

# Traceability & Recall Programs

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# Why is this important?

## Bad Things Happen

Even if at a low frequency...

- Product costs
- Recall costs
- Loss of customer confidence
- Loss of consumer confidence

# Fresh produce has been particularly susceptible

- No kill step in process
- High sensitivity to pathogen contamination
- Very short shelf life
- Increasing demands for ingredient, finished product testing
- Produce companies doing “test and ship”
  - Formula for disaster!

# Who's to Blame? Who's at Fault?

Often, no one

“Fortune favors the prepared”

The image features a large green shape on the left side, which is a square with a white rounded rectangle cut out of its center. The word "Traceability" is written in a bold, dark blue font within the white space. A dark blue horizontal bar with rounded ends extends from the right side of the green shape across the bottom of the page.

# Traceability

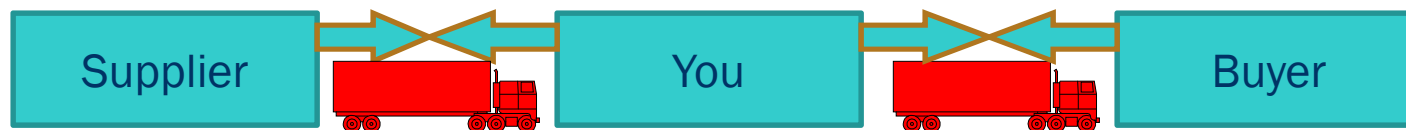
# Why is Traceability Important?

“An effective traceback system can give investigators clues that may lead to a specific region, packing facility, even field, rather than an entire commodity group. Narrowing the potential scope of an outbreak could lessen the economic burden on those industry operators” - FDA

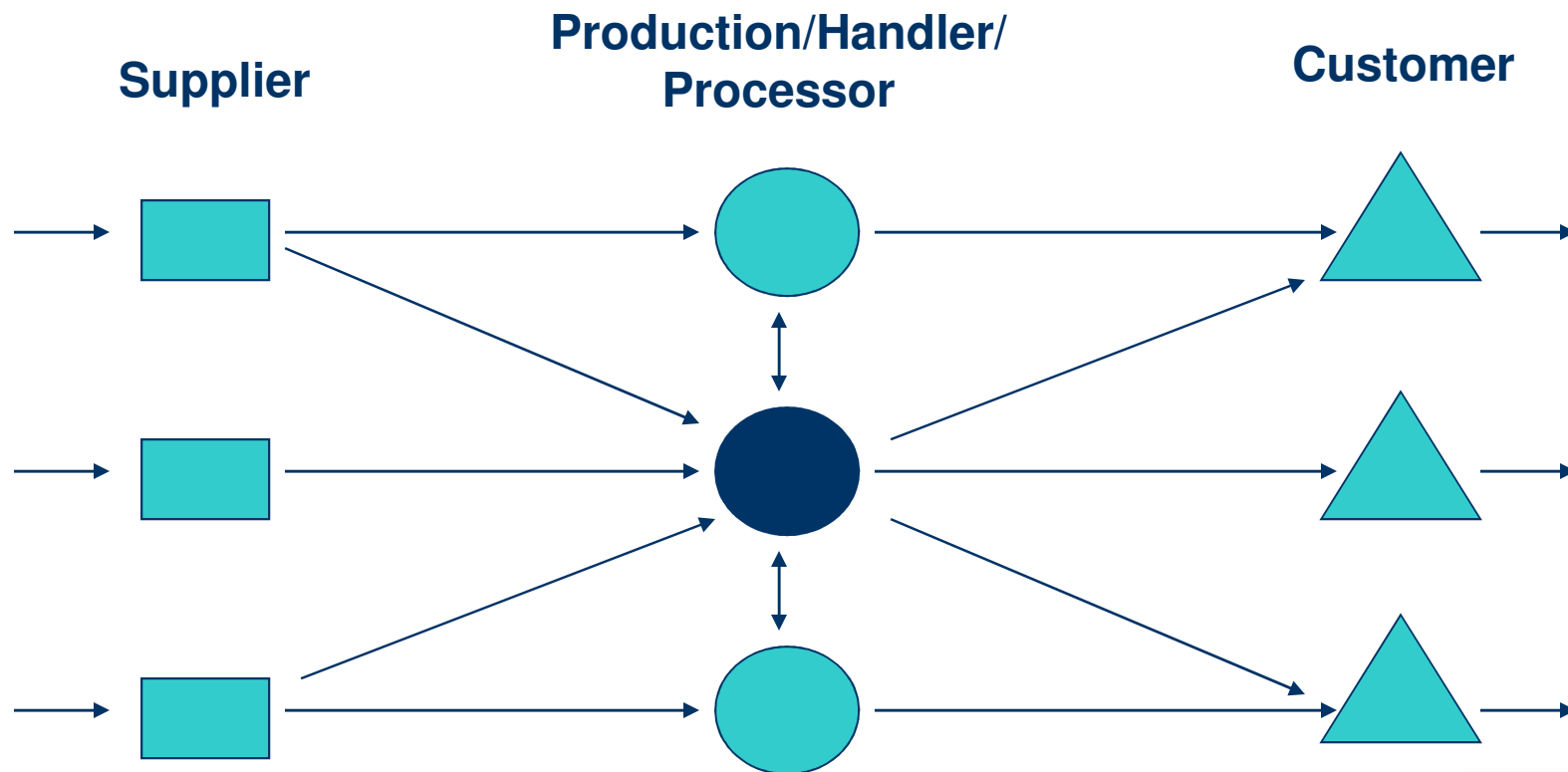
# Why is Traceability Important?

