HOGAN & HARTSON

Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
+1.202.637.5600 Tel
+1.202.637.5910 Fax

www.hhlaw.com

MEMORANDUM

From: Richard S. Silverman
Joseph A. Levitt
Elizabeth Barr Fawell

Date: July 31, 2009

Re: **House Passes Comprehensive Food Safety Legislation**

Late yesterday, on July 30, 2009, the U.S. House of Representatives voted to approve comprehensive food safety legislation. H.R. 2749, the Food Safety Enhancement Act of 2009 was passed overwhelming by a vote of 283 to 142. H.R. 2749 is similar to food safety legislation that has been introduced in the Senate by Senator Richard Durbin (D-Ill), S. 510, the FDA Modernization Act. It also has the support of the Obama Administration. Therefore, with House passage of H.R. 2749, the contents of this bill have a significant likelihood of becoming law. To help clients prepare for the dramatic changes in the way food is regulated by the Food and Drug Administration (FDA) should the legislation be enacted, we have prepared the attached section-by-section summary of the bill. 1/ This memorandum briefly highlights the general content of H.R. 2749.

The Food Safety Enhancement Act (H.R. 2749)

The Food Safety Enhancement Act is a broad bill that would impose new or enhanced requirements on food companies; would grant FDA significant new or enhanced enforcement authorities; would enhance FDA's oversight over imported foods; and would impose new fees on the food industry.

Significant New or Expanded Requirements on Food Companies

- Foreign and domestic food facilities would be required to have food safety plans in place to identify and mitigate hazards through preventive controls.

1/ Previous Hogan and Hartson memoranda have reported on the progress of this legislation. See Hogan & Hartson memoranda dated May 28, 2009; June 11, 2009; and June 18, 2009. Since H.R. 2749 was passed by the House Committee on Energy and Commerce, several changes were made to its contents, primarily fine-tuning changes to address concerns regarding the impact of the bill on farms and on the import community, and, at the request of the food industry, to separate the requirements for food defense plans from food safety plans.

- Foreign and domestic food facilities would be required to have food defense plans.

- Food facilities would be subject to a risk-based inspection frequency, ranging from at least once every 6 to 12 months for high risk facilities, to at least once every 5 years for food warehouses.

- Foreign food facilities would be subject to the same inspection frequency as domestic facilities.

- Facilities would be required to provide FDA with broad access to records, including via remote access.

- FDA would establish performance standards to minimize foodborne contaminants, publish a list of contaminants posing the greatest risk, and could make recommendations to the food industry on product sampling.

- High-risk facilities would be required to report certain finished product test results to FDA, after the agency has conducted prerequisite pilot and feasibility studies.

- FDA would be required to establish product tracing regulations to enable the agency to identify each person that handles an article of food within at least two business days, also after the agency has conducted prerequisite pilot and feasibility studies.

- FDA would be required to establish standards for the production of raw agricultural commodities, including fruits, vegetables, and nuts.

- All reports to the Reportable Food Registry would be required to include any testing results. In addition, farms, restaurants, and retailers would be required to submit reports to the Reportable Food Registry.

- Both processed and unprocessed foods would subject to country of origin labeling, but products already in compliance with either Customs or USDA requirements would not be affected.

- All facilities operating within the U.S. or importing food to the U.S. would have to register with FDA annually.

<u>Significant New or Enhanced Enforcement Authorities</u>

- The bill would substantially increase the criminal penalties available to FDA for knowing violations of the Act.

- The bill would also provide for substantial civil money penalties, with one set of penalties applicable to *any* violation of the act and a second, higher set of penalties applicable to *knowing* violations.

- FDA would be able to suspend or cancel a facility's registration.

- FDA would be granted mandatory, two-tier recall authority, with tier one (regular recall) applying to serious threats of adverse health consequences, and tier two (emergency recall) applying to imminent threats.

- Under a new quarantine authority, FDA would have the authority to restrict the movement of food from a state or a region within a state.

- FDA's administrative detention authority would be expanded.

- The agency would have new subpoena authority.

Provisions to Enhance Oversight of Imported Food

- FDA would be authorized to require imports be certified as complying with the Act where there is a particular reason to do so, and would determine which entities could provide such certification.

