

MEMORANDUM

From: Joseph A. Levitt
Elizabeth Barr Fawell

Date: June 18, 2009

Re: **House Energy and Commerce Committee Approves Food Safety Legislation**

In a move signaling the strong bipartisan support for the bill and the likelihood of eventual passage in the House of Representatives later this year, the House Energy and Commerce Committee voted to approve a comprehensive piece of food safety legislation yesterday. On June 17, 2009, the Energy and Commerce Committee held a markup session to consider H.R. 2749, the Food Safety Enhancement Act of 2009. The bill, as amended by a substitute bill offered during the markup session, was approved by the Committee by voice vote. This memorandum provides a summary of the Committee's markup session and highlights those significant changes that have been made to H.R. 2749. 1/

I. Energy and Commerce Committee Markup

The Energy and Commerce Committee markup hearing and approval of H.R. 2749 demonstrates the Committee's commitment to moving food safety legislation this year. Similar to the markup session held by the Subcommittee on Health last week, members of the Committee repeatedly noted that the bill, as amended, reflects bipartisan efforts, and the input of the Food and Drug Administration (FDA) and key stakeholders.

A. Notable Changes to H.R. 2749

At Wednesday's markup hearing, Committee Chairman Henry Waxman (D-CA) offered an amendment in the form of a substitute to H.R. 2749, which was agreed to by voice vote. The substitute, except for the changes noted below, is substantially the same bill as that passed by Subcommittee on Health last week. Accordingly, the bill contains significant new or expanded requirements on food companies, a number of provisions to enhance FDA's oversight over

1/ For a summary of the House Energy and Commerce Subcommittee on Health markup of H.R. 2749, see Hogan & Hartson memorandum dated June 11, 2009. For a more comprehensive summary of the bill as originally drafted, see Hogan & Hartson memorandum dated May 28, 2009.

imported food, several new or enhanced enforcement authorities for FDA, and new fees for food companies, including registration fees.

Chairman Waxman's amendment made the following substantive changes to H.R. 2749.

- Alternative Preventive Controls. The amended bill contains new language granting food companies flexibility to implement alternative preventive controls. As amended, the bill would allow a facility to implement an alternative preventive control to one established by the Food and Drug Administration (FDA), provided that, in response to a request from the agency, the company can demonstrate that the alternative preventive control effectively addresses the hazard.
- Reporting of Test Results to FDA. The amended bill contains new language regarding finished product testing. FDA would be required to conduct two pilot projects and a feasibility study to evaluate the feasibility and benefits of collecting finished product testing results from Category 1 (high-risk) facilities. Within two years of enactment, or the completion of the feasibility study and pilot projects, whichever is sooner, the bill would require the submission of test results to FDA from Category 1 facilities that document "the presence of contaminants in food in the possession or control of such facility posing a risk of severe adverse health consequences or death. Thus, FDA would establish requirements for reporting of finished product test results, but only where the agency can show a benefit that is feasible to implement, and any reporting to FDA of test results would be tied to a "seriousness" standard. The bill also would require that a facility's food safety plan include, as part of its verification activities, a description of any environmental and product testing programs.
- Records Access. H.R. 2749 would give FDA broad access during an inspection to records bearing on whether an article of food is adulterated, misbranded, or in violation of the Act, including all records relating to preventive controls and food safety plans. In addition, the amended bill would give FDA the authority to:
 - Request, in writing, in advance of an inspection, that a facility have designated records ready for review at the commencement of a planned inspection.
 - Require the submission of records to the agency directly (so-called "remote access") during an emergency, if FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death, as soon as reasonably practicable after receiving written notice.
 - Require facilities to provide (also via "remote access") their food safety plans, supporting documentation, and records of corrective actions, directly to FDA as soon as reasonably practicable after receiving written notice.

If the records that FDA requested to be submitted are available in electronic format, the bill would require such records to be submitted electronically unless otherwise specified by FDA. However, as amended, H.R. 2749 does not authorize FDA to require the maintenance of records in a standardized electronic format, as previous versions did.

- Traceability. The amended bill would exempt the following from the traceability requirements: direct sales from farms and fisheries to consumers, retailers, and

restaurants. However, restaurants and retailers would be required to keep records documenting the farm that was the source of the food, and farms and fisheries would be required to keep records documenting the restaurant or retailer to which the food was sold.

- Mandatory Recall Authority. As amended, H.R. 2749 continues to provide for a two-tiered mandatory recall system.
 - Tier 1, or Regular Recall: FDA would be authorized ask any person to voluntarily recall an article of food that the agency believes is adulterated, misbranded, or in violation of the Act. The amended bill clarifies that if FDA has reason to believe that an article of food may cause “serious” adverse health consequences or death, the agency would have the authority to issue an order requiring any person to immediately cease distribution of the article. The amended bill would no longer require companies to notify the distribution chain of the cease distribution order. FDA would be required to hold an informal hearing within 5 calendar days regarding whether the order should be amended to require a recall or vacated.
 - Tier 2, or Emergency Recall: If FDA has a reasonable belief that an article of food presents an “imminent threat” of serious adverse health consequences or death, FDA would be authorized to require an “emergency recall” before a hearing. Any person subject to an emergency recall order would be required to comply immediately and would have the opportunity to appeal the order and request an informal hearing afterwards, which would be held within 5 days.
- Reportable Food Registry. As amended, H.R. 2749 would continue to require restaurants and retailers to submit reports under the Reportable Food Registry; however, FDA would be required to establish an alternative notification mechanism other than the electronic portal for such establishments.
- Quarantine Authority. The amended bill specifies that any quarantine area would be no greater than is appropriate to protect the public health.
- Civil Penalties. This section has been substantially changed in the amended bill by creating a two-tiered schedule for civil penalties.
 - Tier 1: For unintentional violations involving individuals, the civil penalty would be \$20,000 per violation, not to exceed \$50,000 in a single proceeding. For companies, the civil penalty would be \$250,000 per violation, not to exceed \$1 million.
 - Tier 2: For knowing violations, individuals would be subject to a civil penalty of \$50,000 per violation, not to exceed \$100,000; and companies would be subject to \$500,000 per violation, not to exceed \$7.5 million in a single proceeding.

