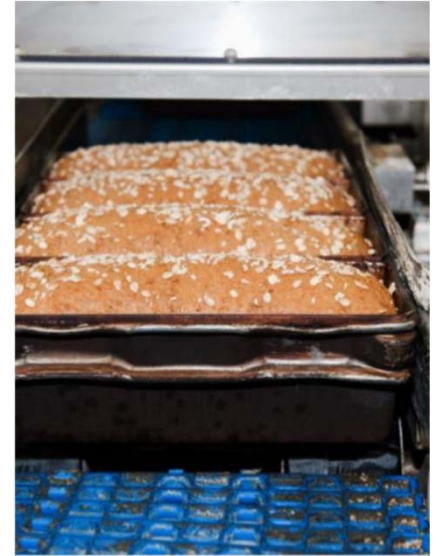


Why FSMA?



Learning Objectives & Content

- Understanding the reasons for change
- Discuss & appreciate 5 key elements of FSMA
- Review of FSMA timelines
- Getting started

Reasons for Change

CDC Estimates of Foodborne Illness¹

- CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) get sick
- 128,000 are hospitalized
- 3,000 die of foodborne diseases

1. CDC report "2011 Estimates of Foodborne Illness in the United States."



CDC Estimates for Two Major Groups of Foodborne Agents/Illnesses

Foodborne Agents	Estimated annual number of illnesses	%	Estimated annual number of hospitalizations	%	Estimated annual number of deaths	%
31 <i>known</i> pathogens	9.4 million	20	55,961	44	1,351	44
<i>Unspecified</i> agents	38.4 million	80	71,878	56	1,686	56
Total	47.8 million	100	127,839	100	3,037	100

Top Five Pathogens Contributing to Acquired Foodborne Illnesses

Pathogen	Estimated number of illnesses	%
<u>Norovirus</u>	5,461,731	58
<u>Salmonella</u> , nontyphoidal	1,027,561	11
<u>Clostridium perfringens</u>	965,958	10
<u>Campylobacter spp.</u>	845,024	9
<u>Staphylococcus aureus</u>	241,148	3
Subtotal		91

Top Five Pathogens Contributing to Foodborne Illnesses Resulting in *Hospitalization*

Pathogen	Estimated number of hospitalizations	%
<u>Salmonella, nontyphoidal</u>	19,336	35
<u>Norovirus</u>	14,663	26
<u>Campylobacter spp.</u>	8,463	15
<u>Toxoplasma gondii</u>	4,428	8
<u>E.coli (STEC) O157</u>	2,138	4
Subtotal		88