## 21 CFR part 1, Subpart J (Bioterrorism rule)

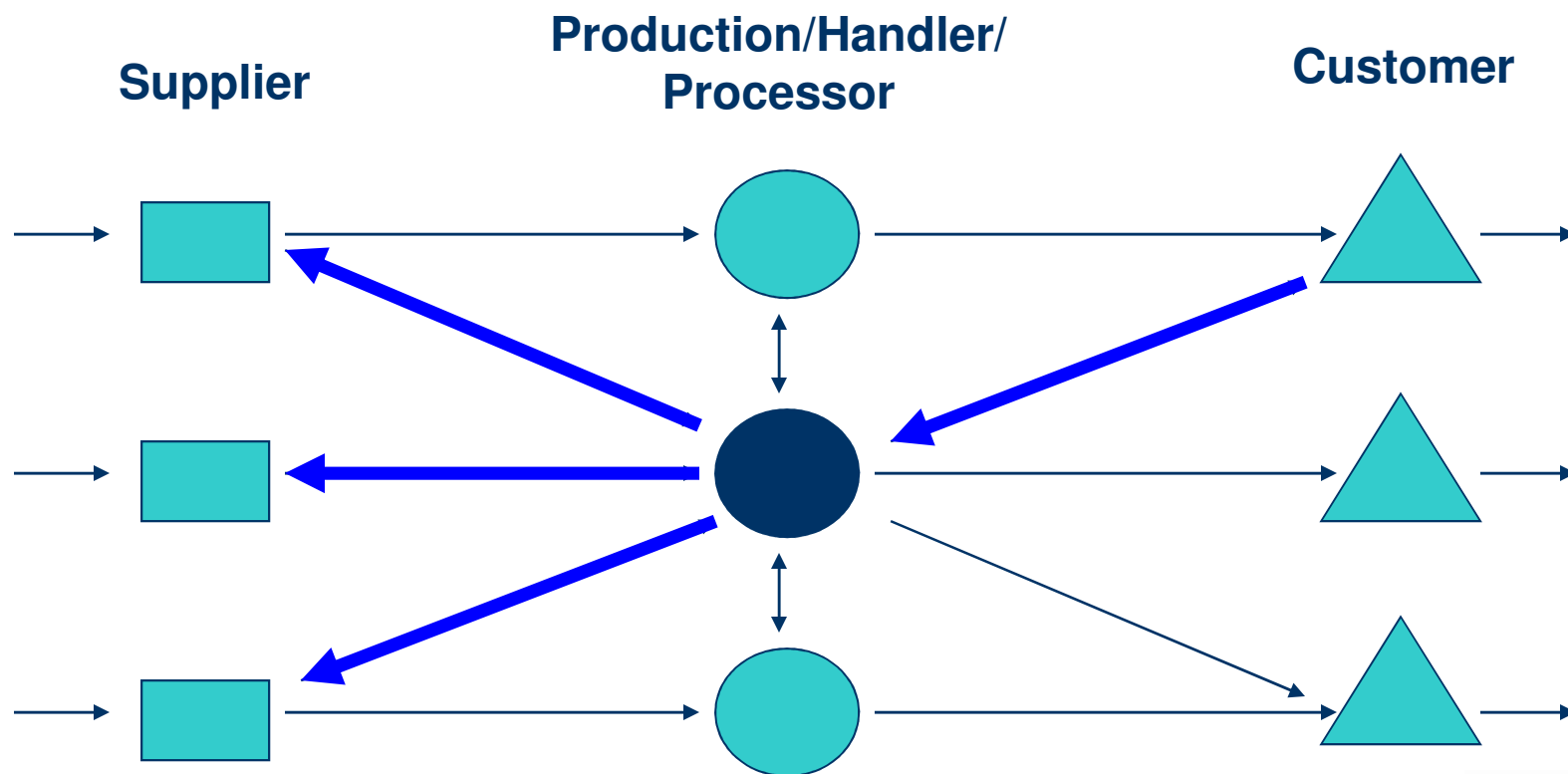
- Immediate previous source...immediate subsequent recipient, whether domestic or foreign
- Transporter and nontransporter
- Name of the firm, address, telephone number...
- Brand name, specific variety of food, date received/ released, lot number, quantity and how packaged
- Farms, restaurants are excluded from requirements



