FOOD AGRICULTURE & BIOFUELS

FDA Food Safety Modernization Act

FAEGRE & BENSON LLP

About Faegre & Benson / Speakers

- International law firm with practice focusing on Food, Agricultural and Biofuels industries
- Offices in Minneapolis, Denver, Boulder, Des Moines, London and Shanghai
- Litigate and counsel on food and agricultural industry litigation

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How Did We Get Here?

- July 2009: House passes HR 2749 by wide margin
- Nov. 2009: Senate HELP committee passes S 510
- Nov. 2010: S 510 comes to Senate floor, passes
- Dec. 2010: Oops! Funding must originate in House
- Late Dec. 2010: House quickly passes bill, Senate follows
- Jan 4, 2011: President signs bill into law

The Big Picture – What Is It?

- Law divided into three general categories
  - Preventative Measures
  - Detection and Response Measures
  - Imported Foods
- Provides for lots of rulemaking and guidance documents within 1-2 years

To Whom Does This Apply?

- FDA-regulated facilities and foods, generally
- What's not covered:
  - As a general matter, relates only to foods regulated by FDA
  - Excludes meat, poultry, and certain egg products regulated by USDA
  - Excludes most alcoholic products and related facilities
- Small-business exemption ("Tester Amendment")
  - Exempt from Hazard Analysis and Produce provisions if:
    - 50%+ of food sold is to consumers, restaurants < 275 miles, and food for sale directly to consumers, and < $500k in yearly sales; OR
    - A "very small business"

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Part 1: Preventative Measures

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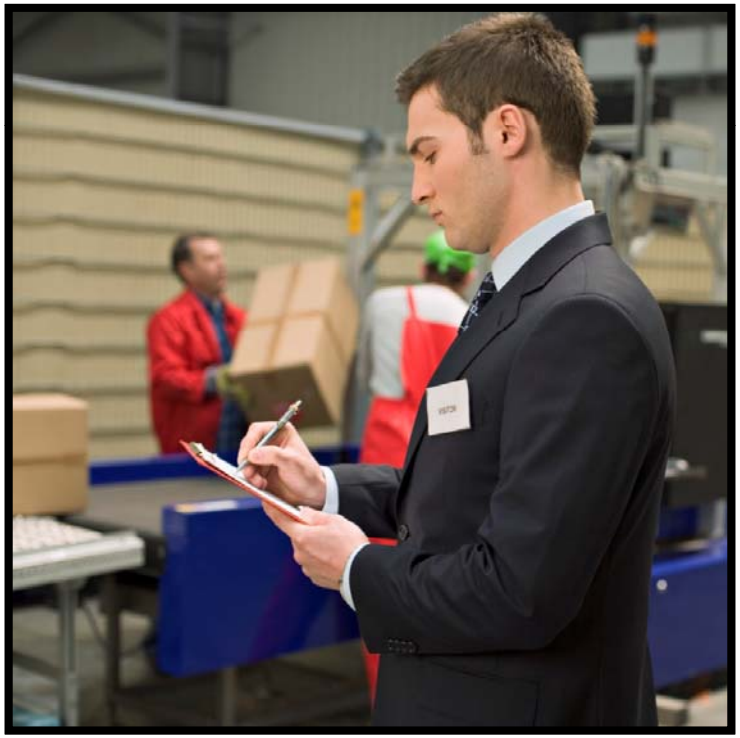
Preventative: Inspection and Registration

- Records Inspections: now includes other food articles inspectors reasonably believe may be affected in similar manner