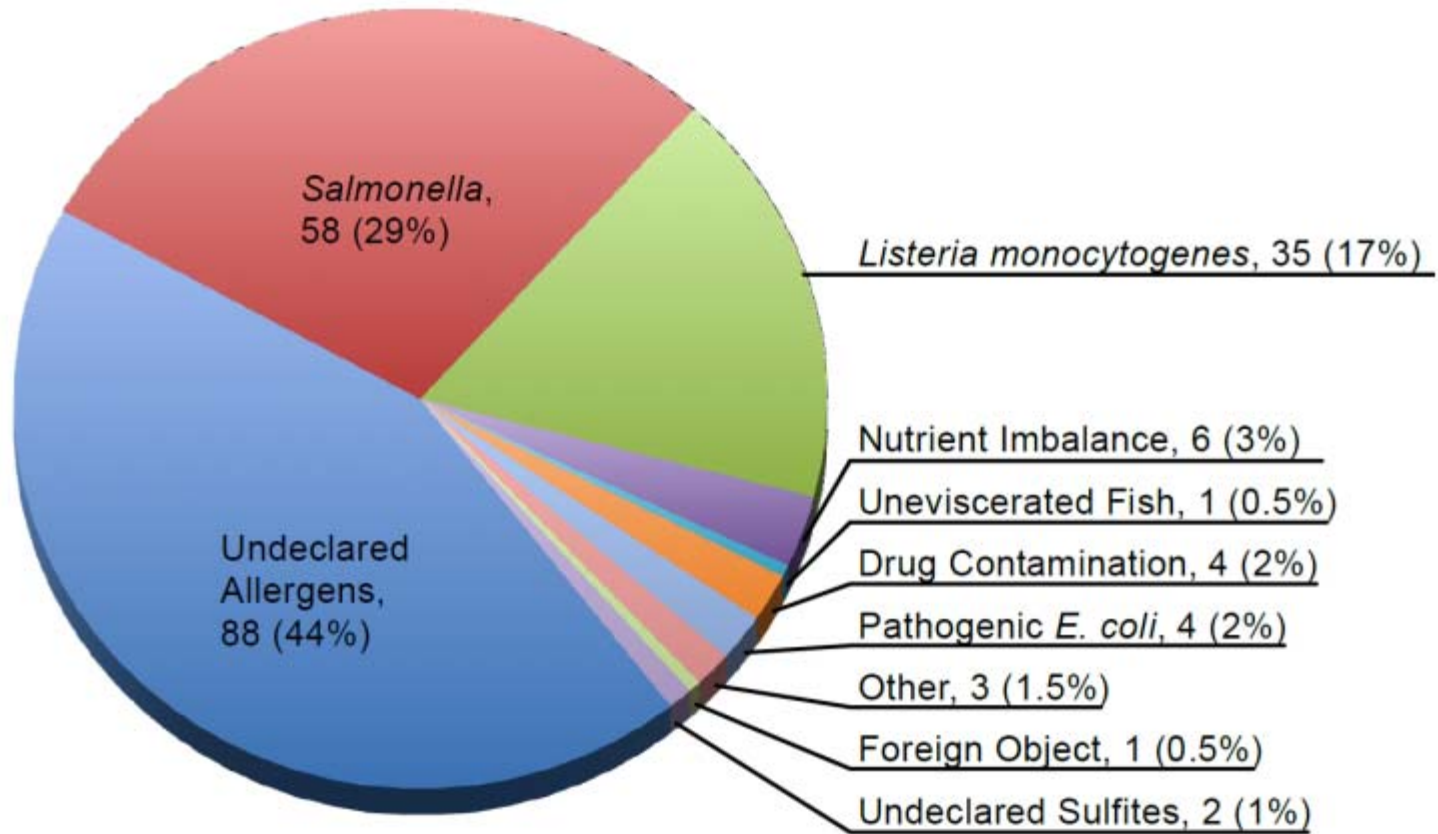
Top Five Pathogens Contributing to Foodborne Illnesses Resulting in *Death*

Pathogen	Estimated number of deaths	%
<u>Salmonella</u> , nontyphoidal	378	28
<u>Toxoplasma gondii</u>	327	24
<u>Listeria monocytogenes</u>	255	19
<u>Norovirus</u>	149	11
<u>Campylobacter spp.</u>	76	6
Subtotal		88

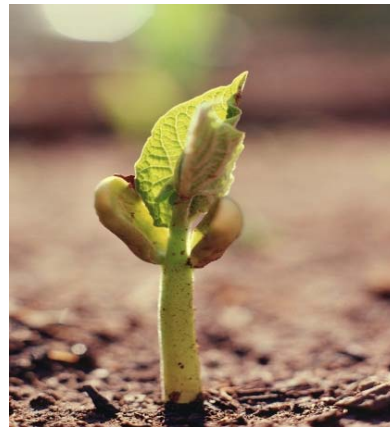
Recalls By the Numbers

- Recalled products typically numbered in the hundreds in the past decade
- By 2009, thousands of products were being recalled annually
- Possible reasons?
 - Increased imports
 - Growing complexity of the supply chain
 - Better detection and recognition of food safety problems
 - Better reporting, i.e., RFR
 - Others?

Recalls By the Numbers¹



Food Safety Issues in the News - Back Then



Food Safety Issues in the News - Today¹



Consumers Do Matter¹

Consumers put a lot of pressure on Congress

- 89% (9 out of 10) of Americans support more aggressive food safety and defense regulation
- 61% STRONGLY support this bill
- 94% agree companies should be mandated to show traceability back to its original source

Intentional Tampering/Contamination

- Bioterrorism/Agroterrorism
 - Heightened awareness and concern after 9/11
- Bioterrorism Act
 - Registration
 - Administrative detention
 - Prior notice
 - Records maintenance and inspection

Actual Tampering or Theft

- **Shanghai, China** – Toxic wax found on oranges sold in local markets
- **Dalton, GA** – Over 1,000 cases of baby formula stolen
- **Calgary and Toronto, Canada** – Dozens of cases of product tampering in retail stores
- **Amarillo, TX** – Meat plant worker puts pieces of broken saw blade into meat

Hoax Reports

- **Beijing, China** – China's largest dairy producer posted internet reports about its competitor's baby formula being contaminated in order to boost sales and increase a manager's bonus
- **New York** – Man arrested after he posted internet videos claiming to have contaminated millions of bottles of baby formula

