Core Catalysts

2016 Regulatory Update: Food Safety Modernization Act (FSMA)

Changes influencing businesses that participate in the food supply chain.

Introduction

This whitepaper introduces certain topics within the Food Safety Modernization Act regulation, known as FSMA. The paper introduces key topics, regulations, and businesses involved in the food supply chain. Lastly, we have included regulatory reference tables that can be useful references to those businesses involved in the food supply chain.

Why is the regulation changing?[1]

It has been over 70 years since the last *major* update the FDA's food safety rules was made. Since then, enhancements in logistics, food processing technology, facilities, communication, and overall knowledge have allowed more food to travel around the world than before. There are also more people today, and changes in health and wellness are allowing people to live longer.

According to research, over the many years, new pathogens have also evolved and adapted. With the increase in food capacity and our greater lifespan, three is also an increased chance for people to get sick or die from a food borne illness. Due to the multitude of people who get sick or die from foodborne diseases each year, this has been called a "significant public burden". According to the Centers for Disease Control and Prevention, each year, 1 in 6 Americans becomes ill from foodborne diseases (Illnesses and germs are classified as bacterial, viral, and parasitic).

The changes in regulation focus on food safety, preventative, and response measures in the United States and spans across imports from other countries. Within the regulation, the FDA has been provided new authorities for food safety.

> *"About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases…"*

Background and Structure:

Who enforces the requirements of the regulation?[2]

The FDA has new enforcement authorities in order to obtain "higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur". In addition to the FDA, regulatory support will come from the Secretary of Agriculture, the Secretary of Health and Human Services as well as the industry, and government agencies (national, state, and local)

Who are non-government entities that administer and are responsible or may be impacted from the requirements of the regulation?

The following non-government entities:

- Food producers
- Food processors and packagers

- Independent food brokers
- Distribution centers and transporters
- Food distributors
- Food wholesalers
- Retailers
- Restaurants

What penalties will result from the regulation?[3]

Certain penalties have been identified but are not meant to be comprehensive:
For some companies, the impact is lost revenues due to shutting down food operations. In other instances, punitive measures may result. For instance, if the Park Doctrine is imposed, corporate executives could become personally liable and subject to penalties, including prison and fines from $100,000 to $250,000.

What is the regulation code?

Regulation can be found in **The Act PUBLIC LAW 111–353—JAN. 4, 2011 124 STAT. 3885 or Title 21 U.S.C., Chapter 27 (§§ 2201 to 2252)** - *"Short title - **FDA Food Safety Modernization Act.** Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)"*

When was the law passed and what is the regulatory timeline of events?

- December 21, 2010 - Congress passes the law
- January 4, 2011 – law executed by President
- *Since January 2013, FDA has proposed seven foundational rules to implement FSMA. Those rules become final in 2015 and 2016.*

How is the regulation structured?

The act has been divided into 5 major elements – preventative controls, inspection and compliance, imported food safety, response, and enhanced partnerships. Within each element are rules that have been created.

"Since January 2013, FDA has proposed seven foundational rules to implement FSMA. Those rules become final in 2015 and 2016". These rules also show "how" the FDA will implement the 5 major elements (listed above):

1. *Preventive Controls for Human Food*
2. *Preventive Controls for Animal Food*
3. *Produce Safety*
4. *Foreign Supplier Verification Program*
5. *Third Party Certification*
6. *Sanitary Transportation*
7. *Intentional Adulteration*

Tables 1.1 – 1.5 organize the rules by their respective elements and Federal Register's docket ID

Table 1.1 – Preventative Controls

Preventative Controls	The FDA now has a legislative directive to require prevention measures across the food supply chain, so that hazards can be prevented or mitigated.	
How will element be implemented?	*Preventive Controls for Human Food: Requires that food facilities have safety plans that set forth how they will identify and minimize hazards. Original rule proposed January 2013; supplemental rule to add specific language for important provisions proposed September 2014. Final rule issued: Sept. 10, 2015.* *Preventive Controls for Animal Food: Establishes Current Good Manufacturing Practices and preventive controls for food for animals. Original rule proposed October 2013; supplemental rule to add provisions geared specifically to animal foods proposed September 2014. Final rule issued: Sept. 10, 2015.* *Sanitary Transportation: Requires those who transport food to use sanitary practices to ensure the safety of food. Proposed January 2014. Final rule issued: Apr. 5, 2016.*	
DOCKET	**RULE**	**DATE**
Docket Number: FDA-2011-N-0920 (Vol. 80, FR 55908)	***Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*** *Note: Current Good Manufacturing Practice referred to as "CGMP"*	Posted: September 17, 2015 Effective: November 16, 2015
Docket Number: FDA-2011-N-0922	***Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals***	September 17, 2015
Docket Number: FDA-2013-N-0013	***Sanitary Transportation of Human and Animal Food***	April 2016
Docket Number: FDA-2011-N-0921 (Vol. 80, FR 74354)	***Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption***	November 27, 2015
Docket Number: FDA-2011-N-0920, FDA-2011-N-0921, FDA-2011-N-0922, FDA-2011-N-0143 (Vol. 81, FR 57784	***The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules*** *Note: For updated compliance dates, see Part III. Extension of Compliance Dates for "Customer Provisions" in Part 117 and Related Rules, Subpart C. Extension of Compliance Dates.*	August 24, 2016