- New powers to suspend registration of regulated facilities



Preventative: Hazard Analysis & Risk-Based Preventative Controls

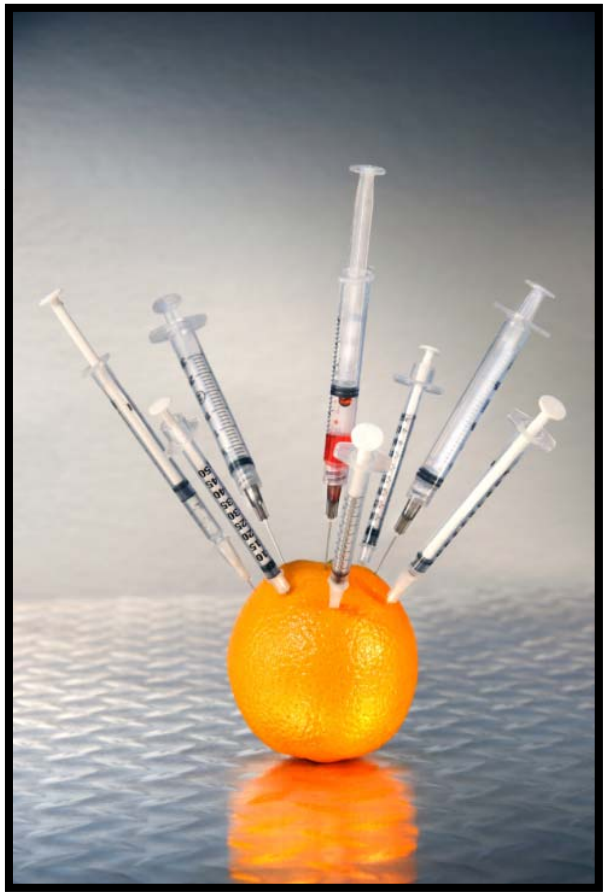
- Requires written Hazard Analysis & Risk-based Preventive Controls plans for most facilities
  - Identify and analyze hazards
  - Identify and implement preventative controls, including at critical control points
  - Monitor effectiveness – does it work?
  - If it doesn't work, take corrective action
  - Verify system is being implemented properly
- Re-analyze at least every 3 years or if significant changes
- Certain exemptions for small businesses
- Rule-making and guidance forthcoming
- Failure to have written Hazard Analysis plan = prohibited act

Preventative: Standards for Produce Safety

- FDA/USDA coordination
- Requires rulemaking re “minimum standards for safe production and harvesting of” certain high-risk, raw agricultural commodities
- Prioritizes high-risk fruits/vegetables with history of outbreaks
- Variances allowed upon request
- Requires flexibility for small businesses
- Limited exemption for some small businesses

Preventative: Intentional Adulteration

- Protection against intentional adulteration – focus on terrorism
- Study to determine foods at high risk
- Rulemaking (18 months)
  - Who should have to comply?
  - What measures should they have to take?
- Exempts farms (but not dairies)
- Guidance documents within a year (but possibly limited distribution)



Preventative: Ag & Food Defense Strategy

- National Agricultural and Food Defense Strategy
- Developed by FDA, USDA, and DHS
- Limited distribution

Preventative: Other Misc. Coordination Efforts

- FDA, USDA, and DHS to coordinate with public and private entities re protecting ag and food systems
- FDA, USDA, and DHS to study variety of issues relating to food security, including regulations, traceback, surveillance, etc…
- Grants to local/state governments

Preventative: New Fees

- Authorizes fees where:
  - Facility is re-inspected due to noncompliance
  - Facility refuses to comply with a recall order
  - Importer participates in voluntary qualified importer program
  - Importer is re-inspected
- Guidelines forthcoming
- Common sense: If we need to come back, we're charging you for it

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Part 2: Detection and Response Measures

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Detection/Response: Targeted Inspections

- Target FDA's limited inspection resources to high-risk facilities/foods
- Identify high-risk facilities/foods, both domestic and imported
- Domestic high risk: At least once by 2016, at least every 3 years thereafter
- Other domestic: At least once by 2018, at least every 5 years thereafter
- Foreign facilities: No fewer than 600 this year, doubling each year in next 5 years
- Coordinate with USDA/DHS to identify high-risk candidates

Detection/Response: Food Laboratories

- Accreditation program for labs analyzing food
- Develop model standards for labs
- Labs to be used for testing food identified by FDA or for certain imported food

Detection/Response: Traceback

- FDA to run at least 1 traceback pilot program each for processed and raw produce

- New record-keeping requirements for facilities involved with high-risk foods.
  - FDA to identify high-risk foods within 1 year
  - Rule-making within 2 years
  - Some exemptions for direct sales from farms, grocery stores, etc…

- New powers to seek farm records in recall-type situations

Detection/Response: FBI Surveillance Systems*

- Directs FDA to improve foodborne illness (FBI) surveillance systems
- More coordination with/assistance to local & state governments
- Funded with $24 million a year through 2015

* FBI = Food-Borne Illness.