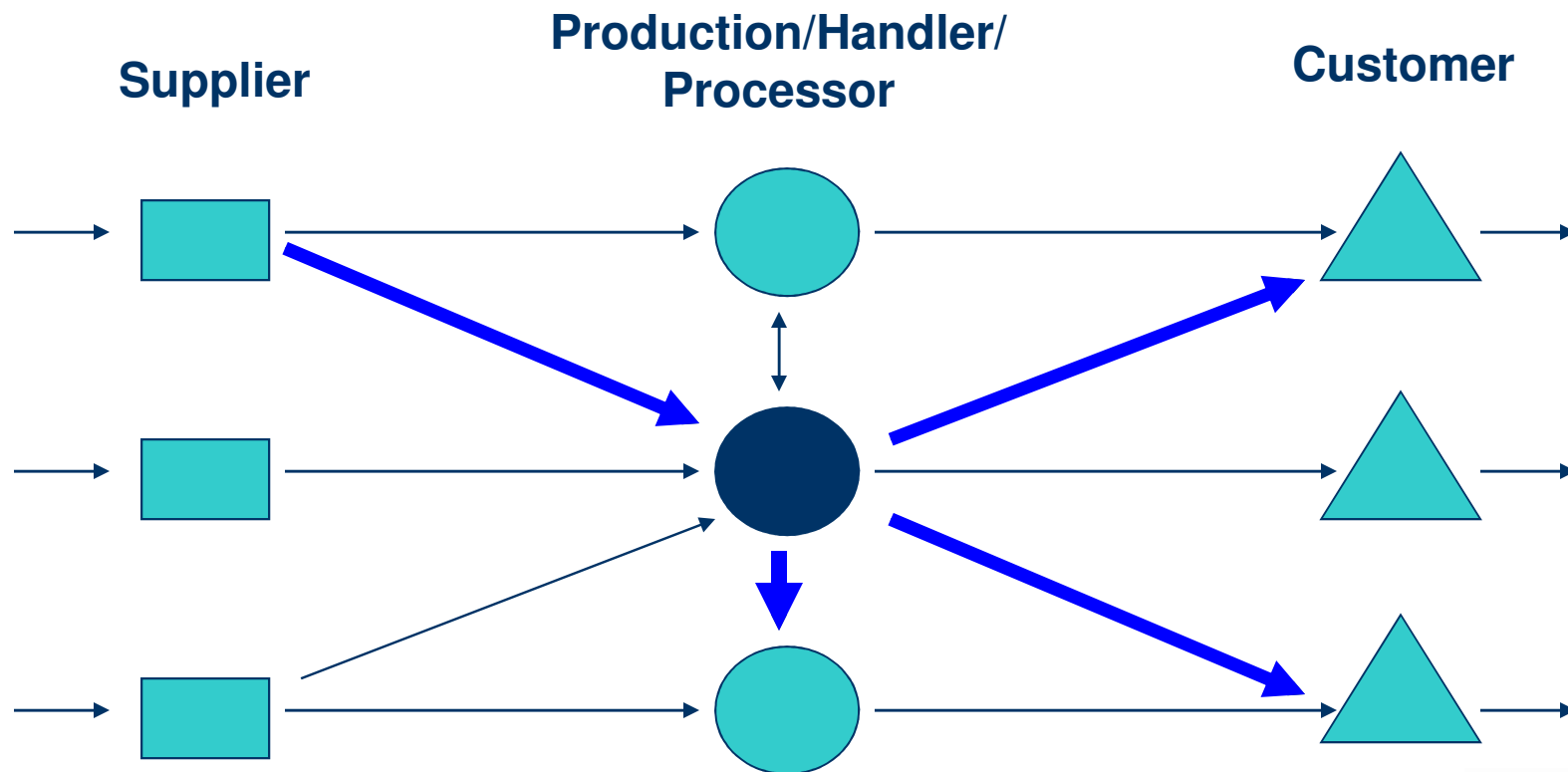
# Traceability



# Traceback



# Trace Forward



# Trace Forward / Reconciliation

$$\frac{(\text{units shipped})+(\text{units