MEMORANDUM

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

Date: August 16, 2010

Re: Senate Leaders Release Manager’s Amendment to The FDA Food Safety Modernization Act

Late last week, pending food safety legislation moved one step closer to passage in the United States Senate later this year with the release of the Manager’s amendment to S. 510, the FDA Food Safety Modernization Act. The Manager’s amendment is a bipartisan agreement of changes to S. 510 as it was cleared by the Senate Health, Education, Labor and Pensions (HELP) Committee last November. These changes were negotiated by HELP Committee Chairman Tom Harkin (D-IA), Ranking Member Mike Enzi (R-WY), authors of S. 510 Dick Durbin (D-IL) and Judd Gregg (R-NH), and lead cosponsors Chris Dodd (D-CT) and Richard Burr (R-NC). If S. 510 is brought to the Senate floor for a vote, the Manager’s amendment would be offered as a substitute bill to the version cleared by the HELP Committee. This memorandum provides a summary of the key changes made to S. 510. 1/

Most Significant Changes to S. 510

The Manager’s amendment to S. 510 is substantially the same bill as that passed by the HELP Committee last fall. Accordingly, as reported previously, the bill contains significant new or expanded requirements on food companies, provisions to enhance the Food and Drug Administration’s (FDA) oversight over imported food, new or enhanced enforcement authorities for FDA, and new fees for food companies.

Notably, the bill does not contain language addressing bisphenol-A (BPA) in food packaging. Senator Dianne Feinstein (D-CA) has indicated that she plans to introduce an amendment on the floor to ban the chemical from being used in baby bottles, sippy cups, baby food, and infant formula containers. Likewise, the bill does not contain the provision addressing the concerns of small farmers authored by Senator Jon Tester (D-MT), although the bill does contain a number of other changes designed to ease the regulatory burden on small farms and small businesses.

1/ For a comprehensive summary of the bill as introduced, see Hogan & Hartson memorandum dated March 3, 2009. For a summary of the significant changes made to the bill as passed by the HELP Committee, see Hogan & Hartson memorandum dated November 19, 2009.
The two most significant changes to S. 510 for the packaged food industry relate to inspection frequency and traceability, as follows:

1. **Inspection Frequency.** The first significant change to the bill is a reduction in the frequency with which FDA would be required to inspect domestic and foreign food facilities. This change was made in order to reduce the overall projected cost estimate of the bill, as calculated by the Congressional Budget Office (CBO), to $1.4 billion over five years. The inspection schedule would continue to draw a distinction between “high risk” and “non-high risk” facilities and would be as follows:

   - **Domestic facilities:**
     - “High risk” domestic facilities would be required to be inspected once in the first five years after enactment and once every three years thereafter.
     - “Non-high risk” domestic facilities would be required to be inspected once in the first seven years after enactment and once every five years thereafter.

   - **Foreign facilities:**
     - In the first year after enactment, FDA would be required to inspect 600 foreign facilities; thereafter, the agency would be required to double the number of inspections of foreign facilities every year for five years. This translates to:
       - 2011 – 600 foreign inspections
       - 2012 – 1,200 foreign inspections
       - 2013 – 2,400 foreign inspections
       - 2014 – 4,800 foreign inspections
       - 2015 – 9,600 foreign inspections

The bill continues to provide that FDA may rely on inspections conducted by other Federal, state or local agencies under interagency agreement, contract, memorandum of understanding, or other obligation. The bill contains a new provision regarding interagency agreements with respect to inspection of seafood, and directs the Secretary to improve coordination and cooperation with the United States Department of Agriculture and the Department of Homeland Security to target food inspection resources. Finally, the bill contains a new provision authorizing the Secretary to consult with any of the agency’s advisory committees, in determining how to allocate inspection resources.

Taken together, even with a somewhat reduced inspection frequency from the prior bill, this provision demonstrates the high importance that Congress places on significantly increasing FDA inspections of food establishments:

   - Based on the inspection schedule specified, CBO estimates that this bill would require approximately 50,000 domestic and foreign food facilities to be inspected in 2015.
   - This represents nearly a 7-fold increase in total inspections compared to fiscal year 2009, in which the FDA inspected only approximately 7,400 domestic and foreign food establishments. Reportedly, FDA considers 28,000 facilities to be high-risk facilities.
   - This new inspection schedule would also significantly increase both the number of foreign inspections (from only a few hundred in FY 2009 to nearly 10,000 in FY 2015), as well as increase the relative proportion of foreign inspections as compared to domestic inspections (from approximately 5% in FY 2009 to approximately 20% in 2015).
2. **Traceability.** The revised bill would require the Secretary to establish a new product tracing system, but with important limitations. Chief among these is that the new requirements would **only** apply to “high risk” foods and would **not** apply to “commingled raw agricultural commodities,” as defined in the bill. Specifically, under the bill:

- FDA would be required to conduct pilot projects, in cooperation with the applicable food sector, to explore methods to improve the tracking and tracing of food. The bill would require separate pilot projects for: (a) packaged food; and (b) fruits and vegetables that are raw agricultural commodities.

- After completion of the pilot projects, FDA would be required to establish within the agency a product tracing system to receive information to track and trace food. FDA would be required to ensure that the parameters of such system are supported by the results of the pilot projects.

- FDA would be required to conduct additional data gathering to assess the cost and benefits associated with adoption of product tracing technologies, the feasibility of such technologies for different food sectors, and whether such technologies are compatible with the statutory requirements for this section.

- FDA would also be required to evaluate domestic and international product tracing practices in commercial use, consider international efforts, and consult with a diverse and broad range of experts and stakeholders.

- As noted, any additional recordkeeping requirements for product tracing would apply only high-risk foods, and FDA would have to consider certain factors when determining whether a food is high-risk for purposes of product tracing.