- Product testing required in support of admission for imported food would have to be conducted by an accredited laboratory and the results submitted directly to FDA.

- Importers and customs brokers would be required to register with FDA. As a condition of registration, importers would be required to comply with good importer practices.

- FDA would be allowed to establish a program for expedited entry of certain imported foods that meet food safety and security guidelines.

Fees

- Each registered facility would be required to pay an annual $500 registration fee, with a cap of $175,000 per company.

- Importers would also be required to pay an annual $500 registration fee.

- Monies collected from registration fees would be applied to food safety-related activities.

- FDA would be allowed to collect fees to offset the costs of conducting reinspections of facilities and carrying out recall-related monitoring activities.

- FDA would be authorized to collect a fee for issuing export certificates, as with other FDA-regulated products.

In addition to the provisions noted above, the bill also contains several other provisions, including those regarding GRAS notifications, infant formula, the review of bisphenol-A (BPA), unique identification numbers for facilities, whistleblower protections, and foodborne illness surveillance.

* * *

With passage of H.R. 2749 by the House, food safety legislation will now move to the Senate and we will monitor its progress there, keeping you apprised of any developments. If you should have any questions regarding the content of H.R. 2749, please do not hesitate to contact us.

THE FOOD SAFETY ENHANCEMENT ACT OF 2009
H.R. 2749

SUMMARY OF KEY PROVISIONS

I. Significant New or Expanded Requirements on the Food Industry

- Hazard Analysis, Preventive Controls, Food Safety Plans (Sec. 102).

  - Each registered facility would be required to conduct a hazard analysis and identify and implement preventive controls to prevent, eliminate, or reduce to acceptable levels the occurrence of food safety hazards that are reasonably likely to occur, including hazards due to the source of ingredients. Preventive controls must include the following controls: sanitation; training; process controls; allergen controls; GMPs; and supplier verification activities.

  - FDA would be allowed to identify hazards that are reasonably likely to occur and establish preventive controls for specific product types. Facilities would be allowed to implement alternative preventive controls to those established by FDA, provided that, upon request, the facility can demonstrate that the alternative control effectively addresses the hazard.

  - Each facility would be required to monitor the controls; establish corrective actions, including procedures to ensure no affected product enters commerce if the controls are not fully implemented; verify that the preventive controls are being implemented and are working, including through the use of environmental and product testing; re-analyze and revise the plan every 2 years, when there is a change that could affect the hazard analysis, or if FDA determines it is appropriate to protect the public health; and maintain records of the above for 2 years.

  - The results of the hazard evaluation and identification of preventive controls would be required to be reduced to writing ("food safety plan"). This plan would include the following: (1) the hazard analysis; (2) the preventive controls; (3) monitoring; (4) procedures for taking corrective action; (5) verification activities including the use of environmental and product testing programs; (6) record keeping procedures; (7) recall procedures; (8) traceback procedures; (9) supply chain management procedures; and (10) procedures to implement the performance standards.

- Food Defense Plans (Sec. 102).

  - Each registered facility would be required to have a written food defense plan. The plan would include a food defense assessment of food hazards that could be intentionally introduced, including by acts of terrorism, and must evaluate processing security, cybersecurity, material security, personnel security, storage security, shipping and receiving security, and utility security.

- Facilities would be required to implement preventive measures to minimize the risk of intentional contamination; check and identify any circumstances in which the measures were not fully implemented or were ineffective; take corrective actions; evaluate the preventive measures and periodically test the effectiveness of the plan; review and revise the plan every 2 years, when there is a change that could affect the food defense assessment, or if FDA determines it is appropriate to protect the public health; and maintain records documenting implementation of the plan.

- FDA would be allowed to establish preventive measures for specific product types. Facilities would be allowed to implement alternative preventive measures, provided that, upon request, the facility can demonstrate that the alternative measure effectively addresses the hazard.

- Reporting of Test Results (Sec. 102). High-risk facilities would be required to report to FDA finished product test results 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." Before FDA requires such reporting, however, the agency would be required to conduct two pilot projects and a feasibility study.