in-house})+(\text{units destroyed})+(\text{units other destinations})}{(\text{units produced})}$$

Target = 100%, in minutes, hours

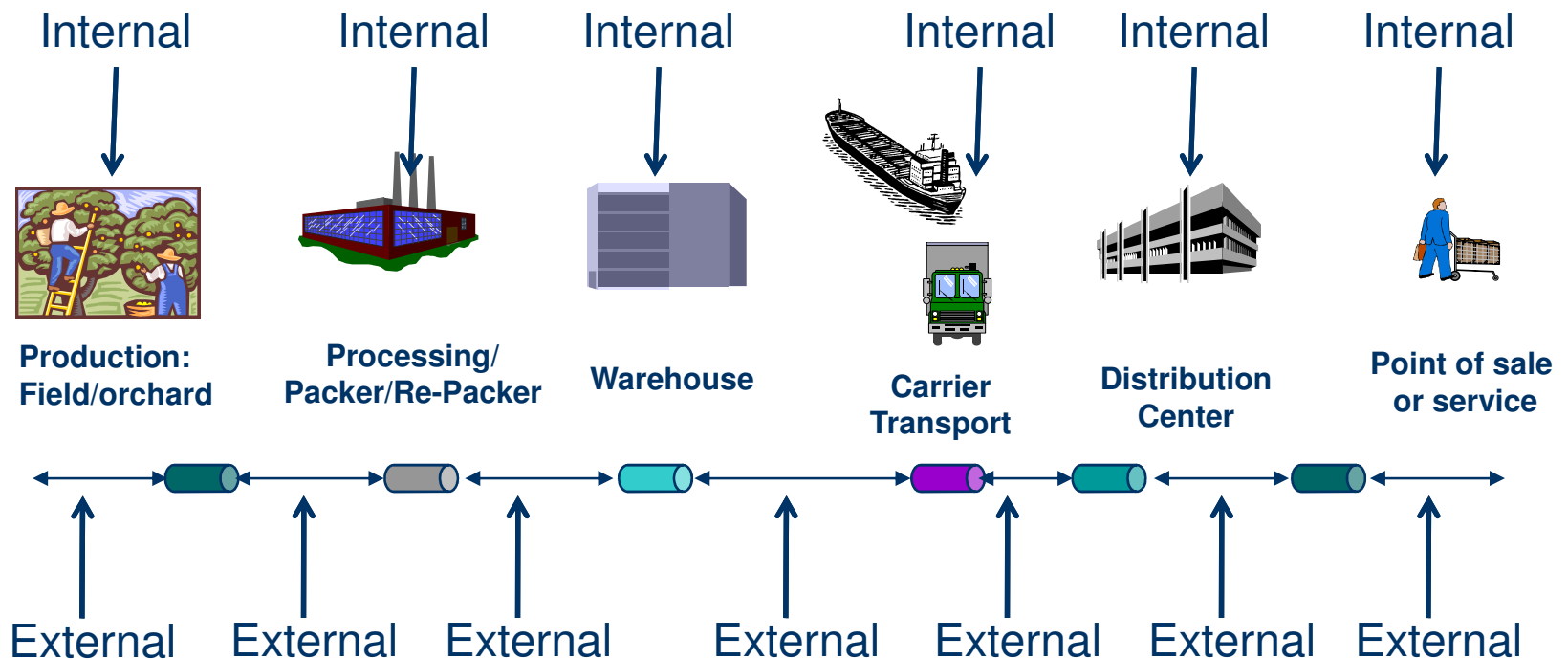
# How to Trace?

