FROM: Robert Guenther

SUBJECT: Report on Energy and Commerce Committee Markup of *Food Safety Enhancement Act of 2009*

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Below are key sections of the House bill that have been modified over the last month during the committee debate on this legislation.

**Changes in registration of food facilities (Section 101)** – This section expands the current registration requirements for food facilities by requiring those to register annually. Currently, under section 415 of the FDCA, food facilities only have to register once (i.e. Bioterrorism requirements). The section also authorizes FDA to suspend the registration of a facility if there is a violation of the FDCA that could result in a serious adverse health consequences or death. Before taking such a step, FDA must notify the owner of the facility and provide the opportunity for an informal hearing. In addition to suspension authority, this section also allows FDA to cancel a facility’s registration. The cancellation can occur no earlier than 10 days after notice from FDA that such action may take place. This suspension authority is now non-delegable.

This section also authorizes an annual registration fee of \$500 for every food facility (domestic and foreign). The \$500 fee will generate approximately \$175 million for FDA’s food safety activities. This registration fee has been reduced significantly from Chairman Emeritus Dingell’s Food and Drug Globalization Act introduced last Congress, where the facility registration fee was \$2,000. There will be a per company cap of \$175,000.

**Hazard analysis, risk-based preventive controls, and food safety plan (Section 102)** – The section requires all registered domestic and foreign facilities to identify known or reasonably foreseeable hazards and implement preventive controls to prevent or reduce to acceptable levels those identified hazards. Each owner or operator is required to have and implement a written food safety plan describing its hazard analysis and preventive controls before the owner enters the food into interstate commerce. The owner or operator also must maintain records, for not less than two years, documenting its steps to implement, correct, monitor and revise its food safety plan. This section provides flexible compliance timeframes for small and very small businesses. Facilities in compliance with existing seafood, juice and low-acid canned food regulations are deemed to be in compliance. The previous version of the bill would have authorized FDA to mandate certain preventive controls for addressing food hazards. This version of the bill allows companies to utilize different preventive controls than mandated by FDA.

This version of the bill also contains new language on testing. First, the bill requires that companies include a description of the facilities’ environmental and product testing programs. Second, the Secretary would be required to conduct a pilot project and a study to evaluate the feasibility, benefits and costs of collecting finished product testing results from Category 1 facilities that are required to comply of Good Manufacturing regulations. After completion of the study, the Secretary could require the submission of finished product test results of Category 1 facilities that must comply with Good Manufacturing regulations.

**Safety Standards for Fresh Produce (Section 104)** – The section gives FDA the authority to set commodity-specific standards for the safe growing, harvesting and packaging of fruits and vegetables. It would require the Secretary to issue a proposed rule within 18 months and a final rule within three years of enactment. In enforcing this section, the Secretary would coordinate with USDA and states. Finally, this section would require the update of the Good Agricultural Practices (GAPS) guidance for fruits and vegetables. Key provisions were included during the debate on this bill to ensure that FDA would develop commodity-specific and risk-based standards for fresh produce commodities.

**Risk-Based Inspection Schedule (Section 105)** – This section sets out the following inspection frequency for all facilities (domestic and foreign): high-risk facilities would have to be inspected every 6 months to one year; low-risk facilities would have to be inspected every 18 months to 3 years; and warehouses would have to be inspected every 5 years.

This section also will require FDA that FDA submit a report on a reasonable inspection frequency for low risk facilities and warehouse and allow FDA to modify the inspection frequency based on the report. This inspection schedule represents a positive step over previous drafts, where the inspection schedule was much more prescriptive.

**Traceability (Section 107)** – This section also has been improved significantly from previous drafts. Under this provision, before the Secretary can issue proposed regulations establishing new traceability requirements, FDA would have to conduct an information gathering process to determine the feasibility and cost/benefit of the system. In addition, FDA would conduct at least one pilot project and two public meetings before issuing a proposed regulation. The previous version of the bill contained very prescriptive requirements on what must be included in the regulations establishing the traceability system. Those requirements have now been moved to the information gathering section of the provision and will not be required to be included in the regulations. The only requirement is that the system must allow the Secretary to conduct the traceback within 2 business days. This provision will also allow the Secretary to exempt farm that have direct sales to consumers, restaurants, and grocery stores. However, both restaurants and grocery stores would be required to maintain records documenting farms that were the source of their food. Finally, the Secretary may exempt (by regulation) a food, type of facility, farm or restaurant if Secretary determines that tracing such food is not necessary to protect public health.

**Safe and secure food importation program (Section 113)** – This section allows FDA to create an expedited entry program for food imports. In establishing who qualifies for such entry, FDA will consider the following factors: (1) personnel of the importers; (2) security of the supply chain; (3) preventive controls; and (4) vendor/supplier information.

**Geographic Quarantine Authority (Section 133)** – This section gives FDA the power to restrict the movement of food from states if it believes that the type of food presents an imminent threat of serious adverse health consequences or death. This authority is non-delegable meaning only the Commissioner or Deputy Commissioner at FDA can authorize this action. This provision has been significantly improved through the process by the insertion of a non-delegation provision and by raising the quarantine standard to “imminent” threat of serious adverse health consequences. The original language only required that FDA had credible evidence that food presented a threat of serious adverse health consequences or death.

**Country of Origin Labeling (Section 202)** – This section has been dramatically changed since the discussion draft was first released. First, foods that already list the country of final processing or country of origin, per the requirements of the Farm Bill or customs, are

exempted from the this section. Second, the website requirements that were present in previous versions have been struck.

**Import Fees and Registration (Sections 204 and 205)** – These sections require importers, customs brokers and filers of food, drugs and devices to register with FDA annually. Similar to Section 101 of the discussion draft, FDA could suspend and cancel the registration. This section also authorizes FDA to charge importers a registration fee of \$500, which is down from \$10,000 in previous drafts. Customs brokers and filers will not pay a registration fee.

## **Conclusion**

As we indicated in our member alert, there has been significant movement in this legislation since we started this process some two years ago. However, work continues to offer further improvements we think will enhance this bill effectiveness and can address the diversity of our industry prior to consideration by the full House. We will also begin a process of talking with Senate folks to determine their anticipated action which will help us gauge how the final legislation will take shape before going to the President.

If you have any questions please do not hesitate to contact me.

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