

Implementation Status of the Food Safety Modernization Act

Presented by Bracey Parr

Regulatory Advisor

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About Bracey Parr

Regulatory Advisor

Bracey Parr holds a Bachelor of Arts degree in Communication (International Emphasis) from Saint Louis University, Madrid Campus. Mr. Parr is based at Registrar Corp's headquarters in Hampton, Virginia, and serves as a Regulatory Advisor for Food Safety Services. Mr. Parr analyzes the major regulations under the U.S. FDA Food Safety Modernization Act (FSMA) and assists companies to understand the rules and identify their requirements. He developed and manages Registrar Corp's [FSMA Compliance Wizard](#). Mr. Parr speaks fluent English and Spanish, and has conducted various webinars and trainings on FSMA requirements.



Presentation Overview

- History of FSMA
- Review of Major Rules
 - Preventive Controls for Human and Animal Food
 - Foreign Supplier Verification Program
- Current Implementation Status
- Summary / Questions & Answers



“The most sweeping reform...in 70 years”



History of FSMA



History of FSMA



History of FSMA

- June 8th, 2009 – Introduced in the House
- June 9th, 2009 – Passed by the House
- December 21st, 2010 – Passed by the Senate
- December 29th, 2010 – Resolved differences
- January 4th, 2011 – Signed by Pres. Obama
– PL 111-353
- Sept. 17th, 2015 - First Final Rule published



PC Rules and FSVP

Review of Major Rules



Preventive Controls



Food Safety Plan

Preventive Controls



Preventive Controls

- Exemptions and modified requirements:
 - Retail establishments (restaurants and stores)
 - **Qualified facilities**
 - Juice and Seafood HACCP
 - Alcoholic beverages
 - Dietary supplements
 - USDA products
 - Farms
 - Unexposed, packaged food in warehouses

Preventive Controls

- Deadlines
- Food Safety Plan
 - Facilities with >500 full-time equivalent employees: **September 19th, 2016**
 - Small business (<500 employees): **September 18th, 2017**
- Qualified facility attestation
 - Qualified facilities and very small businesses: **September 2018**



FSVP – Written Program



Foreign Supplier Verification Program

FSVP

- Qualified Individual



FSVP

- Who must comply?
 - “Importer”: defined as owner or consignee
 - If there is no US owner or consignee, the “Importer” is the U.S. agent or representative of the foreign owner or consignee, as confirmed in a signed statement of consent.

MAERSK LINE		COMBINED TRANSPORT BILL OF LADING	
Shipper's name and address BCD EXPORTS LTD. 100 AEC STREET MISSISSAUGA, ONT. CANADA L4Z 2K5 PHONE: (905) 550-0000 <small>Copy on last page name and address</small>		Booking No. 000 Export reference CFF/99570A	
TO THE ORDER OF UTTARA BANK LTD.		Forwarding agent - reference CROWN FREIGHT FORWARDERS LTD 375 TRADERS BLDG MISSISSAUGA ON L4Z 2K5 <small>Full and complete name and address</small>	
Consignee's name and address PAK TRADING INC. 200 BUTER STREET CHITTAGONG BANGLADESH		Date of receipt of goods 13 SEP 1999	
Port of origin TORONTO	Place of receipt TORONTO	Date of bill of lading 13 SEP 1999	
Name SL CHAMPION	Vessel No. 043E	Port of loading HALIFAX	Date of loading 13 SEP 1999
CHITTAGONG CARRIER'S RECEIPT <small>Container No. Seal No. Marks and Numbers</small> MAEU SEAL 000 BDL 25-31 APNU SEAL 000 BDL 32-39		CHITTAGONG PARTICULARS FURNISHED BY SHIPPER - CARRIER NOT RESPONSIBLE <small>Quantity, description, weight or measure</small> 2 SHIPPERS LOAD, STOW AND COUNT X 20' CONTAINERS S.T.C. 15 BDLs 42.25 M.TONS B.P. SHEET/COLOUR SHEET SECONDARY QUALITY. SIZE: 3 FEET N UP X 6 FEET N UP. THICKNESS: 0.25 mm LIGHTER PACKING: STANDARD EXPORT PACKING L/OPS 113 25 99 005 ON BOARD SL CHAMPION 043E, PORT OF LOADING HALIFAX ON SEPT 13, 99 15 DAYS FREE DEMURRAGE ON BOARD	
Weight or measure 2		Gross Weight 135	Net Weight 94242.000
Date of issue TORONTO SEP 13 1999		Signature of carrier MAERSK CANADA INC. AGENTS FOR THE CARRIER <i>Rafael Andrade</i>	

FSVP

- Exemptions

- Firms subject to juice or seafood HACCP regulations
- Very small importers (\$1 million human/\$2.5 million animal)
- Food for research or evaluation; Food for personal consumption
- Alcoholic beverages and ingredients
- Food transshipped through U.S.
- Meat, poultry, and egg products subject to USDA regulation at time of importation
- Country with equivalent food safety system