Accurate Records

# Current Traceability Challenges

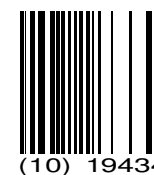
- Internal Traceability = confidential or proprietary data and processes companies use within their own span of operations to track ingredients/product
- External Traceability = the data exchange and business processes that take place between trading partners
- Whole Chain Traceability = Internal + External traceability

# External Traceability



# External Traceability

- Only possible with universal data use
  - Buyer/Receiver ID
  - Lot Number
  - Product Description
  - Product ID
  - Quantity
  - Unit of Measure
  - Shipment ID
  - Vendor/Supplier/Sender ID
  - Date of Receipt
  - Ship From Location ID
  - Ship to Location ID
  - Shipment Date

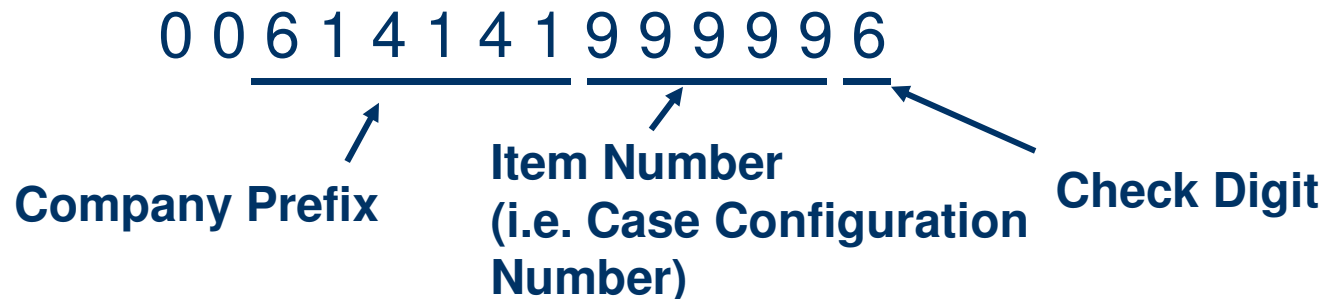


# Produce Traceability Initiative

- Sponsored by United Fresh, PMA, and CPMA
- Steering Committee with 41 participating retail, foodservice, distributor, grower/shipper companies and 6 additional trade associations
  - NRA, IFDA, FMI, NGA, CCGD, CHC
- Met five times, January – August 2008
- Established expectations and strategic milestones for all fresh produce, full supply chain

# Strategic Milestones

1. Brand owners must obtain GS1-issued Company Prefixes and assign 14 digit Global Trade Item Numbers (GTINs) to all unique case configurations – 1Q09



