

# FDA FOOD SAFETY MODERNIZATION ACT



## FSMA—What You Need To Know

An online informational session

### Introduction

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# Food Safety Modernization Act (FSMA)

- FDA FSMA Public Law 111-353, 124 Stat. 3885 expansively amended the Federal Food, Drug, and Cosmetic Act of 1938 (*21 U.S.C. 3001 et seq.*)



- Date of enactment: January 4, 2011



# Why Now?

Food, as we know now, is very different from even just 10 years ago.

- We have a global food supply.
- About 15% of US foods are imported:
  - 80% of seafood
  - 50-60% of fresh produce



# Why Now? (cont'd)

- Our food supply system is complex and technologically advanced.
  - More choices, more pathogens, new pathogens, old pathogens behaving differently
- The U.S. demographics is shifting.
  - Increased food choices, different food handling, social-cultural influence on food safety
  - Aging population, increasing risk for foodborne illness (~30% are at-risk)



# Shifting Focus in Food Safety

- Focus was on **responding** to food contamination.
  - Pure Food and Drug Act (1906)
  - Federal Food, Drug, and Cosmetic Act (1938)
- For the first time, FDA has as legislative mandate to require comprehensive RISK-BASED preventive controls across the food supply
- Focus of FSMA is now on *hazard analysis and risk-based preventive controls* (**prevention** of food contamination)
- Goal remains the same: protection of public health



# Full Regulation 21 CFR 117

The full regulation, *21 CFR 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food*, includes

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice (GMP)

➔ Subpart C – Hazard Analysis and Risk-based Preventive Controls

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

Subpart F – Requirements Applying to Records That Must be Established and Maintained

Subpart G – Supply-chain Program



# FSMA Rules

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	January 16, 2013	August 30, 2015 <b>Sept 17, 2015<sup>◇</sup></b>
Preventive Controls (Animal Food)*	October 29, 2013	August 30, 2015 <b>Sept 17, 2015<sup>◇</sup></b>
Produce Safety*	January 16, 2013	October 31, 2015 <b>November 27, 2015**</b>
Foreign Supplier Verification Program*	July 29, 2013	October 31, 2015 <b>November 27, 2015**</b>
Third Party Accreditation	July 29, 2013	October 31, 2015 <b>November 27, 2015**</b>
Sanitary Transport	February 5, 2014	March 31, 2016 <b>April 6, 2016**</b>
Intentional Adulteration	December 24, 2013	<b>May 27, 2016**</b>

*\*Supplemental proposals published September 2014*

*<sup>◇</sup>Final rule publication date*

*\*\*Final rule made public*



# Published Foundational Final Rules

Regulation	Publication
Preventive Controls (Human Food)*	80 FR 55908 September 17, 2015
Preventive Controls (Animal Food)*	80 FR 5610 September 17, 2015
Produce Safety*	80 FR 74354 November 27, 2015
Foreign Supplier Verification Program*	80 FR 74226 November 27, 2015
Third Party Accreditation	80 FR 74570 November 27, 2015
Sanitary Transport	81 FR 20092 April 6, 2016
Intentional Adulteration	81 FR 34165 May 27, 2016

*\*Supplemental proposals published September 2014*

*◇ Final rule publication date*

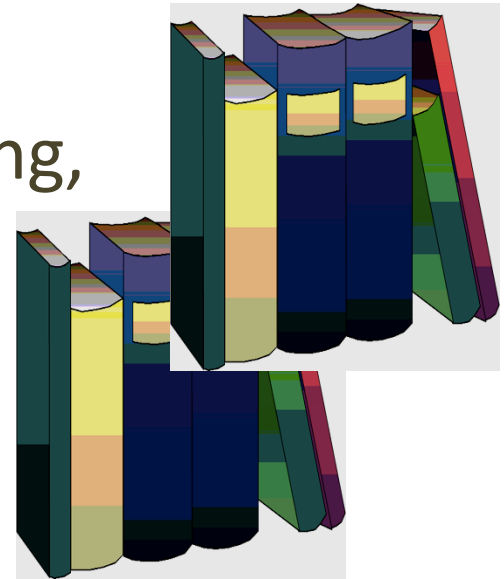
*\*\*Final rule made public*





# Overarching Regulations

- 21 CFR 117 Subpart B: Good Manufacturing Practices (GMP, cGMP)
- 21 CFR Subpart C: Hazard Analysis and Risk-based **Preventive Controls for Human Food** (this is **not** HACCP)
- 21 CFR 112: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption



# If You Have A Question, Ask:

- FSPCA Technical Assistance Network

[http://www.iit.edu/ifsh/alliance/resources/  
technical assistance network inquiry form.sht  
ml](http://www.iit.edu/ifsh/alliance/resources/technical%20assistance%20network%20inquiry%20form.shtml)

- FDA Technical Assistance Network

[http://www.fda.gov/downloads/Food/  
GuidanceRegulation/FSMA/UCM467582.pdf](http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM467582.pdf)



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