Note that, although the version of H.R. 2749 passed by the Subcommittee would have limited the authority to issue civil penalties to the FDA Commissioner, Principal Deputy Commissioner, or the Associate Commissioner for Regulatory Affairs, this provision regarding non-delegation is no longer in the bill as amended by the full Committee. Nonetheless, because the bill would amend the existing civil penalties provision in the

Act applicable to other FDA-regulated products, civil penalties could only be assessed after an opportunity for a hearing.

- Inspection Frequency. As amended, H.R. 2749 would require Category 1 facilities (high-risk) to be inspected every 6 months to 1 year; Category 2 facilities (low-risk) to be inspected every 18 months to 3 years; and Category 3 facilities (facilities that only hold food) to be inspected every 5 years. Within 3 years, FDA would be required to submit a report to Congress recommending changes to the inspection frequency set forth in the bill. Within 6 months of submitting the report, FDA would be authorized to publish in the *Federal Register* adjustments to the inspection frequency mandates for Category 2 and 3 facilities. Importantly, the definition of Category 1 facilities (“high risk”) has been delegated to the FDA to determine, and the detailed definition in the bill as marked up by the Subcommittee, which would have included all products “of animal origin,” has been deleted.
- Suspension and Cancellation of Facility Registration—Non-Delegation. The amended bill contains new language that would limit the authority to suspend or cancel a facility’s registration to the Commissioner, Principal Deputy Commissioner, the Associate Commissioner for Regulatory Affairs, or the Director for the Center for Food Safety and Applied Nutrition (CFSAN).
- Performance Standards. The amended bill would require FDA to publish in the *Federal Register*, every two years, a list of food-borne contaminants that have the greatest adverse impact on public health.
- Importer Registration Fee. As amended, H.R. 2749 would authorize FDA to charge importers a registration fee of \$500, but would no longer require customs brokers or filers to pay a registration fee.
- Bisphenol-A. As amended, H.R. 2749 contains a new section that would require FDA to notify the Committee by the end of the year whether the available scientific data support a determination that there is a reasonable certainty of no harm for approved uses of bisphenol-A (BPA) in food and beverage containers. If such a determination cannot be made, FDA would be required to notify Congress of the actions it intends to take. As FDA has already commenced this review, this section would not change the status quo on this issue.
- Jurisdiction. The amended bill clarifies that it would not alter the jurisdiction between FDA and the U.S. Department of Agriculture (USDA). Specifically, the amended bill would exempt the portions of farms and facilities regulated exclusively by USDA from the bill’s requirements. In addition, the amended bill clarifies that alcohol manufacturers and distributors would be exempt from the bill’s requirements.
- Carbon monoxide. As amended, H.R. 2749 no longer contains a provision treating the use of carbon monoxide in meat, poultry or fish as a color additive.

- Training for Food Protection Activities. The amended bill contains a new section that would require FDA to provide financial and other assistance to appropriate entities to establish and maintain one or more university-affiliated food protection training institutes that conduct training for federal, state and local officials and meet standards developed by FDA.
- Surveillance. As amended, H.R. 2749 no longer would require an assessment of the frequency and sources of food borne illness. Instead, the amended bill would require the Secretary, through the Centers for Disease Control (CDC), to enhance food-borne illness surveillance systems to improve the collection, analysis, reporting and usefulness of data on food-borne illness by, among other activities, coordinating with federal, state, and local surveillance systems; increasing participation in national networks of public health; facilitating the sharing of findings among governmental agencies on a timely basis; and, developing improved epidemiological tools. It would also require the Secretary to develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies.

B. Amendments Considered but Withdrawn

Although amendments to the proposed legislation were offered during the hearing, all were withdrawn based on the willingness of Committee Chairman Waxman to continue to work to address any concerns. These amendments would have:

- Exempted on farm storage of raw agricultural commodities from the facility registration requirement;
- Imposed a labeling requirement on ceramic-ware to identify the presence lead-based glaze;
- Provided for the phased withdrawal of non-therapeutic uses in animals of antibiotics that are intended for use in humans;
- Protected the confidentiality of records from farms; and
- Exempted food produced on fishing vessels from certain traceability requirements.

Even though these amendments were withdrawn, they represent areas where further changes to H.R. 2749 may occur when the bill is considered by the House of Representatives.

* * *

Given the pace at which this proposed legislation has moved in recent weeks, it could receive consideration by the full House of Representatives this summer. Accordingly, we will monitor the progress of this bill and will keep you apprised of significant developments.

If you should have any questions, please do not hesitate to contact us.