

MEMORANDUM

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Re: Congress Passes Landmark Food Safety Legislation

Earlier today, Congress passed landmark food safety legislation after weeks of procedural maneuvering during the lame duck session. ^{1/} Passage of this sweeping legislation followed three years of Congressional hearings and legislative drafting, triggered by a series of high profile outbreaks of foodborne illness linked to both domestic and imported food. The bill is expected to be signed by President Obama and enacted into law. ^{2/}

Because the Senate acted late in the session, there was no time to “conference” S. 510 with the previously passed House bill, H.R. 2749. This meant the House needed to “accept or reject” the Senate version. Therefore, a number of provisions contained only in the original House version are not contained in the final legislation. A list of those provisions is included further below.

Throughout its development, this legislation has contained four main areas of focus: (1) new responsibilities for food manufacturers and food producers; (2) tighter controls over imports; (3) stronger FDA enforcement powers; and (4) new fees on food facilities. A complete section-by-section analysis of this legislation is attached. A brief summary follows:

^{1/} Congressional passage required an unusual series of votes on the bill. The Senate first passed S. 510 in bipartisan fashion on November 30, 2010, but with a procedural glitch that required a re-vote in the Senate after House action. The House incorporated the Senate’s bill into the Continuing Resolution (CR) (H.R. 3082) necessary to keep the government operating, and passed that bill on December 8, 2010. Although the CR did not get accepted by the Senate, the Senate did re-vote on food safety legislation as a stand-alone measure on December 19, 2010 (H.R. 2751). The House re-voted favorably on that bill on December 21, 2010.

^{2/} For important milestones from initial introduction to final passage, see prior memoranda: Hogan & Hartson memorandum: Senator Durbin Introduces Food Safety Bill dated March 2, 2009; Hogan & Hartson memorandum: Senate HELP Committee Approves Food Safety Legislation dated November 19, 2009; Hogan Lovells memorandum: Senate Leaders Release Manager’s Amendment to the FDA Food Safety Modernization Act dated August 16, 2010; and Hogan Lovells memorandum: Updated Food Safety Legislation Side-by-Side following Senate Passage of S. 510 dated December 1, 2010.

HIGHLIGHTS OF MAJOR PROVISIONS

1. New responsibilities on food manufacturers and food producers:

- **Hazard analysis and identification of preventive controls**
 - Each registered facility will be required to conduct a hazard analysis of reasonably foreseeable hazards and put into place preventive controls designed to significantly minimize or prevent those hazards.
 - Each registered facility will be required to implement its preventive controls through a system that includes monitoring, corrective actions, and verification that the system is working properly.
 - Finished product and environmental testing is considered part of the facility's verification process.
- **Supply chain management**
 - Supplier verification activities are expressly listed as one of the preventive controls to be implemented.
 - (See also foreign supplier verification program below under Import Controls.)
- **Records maintenance and access**
 - Each registered facility will be required to document its hazard analysis and preventive controls system, including corrective actions and product/environmental testing, and to make those records available to FDA upon request.
- **Intentionally introduced hazards**
 - Each registered facility will also be required to conduct a hazards analysis of those hazards that may be intentionally introduced, including those introduced by acts of terrorism, and to implement appropriate mitigation steps as deemed necessary by the FDA.
- **Traceability**
 - FDA will be required to conduct pilot tests and issue regulations for "high risk" products; the bill contains many restrictions on FDA's authority, including no "full pedigree" requirements and an express exemption for "commingled raw agricultural commodities."
- **Fresh product standards**
 - FDA will be required to issue mandatory standards for "high risk" types of fresh fruits and vegetables and update its good agricultural practices covering the remaining product categories.
- **Very small business exemption**
 - The bill contains a limited exemption from both the preventive controls provision and from any mandatory produce standards for very small businesses and very small farms, based on limited sales and area of distribution.

2. Tighter controls over imports

- **Foreign supplier verification program**
 - Importers will be required to verify that imported food and food ingredients are produced in accordance with U.S. requirements.
 - Records must be maintained for two years and be accessible to the FDA.

- **Third party certification**
 - FDA has authority to require third party certification for specific types or sources of imported food, based on public health considerations.
 - FDA may refuse admission if certification is not provided.
 - Third parties may be accredited foreign governments or private auditors.

- **Accreditation process**
 - FDA will recognize accrediting bodies which, in turn, are to evaluate and accredit third party auditors.
 - FDA will establish standards for accrediting bodies and conflict-of-interest standards for third party auditors.
 - Third party auditors will be required to report directly to FDA any conditions that could cause or contribute to a serious risk to the public health.
 - False statements made by foreign facilities to third party auditors are subject to criminal penalties.

- **Certified laboratories**
 - FDA will be required to recognize accreditation bodies to accredit laboratories, including laboratories administered by a Federal agency as well as independent private laboratories.
 - Accredited laboratories will be required to be used when FDA has designated an identified or suspected food safety problem.
 - Laboratory results will be sent directly to the FDA in addition to the importer.

- **Voluntary qualified importer program**
 - FDA will provide for expedited entry (i.e., "fast lane") for qualified importers who voluntarily participate in the program.
 - Eligibility includes third party certification, among other factors.
 - FDA will coordinate with Department of Homeland Security, which operates a similar program from the security perspective.
 - Participation will be subject to a fee (see below).