- Performance Standards (Sec. 103). FDA would be required to issue, as appropriate, through guidance or regulation, science-based performance standards to minimize the risk of "the most significant food-borne contaminants and the most significant resulting hazards." FDA would publish periodic lists of contaminants posing the greatest adverse impact on public health (which would likely become the highest priority candidates for performance standards). In addition, FDA would have the discretion to make recommendations to industry for conducting product sampling.

- Traceability (Sec. 107). FDA would be required to establish by regulation, a tracing system for all food, whether produced in the United States or imported, that would enable FDA to identify each person who grows, produces, manufacturers, processes, packs, transports, holds, or sells food within 2 business days.

  - Before issuing a proposed rule to establish such a system, FDA would be required to identify available technologies and methodologies and assess the feasibility, costs, and benefits associated with the adoption of such technologies; hold at least 2 public meetings; and conduct at least 1 pilot project.

  - FDA would have the discretion to require the use of lot numbers, a standardized format for pedigree information, and the use of a common nomenclature for food.

  - There would be certain exemptions for direct sales from farms and fisheries to restaurants, grocery stores, and consumers, as well as for on-farm storage of grain and similar commodities. In addition, FDA would have the authority to exempt or modify the requirements with respect to certain foods or facilities. Nonetheless, "one-up, one-back" recordkeeping requirements would apply to any exempt foods or facilities.

- Records Access (Sec. 106). 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 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.

- Records Maintenance (Sec. 106). FDA would have the authority to require the establishment and maintenance of records of any person who manufactures, processes, packs, transports, distributes, receives, or holds food. Therefore, the bill's amendments to FFDCA 414 and 704 would remove the current exemption for restaurants; but, the only distribution records which may be required of restaurants are those showing the restaurant's suppliers and subsequent distribution to destinations other than consumers.

- Notification and Reporting (Sec. 111 and 112). Section 112 of the bill would expand the requirements of the Reportable Food Registry enacted by Congress in 2007:

    - It would require the submission of reports by farms, retailers, restaurants, and importers. FDA would be required to establish an alternative notification mechanism other than the electronic portal for farms, retailers, restaurants.

    - The bill would amend the existing reportable food requirements by inserting a requirement that the report follow within 24 hours of "a timely review of any reasonably available data and information."

    - Notably, the bill would require the submission of any *testing results* on the article of food, its components, or any environmental testing at the facility where the food was manufactured, processed, packed or held. However, this reporting of test results would be limited to those instances which are reported to the Reportable Food Registry (i.e., Class I recall situations).

Section 111 of the bill also requires registered facilities that have reason to believe food is adulterated or misbranded in a manner that presents a reasonable probability that use, consumption, or exposure to the article will cause a threat of serious adverse health consequences or death to notify FDA as soon as practicable. 2/ In addition, the bill provides that FDA would be able to share trade secrets and commercial or financial information with other federal, state, local, and foreign agencies provided those agencies can assure confidentiality of the information.

- Inspection Frequency (Sec. 105). The bill would establish a risk-based inspection frequency schedule using three categories of food establishments.

  - Category 1 establishments would be "high-risk" facilities and FDA would be required to inspect such establishments at least once every 6 to 12 months.

  - Category 2 establishments would be "low-risk" facilities that manufacture, process, pack, or label food. Such establishments would be inspected at least once every 18 months to 3 years.

  - Category 3 establishments would be those facilities that only hold food (warehouses) and would be inspected at least once every 5 years.

  FDA would have the authority to alter the types of facilities within each category and the inspection frequency specified. Additionally, a related provision in the bill (Sec. 208) directs FDA to establish a dedicated foreign inspectorate and provides that the same inspection frequency would apply to foreign facilities.

- Standards for Produce and Other Raw Agricultural Commodities (Sec. 104). FDA would be required to establish standards for the safe growing, harvesting, processing, packing, sorting, transporting and holding those types of fruits, vegetables, nuts, and fungi for which such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death. FDA would also be directed to update its existing guidance (Good Agricultural Practices) for fruits and vegetables.