FSVP

- When must I comply?
 - Latest of these dates
 - May 2017
 - Six months after supplier is required to become compliant
 - Date the importer must comply with those supply-chain provisions

FSVP

- New information required in the Automated Commercial Environment
 - Name of FSVP importer
 - E-mail address
 - Unique facility identifier





FSMA

Current Implementation Status



Current Implementation Status

7 MAJOR FSMA RULES	PUBLICATION DATE
Preventive Controls for Human Food	September 17 th , 2015
Preventive Controls for Animal Food	September 17 th , 2015
Produce Safety	November 27 th , 2015
Foreign Supplier Verification Program (FSVP)	November 27 th , 2015
Third Party Certification	November 27 th , 2015
Voluntary Qualified Importer Program (VQIP)	Draft Guidance – June 4 th , 2015
Sanitary Transport	April 6 th , 2016
Intentional Adulteration	May 27 th , 2016

**FDA FOOD SAFETY
MODERNIZATION ACT**

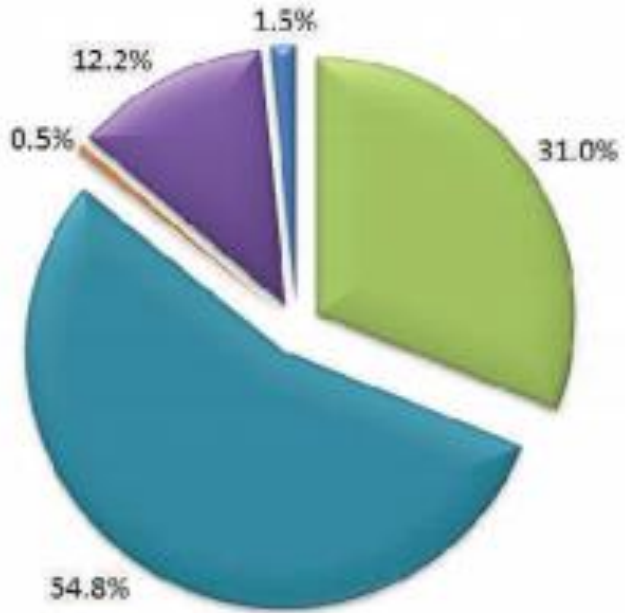
Current Implementation Status



**FDA FOOD SAFETY
MODERNIZATION ACT**

Current Implementation Status

FY 2016 MAJOR ACTIVITIES



- Food Safety
- Medical Product Safety
- Medical Countermeasures
- Tobacco
- Other*

*Major Activities include GSA Rent, Other Rent and Rent Related. Other includes Buildings and Facilities, WO, China Initiative, and Color Certification activities.

Current Implementation Status

- Authority granted immediately
 - Administrative detention if “reason to believe” food may be adulterated or misbranded
 - Mandatory recall for a contaminated food
 - Changes to registration
 - Renewal
 - E-mail of contact person or US agent
 - Suspension authority

Current Implementation Status

- Authority granted immediately
 - Protections for whistle blowers at food facilities
 - Fees
 - Reinspection (2017 - \$221 per hour; \$285 per hour [foreign])
 - Non-compliance with a recall order (same)

Current Implementation Status

- Preventive Controls for Human Food Rule
 - Draft Rule: January 16th, 2013
 - Final Rule: Sept. 17th, 2015
 - Draft Qualified facility attestation guidance: May 16th, 2016
 - Deadline clarifications: August 24th, 2016
 - First deadline: Sept. 19th, 2016
 - Subject companies with more than 500 full-time equivalent employees

Current Implementation Status

- Foreign Supplier Verification Program
 - Draft Rule: July 29th, 2013
 - Final Rule: Nov. 27th, 2015
 - Deadline clarifications: August 24th, 2016
 - First deadline: May 30th, 2017
 - FSVPs for PC-rule subject suppliers with more than 500 full-time equivalent employees
 - Guidance: Forthcoming

Current Implementation Status

- Animal Food
 - cGMPs: Sept. 19th, 2016; PC: Sept. 18th, 2017
- Produce Safety
 - First deadline: (Sprouts) Nov. 27th, 2016
- Sanitary Transport
 - First deadline: April 26th, 2017
- Intentional Adulteration
 - First Deadline: May 28th, 2019

Current Implementation Status

- Third Party Certification
 - July 2015: Released guidance
 - Fees for Accreditation Bodies and Certification Bodies
- Voluntary Qualified Importer Program
 - June 2015: Released guidance
 - Estimated fee: \$16,400 (first year)
 - Jan. 2018: Accept applications
 - Oct. 2018: Program begins

Assistance with FSMA Requirements

- FSMA Wizard: www.fsmawizard.com
 - Free tool to help identify your possible requirements
- FDA Compliance Monitor: www.fdamonitor.com
 - Monitor suppliers for Import Alerts, Warning Letters, Inspection Classifications, Import Refusals
- Food Safety Plans
- Foreign Supplier Verification Programs (FSVPs)
- Food Defense Plans



Questions & Answers