# Strategic Milestones

2. Brand owners must provide their GTINs (and corresponding data) to their buyers – 3Q09

<b>MANDATORY DATA ELEMENTS – PTI Traceability Guide to Implementation (V.2)</b>
Buyer/Receiver ID
Lot Number
Product Description
Product ID
Quantity
Unit of Measure
Shipment ID
Vendor/Supplier/Sender ID
Date of Receipt
Ship From Location ID
Ship to Location ID
Shipment Date

# Strategic Milestones

3. Those packing the product are responsible for encoding the GTIN and Lot# in a GS1-128 barcode, and providing the information in

<b>ORANGES Valencia</b>	<b>10 - 4 LB BAGS</b>
	
<b>(01) 10614141000415 (10) 022208ABC</b>	

barcode and  
human-readable  
format on each  
case – 3Q10

## Reconfiguration, Repacking, Cross-dock

- If case not altered, GTIN, lot# remain the same
- If case altered, new GTIN, lot# assigned

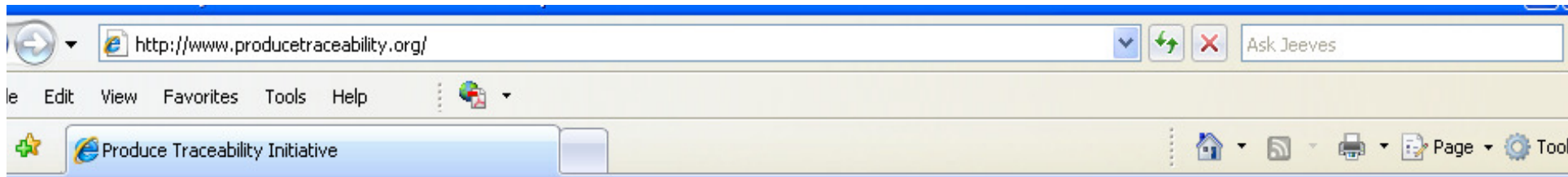


# Strategic Milestones

4. Each subsequent handler of the CASE must have the systems and capability to read and store the GTIN and Lot # from each case of produce RECEIVED (2011) and each case of produce SHIPPED ('12)
  - Early adopters starting now
  - “Critical mass” of compliance by 2012

# Produce Traceability Initiative

- Multiple subgroups working on best practices, implementation issues and FAQs
  - Buyers
  - Suppliers
  - Synchronization
  - Pallet Labeling
  - Repacking/Commingling



Canadian  
Produce  
Marketing  
Association



# The PRODUCE TRACEABILITY INITIATIVE

[Home](#) [Resources & Tools](#) [News & Events](#) [Bulletin Board](#) [Press Room/Contacts](#) [Endorse the PTI](#)



The PTI vision:  
**Supply chain-wide adoption of electronic traceability  
for every case of produce by the year 2012.**

## **PTI Action Plan Implementation Toolkit**

To help you achieve the PTI's vision within your company, we have assembled all the tools you need right here.

[About PTI](#)  [Introduction](#) 

#1 [Complete by: 1st Quarter 2009](#)  
[Obtain Company Prefix](#) 

## **About Us**

The Produce Traceability Initiative, sponsored by Canadian Produce Marketing Association, Produce Marketing Association and United Fresh Produce Association, is designed to help the industry maximize the effectiveness of current traceback

# Produce Traceability Initiative

- FDA still considering response to industry traceability “issues”
  - They’ve been informed; positive response
- Congress is still talking new regulations
- FDA held two public meetings (December 9 and 10, Washington DC) to seek comment on traceability practices for all regulated foods and feeds, with all comments due by March 3



# Recalls



# I'm a grower. Why do I need to know about recalls?

2009

- 11 fresh produce recalls listed on FDA website (melons, green onions, herbs, spinach)
- 6 fresh produce items entered into FDA Reportable Food Registry Sept-Nov 2009
- All were for Salmonella contamination
- All but one were whole produce, and FDA went back to the farm

# Recalls

So, if I implement PTI, I'll be ready for a recall, right?