II. Significant New or Enhanced FDA Enforcement Authorities

- Suspension of Registration (Sec. 101). The bill would allow FDA to suspend the registration of any facility for a violation that could result in serious adverse health consequences or death. Suspension of registration would be preceded by notice and an opportunity for an informal hearing. In addition, FDA would be allowed to cancel a registration that is not updated appropriately or contains false, incomplete, or inaccurate information. Cancelation would be preceded by ten days notice and an opportunity to correct the registration information. A decision to suspend or cancel a facility registration could only be made by top agency officials.

2/ This appears to be a duplicative notification provision to the Reportable Food Registry, which only has minor differences in language.

- Mandatory Recall Authority (Sec. 111). The bill would provide for mandatory recall authority by creating a two-tiered mandatory recall system.

    - Tier 1, or Regular Recall: Under the bill, FDA may ask any person to voluntarily recall an article of food that the agency believes is adulterated, misbranded, or in violation of the Act. 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 to any person to cease distributing the article. Any person subject to such an order would be required to comply immediately and would have the opportunity to appeal the order and request an informal hearing. An informal hearing must be held within 5 days. After the hearing, FDA would determine whether the order should be amended to require a recall or be vacated. A decision to order a regular recall could only be made by a district director or more senior agency official.

    - 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 issue an emergency recall order *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. A decision to order an emergency recall could only be made by top agency officials.

- Criminal Penalties (Sec. 134). The bill would increase the criminal penalties available to up to ten years in prison for anyone who knowingly violates designated prohibited acts. In addition, the bill would conform the available fine the higher levels already in effect in accordance with Title 18 of the United States Code, applicable across government agencies.

- Civil Penalties (Sec. 135). The bill would create 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.

- Subpoena Authority (Sec. 211). The bill would provide FDA with broad subpoena authority to produce records or testimony of company officials. In addition, the bill contains a provision requiring immediate compliance with a subpoena, if FDA deems it necessary to address a threat of serious adverse health consequences or death. Moreover, under certain circumstances, the agency could request that a district court issue an ex parte order barring the disclosure of the existence of a subpoena. The authority to issue a subpoena could only be made by a district director or more senior agency official.

- Seizure Procedures (Sec. 131). The bill would add language to the Act that would streamline the process for seizures sought in federal court.

- Administrative Detention (Sec. 132). FDA's administrative detention authority under the Bioterrorism Act of 2002 would be expanded to provide such authority when the agency has "reason to believe" food is "adulterated or misbranded."

- Quarantine Authority (Sec. 133). The bill would provide FDA with new authority to restrict the movement of food within a state or portion of a state if FDA determines there is credible evidence that an article of food presents an imminent threat of serious adverse health consequences or death, has credible evidence that the food is located within or originated from such state, and determines that the restriction is necessary and that no less drastic action would be feasible. A decision to issue a quarantine order could only be made by top agency officials.

- Delaying Inspection (Sec. 207). Delaying, limiting, or refusing to permit an inspection of any farm, factory, warehouse, or establishment would render food from such facility adulterated.

- False and Misleading Reports (Sec. 210). The bill would make false or misleading reporting to FDA a prohibited act.

III. Provisions to Enhance Oversight of Imported Foods

- Certification of Imports (Sec. 109). The bill would require imports to have a certification of compliance *only if* FDA determined, based on scientific, risk-based evidence, that such certification would help the agency determine whether to admit an article of food based on: (a) the adequacy of controls in the country or region of origin; (b) whether the type of food could pose a significant health risk; or, (c) whether FDA has an agreement with the exporting country to provide such certification. In addition, the bill would provide flexibility to FDA to determine the appropriate certification form. The bill also provides discretion to FDA to determine which entities are qualified to provide certification, and includes a number of specific requirements intended to prevent conflicts of interest.

- Testing by Accredited Laboratories (Sec. 110). Product testing required in support of admission for imported food, or as otherwise required by FDA, would be required to be conducted by an accredited laboratory and the results submitted directly to FDA. In addition, FDA would receive advance notice before any product testing required to be conducted by an accredited laboratory takes place. FDA would not directly accredit certifying agents, but would recognize laboratory accreditation bodies and publish a list of them.