Detection/Response: Mandatory Recall Authority

- Step 1: Give opportunity to do voluntarily recall
- Step 2: If refuses, FDA can order to cease production/distribution, with notice downstream
- Step 3: Hearing within 2 days, if requested
- Step 4: Amend order as necessary, including ordering recall and giving notice to consumers, or vacate the order
- Failure to follow mandatory recall order is a prohibited act

Detection/Response: Administrative Detention

- Lowers standard for FDA inspectors to order administrative detention
- Used to be “credible evidence or information…”, now just “reason to believe”
- Used to be same standard as Class I recall, now just “is adulterated or misbranded”
- Effective in 180 days; regulations forthcoming

Detection/Response: RFR Updates

- FDA can require responsible person to submit “critical information” – i.e. “consumer-oriented information” regarding a reportable food (UPC, contact info, etc…)
- FDA will create fact sheet using that information and distribute online
- Chain grocers to post one-page fact sheet in a conspicuous place to notify consumers
- 18 months out

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Part 3: Imported Foods

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Imported Food: Foreign Supplier Verification Program

- Importers must conduct risk-based foreign supplier verifications
  - Ensure compliance with food safety requirements (including Hazard Analysis and Risk-Based Preventative Controls)
  - Avoid adulteration/misbranding
- Importer = Owner of food item when enters U.S. or if none, U.S. agent/representative of foreign owner
- Records must be kept for 2 years, produced upon request
- Regulations & Guidance must be developed within one year, effective two years after enactment

Imported Food: Voluntary Qualified Importer

- Importers apply for participation in program for expedited review of food products

- Review looks at
  - Risk of food
  - Compliance history (suppliers & importer)
  - Exporting country's ability to ensure compliance with U.S. food safety regulations
  - Recordkeeping
  - Adulteration risk

- Participation reviewed at least once every three years

Imported Food: Import Certifications

- May be required to provide Certificate of Compliance to allow import of certain food items

- Risks evaluated include:
  - Known risks associated with food item
  - Risks related to country/region of origin
  - Finding that originating country cannot adequately ensure U.S. regulations met

Imported Food: Third-Party Auditors

- FDA can authorize third parties to conduct food safety inspections
  - Foreign governments
  - Foreign cooperatives
  - Other third parties
- Must be accredited to conduct audits to ensure compliance with U.S. food safety regulations
- Model accreditation standards developed within 18 months
- Used to determine eligibility for voluntary qualified importer program and if food safety requirements satisfied
- Includes regulations related to potential conflicts of interest

Imported Food: Other Misc. Measures

- Building capacity of foreign governments with respect to food safety
  - Within two years plan developed to "expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries"
  - Developed in consultation with other Departments, such as Agriculture, State & Homeland Security, and industry representatives
- Inspection of foreign food facilities
  - If inspection not allowed, food products denied entry to U.S.
- Foreign offices
  - FDA will establish foreign offices for support & risk-based inspections

Whistleblower Protections

- Expansive new protection for whistleblowers in the food industry
- Effective immediately
- Protected from retaliation for:
  - Providing information to employer or government for violations of Act
  - Testifying about violation
  - Assisting in investigation or proceeding
  - Preparing to testify or assist
  - Objecting to/refusing to participate in activity believed to violate Act

- Employee-friendly burden-shifting regime
- Nominal relief when employee makes frivolous complaint

When Do I Need to Start Complying?

- Effective Already:
  - Beefed-up authority to FDA to access and inspect records
  - Mandatory recall authority
  - Whistleblower provisions
  - Refusal of admission to imported foods where inspectors refused admission to foreign facility
- What about Hazard Analysis & Protective Controls plan?
  - July 2012 (most businesses)
  - Later for small/very small businesses

Where Do We Go From Here?