3. Stronger FDA enforcement powers

- **More frequent FDA inspections**
 - Domestic facilities will be inspected based on risk: high risk facilities at least once every 3 years, and low risk facilities at least once every 5 years.
 - Foreign facilities to be inspected with increasing frequency over time: 600 total foreign facility inspections in the first year, to double each year for 5 years, reaching 9,600 foreign facility inspections by 2015.
- **Mandatory recall authority**
 - FDA will be given authority to mandate a food product recall if the company refuses to do so voluntarily and the hazard meets the criteria for a Class 1 recall.
 - Only the FDA Commissioner has authority to mandate a recall, following an opportunity for an informal hearing.
 - A company will face civil money penalties for refusing to conduct a mandatory recall.
- **Suspension of registration**
 - FDA will be given authority to suspend a company's registration, thereby revoking its license to operate, when the food presents a reasonable probability of causing serious adverse health consequences or death.
 - For a company that only packs, received or holds food, there is the added requirement that the company "knew or should have known" of the problem conditions.
 - Only the FDA Commissioner has authority to suspend a company's registration, following an opportunity for an informal hearing.
 - The bill provides a process for subsequent reinstatement based on corrective action.
- **Enhanced administrative detention authority**
 - Standard for administrative detention of food is broadened to "has reason to believe" the food is "adulterated or misbranded." (Under prior law, detention was limited to where there was "credible evidence" that the food presents a "threat of serious adverse health consequences or death.").
 - Administrative detention remains a temporary measure, lasting until the agency institutes a formal seizure action in Federal court.

4. New fees on food facilities

- **Reinspection fees**
 - Fees will be assessed to reimburse FDA for reinspection-related costs for domestic facilities and importers.
- **Recall fees**
 - Fees will be limited to the reimbursement of FDA for recall-related costs when a company refuses to conduct a mandatory recall.
- **Voluntary qualified importer program fees**
 - Fees are intended to reimburse FDA for costs associated with operating a voluntary qualified importer program (i.e., fast lane).
- **Export certificate fees**
 - Fees will reimburse FDA for costs associated with providing export certificates to companies that voluntarily request them.
 - This fee has long been assessed against exporters of other FDA-regulated products.

ADDITIONAL PROVISIONS OF NOTE

The final bill also contains the following provisions:

- **Records access** – The general records access authority under the Bioterrorism Act is expanded to include access to other, similar articles of food.
- **Bi-annual registration** – Food companies will be required to re-register with FDA every two years, instead of just initially, with an abbreviated process for companies reporting no changes.
- **Performance standards** – FDA is directed to periodically review existing food contaminants and to issue, when appropriate, science-based guidance documents to help prevent adulteration.
- **FDA command center for recalls** – FDA is required to establish an incident command center for every Class 1 recall.
- **Recall information for consumers** – FDA may require food companies, through the reportable food registry, to provide information needed by consumers to identify recalled food; grocery stores will be required to post recall information in one of a list of locations designated by the FDA.
- **Prior notice of imported food** – The bill adds the requirement that importers list any country that has refused entry to the food.
- **Smuggled food** – FDA will be required to implement a strategy for better identifying smuggled food and to prevent smuggled food from entering the U.S.
- **Whistleblower protections** – Whistleblowers will receive protection against retaliation or discrimination.

PROVISIONS AFFECTING PARTICULAR SECTORS

- **New dietary ingredients** – FDA is directed to issue guidance on the regulation of new dietary ingredients and to notify the Drug Enforcement Administration of any new dietary ingredient that may be an anabolic steroid.
- **Raw oysters** – FDA is required to notify Congress before instituting new requirements for the post-harvest treatment of raw oysters.
- **Alcohol-related facilities** – The bill clarifies that most of its provisions do not apply to alcohol facilities that are required to obtain a permit or register with the Department of the Treasury.
- **Jurisdictions maintained** – The bill clarifies that it does not change the pre-existing jurisdiction between FDA and USDA, Department of Homeland Security, or the Alcohol, Tax and Trade Bureau.

PROVISIONS FROM ORIGINAL HOUSE BILL NOT IN FINAL LEGISLATION

Importantly, because the House passed the Senate bill (S. 510), a significant number of provisions originally contained in the House bill (H.R. 2749) are not in contained in the final food safety legislation.^{3/} These include:

- Annual registration fees
- Civil money penalties (except for refusal to conduct a mandatory recall)
- Enhanced criminal penalties
- Subpoena authority
- Quarantine authority
- Reporting to FDA of positive test results
- Remote access to records by FDA
- “Full pedigree” traceability
- Country of Origin Labeling
- Provisions addressing GRAS substances, BPA, infant formula, and lead in ceramicware

EFFECTIVE DATES

The bill contains a series of effective dates. The most important effective dates for food companies are: (1) the central requirement for preventive controls takes effect for large companies in 18 months; and (2) the foreign supplier verification requirement takes effect in 2 years. We will prepare a separate memorandum summarizing these effective dates and related implementation issues.

CONCLUSION

This food safety legislation represents the most significant expansion of FDA’s oversight of the safety of the nation’s food supply since the original Pure Food and Drug Act of 1906. Food companies will need to become familiar with all of its major provisions and begin implementation as soon as possible. Attached is a Section-by-Section Analysis to assist in that process.

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Please let us know if we can assist you in any way in your implementation of this new landmark legislation.

^{3/} For a complete summary of the original House bill (H.R. 2749), see Hogan & Hartson memorandum: House Passes Comprehensive Food Safety Legislation dated July 31, 2009.