Radiological Concern

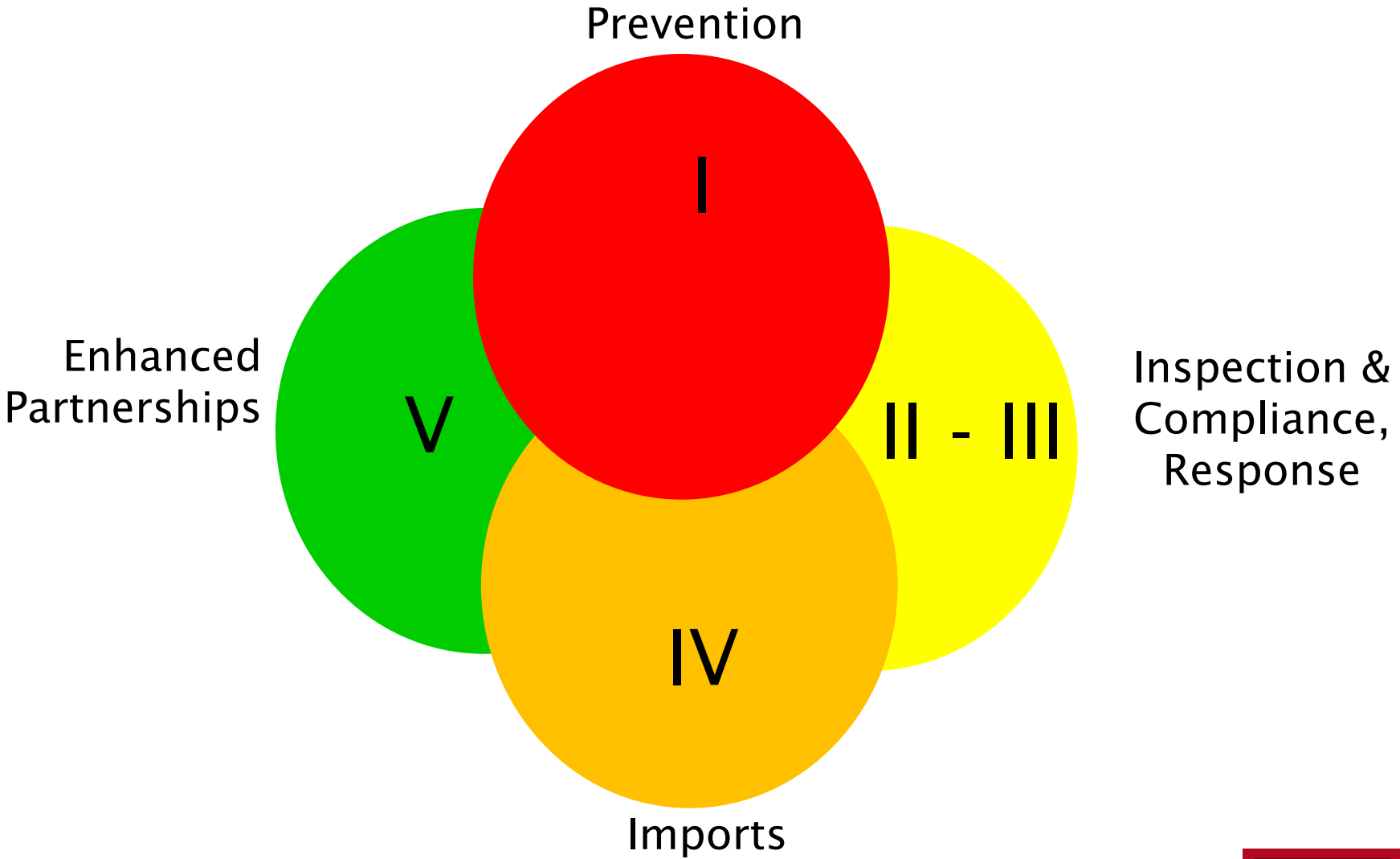
- In response to the Fukushima nuclear power plant incident caused by the earthquake in Japan in March 2011, the Centre for Food Safety (Hong Kong) has been conducting targeted radiation testing on food imported from Japan at import
- April 3, 2012, green tea leaves imported from Japan were sampled during surveillance and were found to have low radioactivity levels, a spokesman for the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department said. However, there is no health concern in consuming the product concerned.

Development of FSMA

- During the 111th U.S. Congress,¹ more than 20 bills were introduced to address food safety concerns
- Two comparable bills advanced
 - HR 2749 – Food Safety Enhancement Act
 - S. 510 – Food Safety Modernization Act
- Jan. 4th of 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law

1. January 3, 2009 until January 3, 2011

5 Key Elements of FSMA



FSMA

- Most significant change in US food laws since the Food, Drug and Cosmetic Act of 1938.