- Importer Registration (Sec. 204). The bill would require importers and customs brokers to register in order to import food into the United States and submit unique facility identifiers as part of registration. Importers would be required to follow good importer

practices as a condition of registration, which FDA would be required to issue through regulations. FDA would have the authority to inspect importers' and brokers' facilities and any related records.

- Fast Lane for Imports (Sec. 113). FDA would be allowed to establish a program for expedited entry of certain imported foods for importers that meet FDA food safety and security guidelines.

- Import Entry Filings (Sec. 136). The bill would prohibit import entry filings that contain inaccurate or incomplete information and would allow FDA to require, by regulation or guidance, the submission of any documentation for an imported article of food.

- Extraterritorial Jurisdiction (Sec. 213). The bill states that FDA jurisdiction extends to products that are intended for import into the U.S. The bill also would make it a prohibited act to manufacture, prepare, produce, hold or distribute an adulterated or misbranded article of food with the knowledge or intent that the article will be imported into the U.S.

IV. Fees

- Registration Fee (Sec. 101). Each registered facility would be required to pay an annual registration fee of $500, with a per company cap of $175,000. Importers would also be required to pay a $500 registration fee. Fees collected could only be used by the agency to support designated food safety-related activities.

- Reinspection Fee (Sec. 108). FDA would collect fees from each facility that undergoes an additional inspection due to any violation of the Act. Such fees would reimburse FDA for the costs associated with the reinspection.

- Recall Fee (Sec. 108). FDA would collect fees from food companies conducting product recalls to cover the agency's costs associated with monitoring the recall activities.

- Export Certificate Fee (Sec. 203). FDA would impose a fee for issuing export certificates, similar to fees already in place for other FDA-regulated products.

V. Additional Provisions

- Annual Registration (Sec. 101). Food facilities, both domestic and foreign, would be required to register with FDA annually.

- Country of Origin Labeling (Sec. 202). The bill would require the labeling of all processed foods to identify the country of origin where final processing took place. Similarly, the country of origin for non-processed food would be required to appear on the labeling of the food. Food already in compliance with U.S. Customs and Border Protection country of origin marking requirements or U.S. Department of Agriculture requirements would be in compliance with this section.

- Unique Facility Identifier (Sec. 206). The bill would require the submission of a unique facility identifier along with the registration of a food facility or an importer.

- Bisphenol-A (Sec. 215). FDA would be required to notify Congress 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.

- GRAS Substances (Sec. 201). The bill would require FDA to post on its website GRAS notification determinations, as well as the supporting justification, within 60 days after receipt.

- Whistleblower Protections (Sec. 212). Whistleblowers would received protection against retaliation or discrimination.

- Training for Food Protection Activities (Sec. 214). The bill 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, Public Education, Research (Sec. 121, 122, and 123). The 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. In addition, it would require FDA to implement a national public education program on food safety and conduct food safety-related research.

- Field Laboratories (Sec. 209). FDA would be prohibited from closing or consolidating field laboratories or district offices without congressional review of the reorganization plan.

- Infant Formula (section 114). New ingredients in infant formulas would need to be approved food additives or authorized under the GRAS notification program; or companies could include the safety data for new ingredients in the infant formula premarket notification. In such instances, the 90-day period for completing the review of the premarket notification would not begin until FDA notifies the company that it has completed its review of the safety data.

- Jurisdiction (Sec. 5 and 6). The bill states that it would not alter the jurisdiction between FDA and the U.S. Department of Agriculture (USDA). Specifically, the bill would exempt the portions of farms, facilities, and foods, to the extent they are regulated by USDA, from the bill's requirements. In addition, alcohol manufacturers and distributors would be exempt from the bill's requirements.

- Rule of Construction (Sec. 4). The bill states that the legislation should not "be construed to prohibit or limit" any cause of action under state law or "the introduction of evidence of compliance" with federal law into any such proceeding.

- Lead in Ceramicware (Sec. 216). Ceramic tableware and cookware that bears a lead-based glaze would be required to bear a statement advising that it bears a lead-based glaze consistent with FDA guidelines or be in compliance with 21 CFR § 109.16.