- Extensive rulemaking forthcoming
- Proliferation of guidance documents in next two years
- Greatly increases the amount of work FDA needs to do and amount of people it needs to hire
- Biggest issue: What will happen with funding?

Practical Tips for Compliance

- Participate in the rule-making and guidance document process
- Review policies/practices with respect to the whistleblower provisions
- Begin working with foreign suppliers to prepare for future regulations
- Review and update record-keeping policies/procedures
- Prepare for your next inspection – know who is going to participate, where your relevant documents are, how you respond, etc…

Questions?

- Please email general questions to Kristin, Jennie or Steve

- If you have questions beyond that or ones specific to your situation, please contact your legal counsel

- Visit our blog at http://www.FoodAgBiofuels.com/ and the FAB Practice page at: http://www.faegre.com/2429

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THE NATIONAL LAW JOURNAL

Food safety bill passes, but many questions remain

Kristin Eads, Steven Toeniskoetter and Jennifer Williams Zwagerman
March 14, 2011

After more than a year of delays and significant wrangling, Congress passed the Food Safety Modernization Act (FSMA) last December, and President Obama signed it in January. The FSMA addresses three broad categories: preventative measures; detection and response measures; and imported foods. The law contains a number of important provisions that could have substantial effects on a number of industries.

The FSMA applies to U.S. Food and Drug Administration-regulated facilities and food. It generally excludes products regulated by the U.S. Department of Agriculture (USDA) — i.e., meat, poultry and certain egg products. If a facility has to register with the FDA under the Bioterrorism Act of 2002, it is most likely affected by the FSMA.

One of the more controversial parts of the FSMA is a section known as the "Tester Amendment." It exempts businesses from the act's hazard analysis and plan and its produce safety provision, discussed below, if the facility has less than $500,000 in yearly sales, and the majority of its food is sold directly to consumers or to restaurants within the same state or within 275 miles. It also exempts "very small businesses," a term that the FDA will define via rulemaking.

The first broad category of the FSMA covers preventative measures. A key provision here is the new requirement that facilities create, follow and update a written hazard analysis and plan. Although many companies already have similar plans, including USDA-regulated plants and juice and canned-food makers, the FSMA for the first time makes plans mandatory for all FDA-regulated food facilities.

There are some exemptions from this requirement, including for certain foods already covered by their own hazard analysis and critical control point (HACCP) regulation and certain small and very small businesses. The FDA is to create regulations within 18 months that establish minimum standards for implementing the HACCP requirement. Companies that already have HACCP or HACCP-like plans should watch for these regulations and guidance documents and prepare to amend their plans.

Another one of the FSMA's most controversial provisions relates to standards for produce safety. The FDA has historically had little, if any, role in on-farm activities. The produce safety provision directs the FDA, in coordination with the USDA, to establish "science-based minimum standards for the safe production and harvesting of" certain high-risk raw fruits and vegetables. Limited variances will be allowed, as well as limited exemptions for certain small and very small businesses. The rulemaking process and hearings for this provision are expected to be very contentious.

DETECTION AND RESPONSE

The second broad category relates to detection and response measures. One such provision gives the FDA, for the first time, mandatory-recall authority. The FDA has always had other tools at its disposal, such as the power to administratively detain food. The significance of this new provision, however, is that it establishes a formal process the FDA must follow and gives companies the opportunity to challenge a recall, albeit after the fact. A related provision lowers the standard that must be met before the FDA may administratively detain food articles. These two provisions, along with enhanced record-inspection powers and new powers to suspend registration of regulated facilities in recall-like situations, give the FDA powerful new tools to use when companies choose not to follow the

FDA's requests in recall situations.

The provision that most directly affects the largest number of companies is the mandate that the FDA increase inspections of regulated facilities. The FDA is directed to identify high-risk facilities and/or foods and direct resources for more frequent inspections of those high-risk facilities or foods. A company may find itself in the high-risk category based on its overall compliance history — such as previous recalls or troublesome inspections — or if it makes, packs or holds types of foods more commonly linked to food-borne illness outbreaks.