From Reaction to Prevention

- From 402(a)(3) to 402(a)(4)

Inspection, Compliance, and Response

- From “credible and verifiable information” to “reason to believe”

Imports

- More than 120 countries and 300,000 facilities exporting to the US

Enhanced Partnerships

- Foreign offices and liaison with counterparts

FSMA Timeline

January 4, 2011, law signed by President Obama

- Some sections became effective immediately
- Increase the number of annual inspections
- Record access
- Suspension of registration
- Carry out recalls
- Bi-annual plant registration
- Import notification
- Administrative detention
- Reportable Foods Registry

Some FSMA Final Rules Publication Datelines

- 8/30/15
 - Preventive controls for human and animal food
- 10/31/15
 - Imported food and foreign suppliers
 - Produce safety
- 3/31/16
 - Sanitary food transportation
- 5/31/16
 - Intentional adulteration of food

FSMA is Here

- Major changes and challenges for FDA and the food industry
- So:
 - What changes do you have to make as a company?
 - How do you implement these changes?
 - How do you train and educate all parties to your organization?
 - How will you manage this transition?

Access to Records

Situational Access:

- When reasonable belief that food will cause...
- adulterated
- misbranded

Access to Records

Examples of records that FDA can access and copy:

- Receiving, manufacturing/process, holding/inventory, shipping/distribution, imports/exports
- Tests
- Recalls
- Reportable foods
- Customer distribution lists
- Complaints and adverse event records
- Corrective actions

Bi-Annual Registration

All food facilities registered with the FDA must renew their registration during the time period of **October 1** and **December 31** of each **even-numbered** year.

Bi-Annual Registration

Plenary discussion

- What does “bi-annual registration” really mean?
- What are consequences of failing to re-register?
- How are you organized to meet this requirement?
- Who is responsible?
- Is it imbedded in the calendar?
- Is it fool-proof?

Prior Notice

Required information before a food shipment arrives at entry point:

- Who submits the PN? _____
- When is the PN submitted? _____
- To whom is the PN submitted? _____
- How is the PN submitted? _____

Prior Notice

Required information before a food shipment arrives at entry point:

- Who submits the PN? The submitter / transmitter
- When is the PN submitted? 2, 4, 8 hours, depending
- To whom is the PN submitted? FDA
- How is the PN submitted? Web entry

Violative Products

Expansion of Reportable Food Registry

What is a Reportable Food?

Violative Products

Expansion of Reportable Food Registry

What is a Reportable Food?

“A reportable food is any article of food for which there is a reasonable probability that the use of or exposure to such article of food will cause SAHCODHA”

SAHCODHA: Serious Adverse Health Consequences or Death to Humans or Animals



Violative Products Expansion of Reportable Food Registry

Additional information:
Contact information for
responsible party



Violative Products

Expansion of Reportable Food Registry

- Grocery stores in the US must post information on RFR items they have sold.



Violative Products Administrative Detention

- Lowered threshold
 - Reason to believe
 - SAHCODHA
 - adulterated
 - misbranded
- Effective July 2011
- FDA guidance document



Administrative Detention

Q. How long can FDA hold a detained food?

A. _____ days

Q. Who receives detention notification?

A. _____, and

Q. Can the administrative detention be appealed?

A. _____

Administrative Detention

Q. How long can FDA hold a detained food?

A. 30 days

Q. Who receives detention notification?

A. Owner of LOCATION where product is detained, and owner of the article of FOOD being defined

Q. Can the administrative detention be appealed?

A. Yes

Violative Products

Mandatory Recall Authority

If FDA determines that there is reasonable probability of SAHCODHA, responsible party is provided the opportunity

- To initiate voluntary recall, or
- Hold informal hearing within 2 days of issuance of recall order to provide evidence why product should not be recalled.

Violative Products

Mandatory Recall Authority

- If order is upheld it is amended to proceed with the voluntary recall.
- If refused, the FDA will:
 - Mandate the recall
 - Issue civil penalties
 - Make public notifications
- If it is determined that the product should not be recalled, the order is rescinded.

Access to Records

Automatic Access:

- Records in plain sight
- Records of interstate/international commerce
 - Shipping and receiving
 - Traceability

Access to Records

Situational Access:

- When reasonable belief that food will cause...
- adulterated
- misbranded

Access to Records

Examples of records that FDA can access and copy:

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Questions



Thank You