Table 1.2 – Inspection and Compliance

Inspection & Compliance	FDA will be applying new methods and risk-based approaches for inspections that hold industry participants accountable for producing safe food.	
How will element be implemented?	*Produce Safety: Establishes science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. Original rule proposed January 2013; supplemental rule to amend key areas proposed September 2014. Final rule issued: Nov. 13, 2015.*	
DOCKET	**RULE**	**DATE**
Docket Number: FDA-2002-N-0153 (Formerly Docket No. 2002N-0277) (Vol. 79, FR 18799)	***Record Availability Requirements: Establishment, Maintenance, and Availability of Records***	April 4, 2014
Docket Number: FDA-2011-N-0197 (Vol. 78, FR 7994)	***Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption***	February, 5 2013

Table 1.3 – Imported Food Safety

Imported Food Safety	FDA is now allowed to implement new controls for food safety such as accrediting qualified third party auditors for certifying compliance of foreign food facilities	
How will element be implemented?	*Foreign Supplier Verification Program: Importers will be required to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of U.S. food producers. Original rule proposed July 2013; supplemental rule to provide, among other provisions, more flexibility in determining appropriate verification measures proposed September 2014. Final rule issued: Nov. 13, 2015.* *Intentional Adulteration: Requires domestic and foreign facilities to address vulnerable processes in their operations to prevent acts intended to cause large-scale public harm. Proposed December 2013. Final rule deadline: May 31, 2016.*	
DOCKET	**RULE**	**DATE**
Docket Number: FDA-2011-N-0179 (Vol. 78, FR 32359)	***Information Required in Prior Notice of Imported Food***	May 30, 2013
Docket Number: FDA-2011-N-0143 (Vol. 80, FR 74226	***Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals***	November 27, 2015
Docket Number: FDA-2011-N-0143 (Vol. 81, FR 25326	***Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Technical Amendment***	April 28, 2016

Table 1.3 – Imported Food Safety (Continued)

DOCKET	RULE	DATE
Docket Number: FDA-2011-N-0146 (Vol. 80, FR 74569)	***Accredited Third-Party Certification***	November 2015
Docket Number: FDA-2011-N-0920, FDA-2011-N-0921, FDA-2011-N-0922, FDA-2011-N-0143 (Vol. 81, FR 57784)	***The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules*** *Note: For updated compliance dates, see Part III. Extension of Compliance Dates for "Customer Provisions" in Part 117 and Related Rules, Subpart C. Extension of Compliance Dates.*	August 24, 2016

Table 1.4 – Response

Response	The FDA now has authority to granted mandatory recalls on all food products. Authorities include: "*expanded administrative detention of products that are potentially in violation of the law, and suspension of a food facility's registration.*"	
How will element be implemented?	*"Under FDCA section 423(a), FDA is required to first give a responsible party the opportunity to cease distribution and conduct a voluntary recall of an article of food. If the responsible party refuses to or does not voluntarily cease distribution or recall such food within the time and in the manner prescribed by FDA, FDA may proceed under the mandatory recall authority as set forth in FDCA section 423*." In section 204, are two major requirements for implementing a product tracing systems. A product tracing system should include documentation of *"the production and distribution chain of products so that in the case of an outbreak or evidence of contaminated food, a product can be traced back to a common source or forward through distribution channels."* 1. FDA, the U.S. Department of Agriculture (USDA) and State agencies, must establish pilot projects in coordination with the food industry to explore and evaluate methods and appropriate technologies for rapid and effective tracking and tracing of foods. 2. FDA must publish a notice of proposed rulemaking to establish recordkeeping requirements for high risk foods to help in tracing products."	
DOCKET	**RULE**	**DATE**
See "Rule"	*FDCA section 423(a)*	
See "Rule"	SEC 204. Enhancing tracking and tracing of food and recordkeeping	