- The new recordkeeping requirements could not prescribe the use of specific technologies, could not require the creation of duplicate records, and could not require the full pedigree of the food.

- The new requirements would not apply to certain farm sales of food, fishing vessels, or commingled raw agricultural commodities, and FDA would not be permitted to impose any limitations on the commingling of food.

- A “commingled raw agricultural commodity” would be defined as any commodity that is combined or mixed after harvesting but before processing, but would not include certain types of fruits and vegetables as determined by FDA. The term “processing” would mean operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

- FDA would be able to provide additional exemptions or modifications for specific types of food or facilities if the agency determines that such requirements are not necessary to protect the public health.

- During an active investigation of a foodborne illness outbreak, FDA would be able to request that a farm identify potential immediate recipients of the food that is the subject of the investigation.
Within 2 years of enactment, FDA would be required to publish a proposed regulation covering the additional recordkeeping requirements associated with product tracing of “high risk” foods, to be followed by public meetings to obtain input from different regions of the country. Such proposed requirements would, among other things:

- be required to be science based;
- ensure that the public health benefits outweigh the costs of compliance;
- be scale appropriate;
- minimize the number of different requirements for facilities that handle more than one type of food; and
- ensure that FDA has procedures in place to protect trade secret or other confidential information.

The new traceability requirement would also apply to imported products.

**Additional changes to S. 510**

The Manager’s amendment also made the following modifications to S. 510, including some additions and some deletions from earlier provisions:

1. **Suspension of Registration.** The Manager’s amendment would narrow the ability of FDA to suspend the registration of a facility that merely packs, receives, or holds food with a reasonable probability of causing serious adverse health consequences or death to those circumstances where the facility knew or should have known that a food posed such a risk. The revised bill also would require FDA to review a facility’s corrective action plan for reinstatement of its registration within 14 days.

2. **Hazards Intentionally Introduced.** Although the revised bill continues to require that a facility’s food safety plan address both naturally occurring hazards (food safety-related) and intentionally introduced hazards (food defense-related), the bill now contains new language that draws a distinction between the two types of hazards and recognizes that intentionally introduced hazards may not be reasonably foreseeable.

3. **Performance Standards.** The revised bill would clarify that FDA can set different performance standards for animal feed from those for human food. The provision references the agency’s Good Manufacturing Practices for food, and recommendations of the agency’s Food Advisory Committee, as sources of information for FDA to consider in determining the most significant foodborne contaminants.

4. **Produce Safety Standards.** The Manager’s amendment would provide a process for small farms producing low risk foods to be exempt from the produce safety standards.

5. **Product Recalls.** In order to improve recall communications, the revised bill would require FDA to establish an incident command operation that would operate within 24 hours of the initiation of a class I recall, regardless of whether the recall was mandated or conducted voluntarily. Additionally, FDA would be required to provide an annual report to Congress identifying when the agency used the mandatory recall authority and the circumstances by which the agency concluded that the situation warranted use of such authority.
6. **Reportable Food Registry.** The revised bill contains a new section amending the existing statutory provision on the reportable food registry (RFR). It would allow FDA to require a responsible party to submit consumer-oriented information to the RFR to enable a consumer to identify whether the consumer possesses the reportable food. In addition, individual grocery stores would be required to post this information in a standardized format prepared by FDA. The criteria triggering an RFR report would remain unchanged by the bill.

7. **Imported product samples.** FDA would be required to establish an exemption from the foreign supplier verification program for articles of food imported in small quantities for research and evaluation purposes, provided such foods are not intended for retail sale and are not sold or distributed to the public. This would allow for the importation of product samples. The same exemption would extend to imports for personal consumption.

8. **Third Party Certification of Imported Food.** The Manager’s amendment clarifies that certification can apply to a particular food or to a facility. In addition, this section and other sections on imported food were revised to ensure consistent use of terms throughout.

9. **Small Farms and Small Businesses.** The manager’s amendment contains a number of provisions throughout designed to ease the regulatory burden on small farms and businesses. These include additional time to comply with new requirements and the requirement that FDA publish several small entity compliance guides to assist in the implementation of new practices.

**New or Deleted Sections**

The Manager’s amendment adds three new sections in specific topics and deletes one section, as follows:

1. **New Dietary Ingredients (Section 113).** The revised bill contains new language directing FDA to issue guidance on new dietary ingredients and the safety of such substances. It also states that if FDA has concerns with a new dietary ingredient notification because the substance is an anabolic steroid, the agency must notify the Drug Enforcement Administration.

2. **Raw Oysters (Section 114).** The revised bill contains a new section directing FDA to submit a report to Congress prior to issuing a new guidance, regulation or other related action with respect to the post-harvest processing of raw oysters.

3. **Port Shopping (Section 115).** This provision would direct FDA to coordinate with the Department of Homeland Security on any food refused admission into the U.S. in order to prevent port shopping by the importer.

4. **Review of a Regulatory Authority of a Foreign Country (former Section 305).** The Manager’s amendment deleted former section 305 which provided FDA with authority to review the adequacy of a foreign government’s food regulatory system. The current bill retains, however, FDA’s authority to accredit a foreign government for conducting regulatory audits of food establishments within its borders, for food intended for export to the U.S.
Next Steps

Last Thursday, Senate staff involved in the Manager’s amendment held a stakeholder briefing highlighting the more significant revisions made to the bill. Staff explained they are hoping to gather feedback from other Senate Members over the coming weeks. Due to time constraints in the Senate Calendar, staff noted that the sponsors of the bill will need to demonstrate to the Senate leadership that the bill can be voted on in a short time period with limited amendments.

* * *

We will provide an updated side-by-side comparison of S. 510, as revised, with H.R. 2749, in near future. In addition, we will continue to 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.