Domestic facilities designated as high- risk will now be inspected at least once by 2016 and then at least every three years after that. All other domestic facilities can expect to face an FDA inspection at least once by 2018 and at least once every five years thereafter. Likewise, inspections of foreign facilities are to increase dramatically during the next five years.

Finally, the FSMA establishes a series of "whistleblower" provisions. These provisions prohibit companies from terminating or discriminating against employees who engage in certain protected activities, such as reporting violations of food safety regulations. This type of federal whistleblowing provision is new to the food industry, and companies should review their current policies and practices, including discipline and discharge policies, to assure compliance.

IMPORTED FOODS

The third broad area of the FSMA relates to imported foods. The FSMA's focus on establishing new regulations for imported foods reflects consumer concerns as food imports have increased in volume

First, the FSMA requires importers to implement a new foreign supplier verification program. This program will require importers to conduct risk-based verifications of their foreign suppliers to ensure the suppliers are complying with food safety requirements. For instance, importers would need to implement a program verifying that foreign suppliers are following the new HACCP-like requirements and/or the new produce safety requirements as appropriate. Importers would also need to verify that foreign suppliers are not producing adulterated or misbranded food. Importers are responsible for verifying foreign supplier compliance and keeping records of those verification efforts.

One of the more interesting aspects of the FSMA is the new voluntary qualified-importer program. This program will allow importers to seek expedited review and importation of certain foods from qualified foreign facilities. In other words, this will be a fast track for importing certain foods for importers who opt in. The FDA will look at a number of factors, including the food type's risk, the importer's compliance history, the exporting country's food safety system, the importer's record-keeping practices and the risk of adulteration, to determine if importers are qualified. Details of the program are sparse at this point, but it could be very useful for importers who import foods from high-quality foreign facilities.

The FDA is also empowered to require a certificate of compliance before it allows the import of certain high-risk foods. These would be foods identified due to known risks associated with that food, risks relating to country of origin and/or a finding that the country of origin cannot adequately ensure that U.S. food safety standards are being met.

To meet its goal of improving safety in imported foods, the FSMA authorizes the FDA to create a program for accrediting third-party auditors, including foreign government agencies, to conduct food safety inspections. Only these accredited auditors will be able to conduct audits necessary to ensure compliance with U.S. food safety regulations. The certifications issued by these accredited auditors will be used to determine whether food is eligible for import into the United States and whether a facility is eligible for the voluntary qualified importer program.

MUCH RULEMAKING TO COME

As always, the devil is in the details. One of the most striking aspects of the FSMA is its lack of detail. It sets a skeletal framework and then requires the FDA to draft guidance documents and reports to Congress, conduct studies and undertake an extensive amount of rulemaking to implement the FSMA's mandates. As each of those rules or guidance documents is released, there will be significant opportunity for industry and public input.

Largely due to all the significant rulemaking and guidance documents forthcoming, most of the FSMA's provisions are not yet in effect. Those in effect now include the FDA's record-inspection powers, the mandatory-recall

authority, the whistleblower provisions and the refusal of admission for certain imported foods. The remainder will be phased in during the next six months to two years.

All these provisions substantially increase the amount of work the FDA is required to do, especially during the next two years. The FSMA specifically requires the FDA to increase its staff members by a significant amount each year through 2014, but it is still unclear how the FDA can accomplish all it needs to do with the limited resources it currently has. The FSMA merely authorizes the appropriation of "such sums as may be necessary" for fiscal years 2011 through 2015. With expected austerity measures and a renewed focus by the government on reducing our national debt, funding for all this work is far from certain.

Although it is difficult to provide practical tips when so many of the details are still to come, companies can take some steps to prepare themselves. First, they can participate in the rulemaking and guidance-document process to ensure the industry is well represented. Second, they can review employee handbooks or policies and procedures with respect to the whistleblower provision. Third, they can begin working with foreign suppliers to prepare for future regulations. Finally, they can get prepared for their next inspection, including knowing who will participate, where the relevant documents are located and how they will respond. As the FDA releases the regulations that will implement the various provisions of the FSMA, companies will need to review other policies, documents and contracts.

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