Table 1.5 – Enhanced Partnerships

Enhanced Partnerships	The FDA is expected to increase collaboration among partners such as National Integrated Food Safety System (IFSS) *(1.8)*	
How will element be implemented?	*Third Party Certification: Establishes a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals. Proposed July 2013.* *"FDA intends to implement this program as soon as possible after publication of the final Model Accreditation Standards guidance, and the final user fee rule, both of which will be published separately."* *"There are two kinds of audits that accredited third-party certification bodies can perform as part of the program, consultative and regulatory. In both kinds, auditors will examine compliance with applicable federal food safety requirements.* *.* *An accredited third-party certification body could be a foreign government or other third-party entity or individual."*	
DOCKET	**RULE**	**DATE**
FDA-2011-N-0146 (Vol. 80, FR 74569)	***Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications*** **Note:** see 21 U.S.C. 384d, Pub. L. 111-353, sec 307 FDA Food Safety Modernization Act, 21 U.S.C. 371, 21 U.S.C. 381, 21 U.S.C. 384b,	November 27, 2015

Looking Forward:

How can businesses comply and protect themselves?

Below are a few methods of compliance that may be executed by businesses in the food supply chain.
Note: *in this whitepaper, we have done our best to keep dates and information as up-to-date as possible. Regulation and dates may evolve over time; it's important to monitor the FDA website, particularly information specified for FSMA (http://www.fda.gov/Food/GuidanceRegulation/FSMA/) as well as the Federal Register (https://www.federalregister.gov/) for notices, proposed rules, and final rules.*

I. Preventative Controls

Develop a written preventative controls plan that includes:

- Operational procedures for evaluating all types of hazards – natural, unintended, and intentional (e.g. purposeful adulteration or contamination of foods)
- Specific prevention steps and controls that reduce hazards
- Develop key performance indicators to monitor plan effectiveness
- Maintain records of monitoring measures
- Create procedures that identify corrective actions

Follow mandatory science-based minimum Produce Safety Standards set by FDA
Standards will consider natural, unintended, and intentional hazards and will assess soil, hygiene, packaging, temperature controls, animals near growing areas, and water.

- Review FDA's standards and laboratory methods for testing foods for contaminants

II. Inspection and Compliance

Be prepared for an inspection and understand how your risk is classified by FDA.
Depending on the risk level, your facility may receive a more frequent inspection.

- High-risk domestic facilities – inspection 5 years after FSMA enactment; 3 years thereafter
- FDA to inspect at least 600 facilities within 1 year of FSMA enactment
- FDA to double inspections each year for the next five years: 1,200 (year 2), 2,400 (year 3); 4,800 (year 4), 9,600 (year 5), 19,200 (year 6).
- Consider a "consultative audit" whereby your facility can evaluate compliance with federal standards.

Depending on the food your facility produces, you will need to verify your food testing is being performed by FDA accredited laboratories
According to the FDA's "Submission of Laboratory Packages by Accredited Laboratory" guidance, a laboratory can be accredited by an accreditation body. The accreditation body should be a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- Verify accreditation bodies through the ILAC's MRA Signatory Search (http://ilac.org/signatory-search/)

III. Imported Food Safety

If your facility is categorized as "high-risk" be prepared for unannounced audits by an accredited third party auditor.
Note: The FDA is allowing third party auditors to use the International Organization for Standardization and the International Electrotechnical Commission (a.k.a. ISO/IEC standards); also for definition of high-risk foods, see February 2014 document titled *"FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA"*

- Consider a consultative audit by an accredited third party auditor.
- If you are needing expedited review of your imports, see the FDA's "*Draft Guidance for Industry: FDA's Voluntary Qualified Importer Program*" (VQIP). Note: the VQIP User Fee will be applied annual, and rates are published in Federal Register. Per vol. 80, no. 108 Federal Register 32136 (June 5, 2015), the annual rate is $16,400.
- Compliance dates vary based on size of supplier, nature of importer, and other factors impacting the regulations applied to the organization.

IV. Response

Follow the FDA's pilot programs for product tracing and record keeping

- Review February 2014 document titled "*FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA*"
- Review FDA's current thoughts on record keeping titled "*Guidance for Industry: What You Need to Know About Establishment and Maintenance of Records; Small Entity Compliance Guide"*
- *Review any food safety materials as set forth by association, council, membership, group, or boards (i.e. U.S. Poultry and Egg Association, National Pork Producers Council America, etc.)*

V. Enhanced Partnerships

Follow the various FDA partnerships

- Supporting agencies and programs include:
  - U.S. Department of Agriculture (see National Organic Program)
  - National Association of State Departments of Agriculture (NASDA)
  - National Integrated Food Safety System (IFSS) – see also the Partnership for Food Protection (PFP)

About Core Catalysts

Core Catalysts is a management consulting firm based in Kansas City, and we serve clients across the U.S. in various industries. Core Catalysts provides services such as process improvement, product/service commercialization, revenue enhancement, financial modeling, program/project management, software selection, enterprise risk management and business performance improvement through a team that is composed of results oriented individuals.

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