Food Safety Modernization Act - Impacts on the Grain and Feed Industry

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Food Safety Modernization Act

- **Signed into Law – Jan. 4, 2011 (P.L. 111-353)**
- **Paradigm Shift – Biggest Change in U.S. Food, Feed Safety Law Since 1938**
- **Major Principles**
  - Covers all 'food' *(food for humans and animals)*
  - Prevention-based focus
  - Import provisions 'groundbreaking'
- **"Historic" legislation**
  - It's NOT just recalls and inspections
  - It's a call for a new, prevention-oriented food safety system to ensure the safety of feed/food products

Food Safety Modernization Act

- **Rules, Guidances, Reports:** Requires FDA to develop and issue more than 50 regulations, guidance documents, reports
- **While Timelines Mandated, Implementation Will Be Multi-Year Process**
  - Heavily dependent upon FDA resources
  - Will necessitate phased approach

Common FSMA-Related Questions

- **Applicability Issues**
  - Who's covered, who's not
  - Exemptions/modifications
- **Hazard Analysis and Preventive Controls**
  - Written food safety plans – what will it entail
- **Traceability Requirements**
  - Tracking/tracing of food products through the chain
- **NGFA Activities**

FSMA – Applicability Issues

- ***Question:*** Who's covered by the food/feed safety law?
- ***Answer:*** All facilities registered with FDA under Bioterrorism Act of 2002. Those facilities are domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. For purposes of the law, the term "facility" does not include farms, restaurants, and retail food establishments
  - Interstate or intrastate commerce
  - Commercial feed mills, feed ingredient manufacturers, pet food manufacturers
  - Grain elevators, grain processors, flour/corn millers
  - Biofuel facilities manufacturing co-products used as feed ingredients *(e.g., distillers grains)*

FSMA – Applicability Issues

- ***Question:*** What is FDA's definition of a "farm"?
- ***Answer:*** A "farm" means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes:

  (1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

  (2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership

FSMA – Applicability Issues

- ***Question:*** What about transporters like trucking firms, barge operators and railroads, are they covered?
- ***Answer:*** Transporters are not required to register as a food facility under the Bioterrorism Act since they hold food only to transport it from one location to another. Since transporters are not required to register as a food facility, they are not covered by the law.

  However, FSMA directed FDA to reinitiate rulemaking associated with the *Sanitary Food Transportation Act of 2005,* which will apply to transporters and address a variety of issues associated with the safe transportation of food

FSMA – Applicability Issues

- ***Question:*** What about small companies, are they exempt?
- ***Answer:*** FSMA requires FDA to establish modified hazard analysis and preventive control requirements for "qualified facilities." In general, a qualified facility is a facility that either: 1) is a very small business, as to be defined by FDA (the proposed human rule offers three options for comment: under $250,000, $500,000, or $1,000,000 in total annual sales of food); or 2) had average food sales of less than $500,000 during the preceding 3-year period, and that primarily sells food directly to "qualified end-users" (i.e., consumers of the food or restaurants or retail food establishments located within the same state or 275 miles or the facility and purchasing the food for sale directly to consumers).

FSMA – Applicability Issues

- ***Question:*** Doesn't FSMA have language that exempts facilities that only store and distribute grains and oilseeds from the hazard analysis and preventive control requirements ?
- ***Answer:*** FSMA contains language that states FDA *may*, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man, *the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing*, or the storage of packaged foods that are not exposed to the environment.

Hazard Analysis and Preventive Controls

- ***Question:*** For effected facilities, will the hazard analysis and preventive control requirements require a HACCP plan?
- ***Answer:*** Based on the proposed human food rule, not exactly, but close. The proposed rule states, "FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 *[hazard analysis and preventive controls]* of FSMA."

Principle	HACCP - National Advisory Committee on Microbiological Criteria for Foods	Proposed Human Food Rule
----	Five Preliminary Steps: (1) Assemble HACCP team; (2) describe food and its distribution; (3) identify intended use/consumers; (4) develop flow diagram; (5) verify flow diagram	No
1	Conduct Hazard Analysis	Yes
2	Determine Critical Control Points	Yes, determine preventive controls, including critical control points, if any
3	Establish Critical Limits for Critical Control Points	Yes, establish parameters for controls
4	Establish Monitoring Procedures	Yes
5	Establish Corrective Actions	Yes
6	Establish Verification Procedures	Yes
7	Establish Record and Documentation Procedures	Yes

Hazard Analysis and Preventive Controls

- ***Question:*** Will effected facilities need to submit their written food safety plans to FDA in advance of an inspection?
- ***Answer:*** FDA did not include this requirement in their proposed human food rule, however the agency is asking for comment about whether to require submission of a subset of information that would be in a food safety plan. FDA suggests that the facility "profile" submission could include: contact information; facility type; products; hazards identified; preventive controls; third-party audit information; training information; facility size (square footage); and operations schedule.