**No, traceability is only one part of being prepared for a recall**

# What does it take to be ready?

- Recall team
- Recall plan
- Traceability, production records
- Know your rights and obligations
- Know who you need to communicate with, when to communicate and what to say
- Practice

# What's Involved?

## Recall Team

- Internal
  - Top management
  - Operations
  - QA
  - Legal, Regulatory
  - Communications
  - Sales, HR, Procurement
- External
  - Everything you don't have internally
  - Someone to review what you plan to do, say

# What's Involved?

## Recall Plan

- Responsibilities, contact information
- Information collection
- Decision points – when to decide to recall
- Sequence of recall events
  - Scope of recall, trace/segregation, disposition
- Communication
  - Customers, Government, Media, Internal
- Follow-up
  - What went wrong? Prepare for the next recall

# What's Involved?

## Your rights and responsibilities

- Is this a recall or “withdrawal”?
- Do I have to contact FDA and, if yes, who?
- What's a Reportable Food Registry?
- What records do I have to share with FDA?
- Do I have to issue a press release?
- Do I have to talk with the media?
- When does this end?
- Who's going to pay for this?

## Safety

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Home > Safety > Recalls, Market Withdrawals, & Safety Alerts

### Recalls, Market Withdrawals, & Safety Alerts

Archive for Recalls, Market Withdrawals & Safety Alerts

Enforcement Reports

Industry Guidance

Major Product Recalls

## Recalls, Market Withdrawals, & Safety Alerts

Search Firm Recalls

go

This section includes the most significant product actions over the last five years based on the extent of distribution and the degree of health risk. In this section, you will find a listing of FDA and industry press releases regarding the product recalls.

This page includes the most significant product actions of the last 60 days, based on the extent of distribution and the degree of health risk. The recalls on the list are mainly Class I. A record of all recalls (Class I, II, and III) can be found in the FDA Enforcement Report. Definitions of Class I, II, and III recalls.

### Spotlight

- Slim-Fast Recall Information from FoodSafety.gov
- Food Safety Alerts and Tips Widget
- FoodSafety.gov: Your Gateway to Federal Food Safety Information
- FDA Informs Consumers of a Nationwide Voluntary Recall of Certain Tylenol Products
- Stolen Albuterol Sulfate Inhalation Solution

### Resources for You

- Medical Product Safety Information
- Recalls (Biologics)
- Recalls (Medical Devices)
- FDA Food Safety Recalls RSS Feed
- Recalls.gov
- Follow FDA Recalls on Twitter

### January 2010

- January 05, 2010 - ev3 Endovascular Inc. Trailblazer Support Catheter: Class I Recall
- January 04, 2010 - Harry London Candies, Inc. announces a voluntary and limited recall of Harry London Chocolate Pecan Caramel Stars due to an undeclared allergen



## Safety

Recalls, Market Withdrawals, & Safety Alerts

▶ Industry Guidance

## Industry Guidance

### Information on Recalls of FDA Regulated Products

#### FDA ORA/Office of Enforcement DCMO

Last Update: 2-6-2009

- [Industry Recall Guidance: Product Recalls, Including Removals and Corrections](#)
- [Recalls Background and Definitions](#)
- [Index of Model Press Releases:](#)
  - [Allergens \(Allergy Alert\)](#)
  - [Listeria monocytogenes](#)
  - [Clostridium botulinum](#)
  - [Salmonella \(all serotypes\)](#)
    - [Pet Food and Pet Treats](#)
  - [E. coli 0157:H7](#)
  - [Medical Device](#)
- [District Recalls Coordinators](#)
- [Index of Model Letter Exhibits in FDA Regulatory Procedures Manual, Chapter 7 "Recall Procedures"](#)
  - [7-1 - Effectiveness Check Letter](#)
  - [7-2 - Effectiveness Check Response Format](#)

# What's Involved?

## Practice

- Mock recalls
- Generic press releases
- Prepare for the unexpected events, unexpected times
- Up-to-date contact information
- FDA recall coordinator
- [RFR.fda.gov](http://RFR.fda.gov)

# Preparation for a Recall

**The worst time  
to develop a recall plan  
is in the middle of a recall!**

# United Fresh Workshop

*“Training for a Recall,  
Communicating Under Fire”*

# Traceability & Recall Programs

Questions?

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