Hazard Analysis and Preventive Controls

- ***Question:*** Will effected facilities need to have their written food safety plans "certified" by a third-party auditor?
- ***Answer:*** No, FSMA specifically states that the regulations "shall not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventative controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party"

Hazard Analysis and Preventive Controls

- ***Answer (cont.):*** Related to third-party inspections, FSMA also requires FDA to "establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible foreign entities *[foreign facilities]* meet the applicable requirements of this section"

Hazard Analysis and Preventive Controls

- ***Question:*** What food safety hazards will effected facilities need to address within their food safety plans?
- ***Answer:*** FSMA requires facilities "to identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility." Within FDA's proposed human food rule, the agency defines "hazard" to mean "any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control."

Hazard Analysis and Preventive Controls

- ***Answer (cont.):*** Sources of information concerning hazards that facilities likely will need to consider include:
  - Hazards for which FDA already has established tolerances or action levels
  - Hazards associated with recalls and reports submitted to FDA's Reportable Food Registry
  - Further FDA hazard guidance currently being developed

Hazard Analysis and Preventive Controls

- ***Question:*** What preventive controls will be deemed to be effective in controlling identified hazards?
- ***Answer:*** Within its proposed human food rule, FDA defines "preventive control" to mean "those risk-based, reasonably appropriate procedures, practices, and processes that a *[knowledgeable]* person would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding at the time of the analysis." FDA is developing further guidance for this topic.

Hazard Analysis and Preventive Controls

- ***Question:*** Will effected facilities be required to test products?
- ***Answer:*** Within its proposed human food rule, FDA did not include requirements to test raw materials, ingredients and finished products. *However*, FDA states that it believes testing "plays a very important role in ensuring the safety of food" and asks for comments on this topic.

Hazard Analysis and Preventive Controls

- **Question:** Will effected facilities be required to have supplier verification and approval programs?
- **Answer:** FDA did not include supplier verification and approval program requirements in its proposed human food rule, but states that almost 40 percent of Class I and Class II recalls that occurred during 2008-09 were directly linked to the lack of supplier controls. FDA is seeking further comment on this issue, and states that supplier controls could include: 1) on-site audits; 2) testing and/or requiring COAs; 3) review of supplier safety plans/records; or 4) combinations of these activities

Hazard Analysis and Preventive Controls

- **Question:** The proposed requirements for food safety plans include establishing and maintaining many records. How long to I have to keep them? Can I keep them in electronic format?
- **Answer:** FSMA mandates that records be kept for two years. FDA is seeking comment on whether to allow records to be kept in an electronic format.

Hazard Analysis and Preventive Controls

- **Question:** FDA is proposing that a "qualified individual" perform or oversee activities associated with the required food safety plan. What does that mean?
- **Answer:** According to FDA, a "qualified individual" would be one that has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience. FDA also has proposed that the qualified individual may be, but is not required to be, an employee of the facility.

Food Safety Preventive Control Alliance

- Consists of government officials, academia, and industry representatives
- Goals are to:
  - Develop standardized hazard analysis and preventive controls training and distance education modules for food industry and regulatory personnel
  - Develop commodity/industry sector-specific guidelines for hazards and preventive controls

Traceability of Food

Question: Does the law expand the traceability requirements for food?

Answer: FSMA requires FDA to initiate rulemaking on enhancing the tracking and tracing of "high-risk" foods to evaluate whether additional recordkeeping requirements would assist in preventing or mitigating outbreaks of foodborne illnesses. FDA has yet to define "high-risk" foods, but when doing so is required to consider known safety risks of a food based on foodborne illness data and the likelihood that a particular food has a high potential risk for contamination. FDA has conducted two pilot projects pertaining to enhanced traceability of foods, and currently is seeking comments on recommendations emanating from the projects.

NGFA FSMA-Activities

Question: What's NGFA doing about all of this?

Answer: A lot…

- Soliciting feedback from NGFA Committees and working groups
- Actively participating in stakeholder meetings
- Serving as a member on the FSPCA Steering Committee
- Submitting written comments
  - Food Traceability Recommendations, April 4
  - Proposed Human Food Rule, May 16
  - Proposed Animal Feed, Pet Food Rule, ???
  - Many other rulemakings to come…

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