



# FDA Requirements for Food Products

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# *Safe, Wholesome, Sanitary Foods*





# FDA Jurisdiction

**All foods **except** those with:**



**3% meat or  
more**

- ❖ USDA/Food Safety Inspection Service
- ❖ Except exotic meats

**2% poultry  
or more**

- ❖ USDA/Food Safety Inspection Service
- ❖ Includes ratites

**Alcoholic  
Beverages**

- ❖ DOC/Bureau of Alcohol, Tobacco and Firearms
- ❖ Except wine beverages with less than 7% alcohol

# Special Requirements

- ❖ Dietary Supplements
- ❖ Hazard Analysis  
Critical Control Point  
(HACCP)
  - Seafood
  - Juice
- ❖ Infant Formula
- ❖ Medical Foods

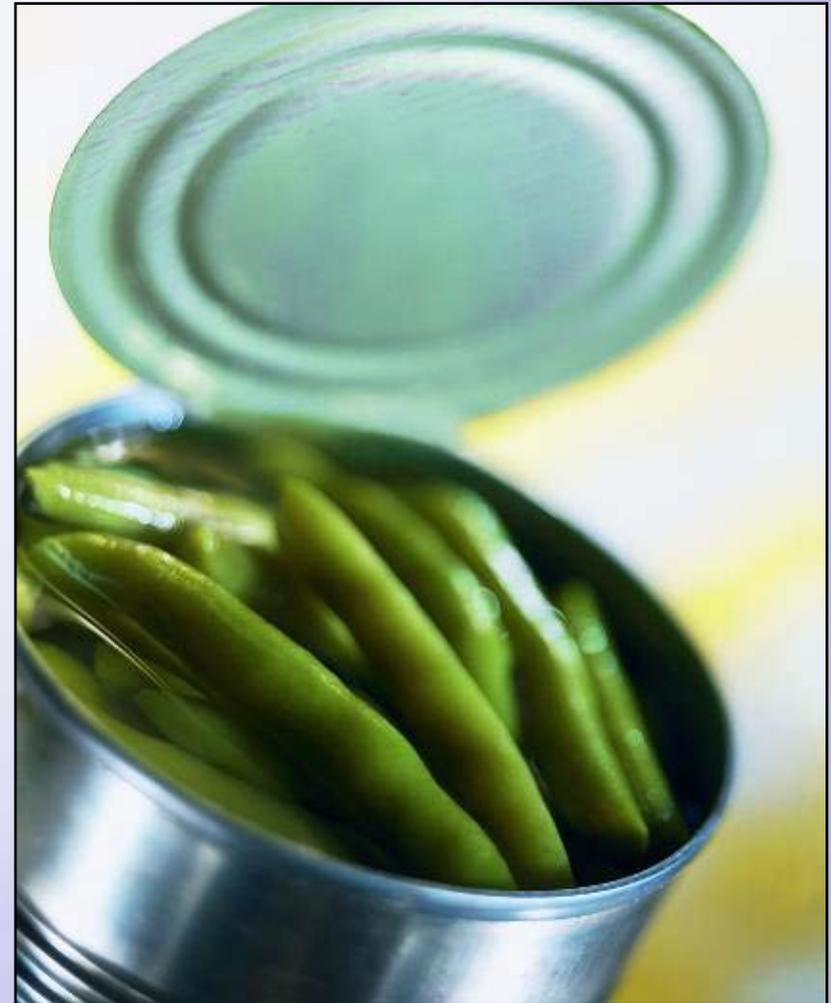


# Low-Acid Canned Foods (LACF)

pH (acidity) > 4.6

$a_w$  (water activity) > 0.85

not refrigerated or frozen



# Acidified Foods

Natural pH > 4.6

Final pH < 4.6

$a_w > 0.85$

not refrigerated or frozen

not fermented



# What are Laws?

The basic enabling authority enacted by Congress

- ❖ Food, Drug and Cosmetic Act (FD&C)
- ❖ Fair Packaging and Labeling Act (FPLA)
- ❖ Nutrition Labeling and Education Act (NLEA)
- ❖ Food Allergen Labeling and Consumer Protection Act (FALCPA)
- ❖ **Food Safety Modernization Act (FSMA)**

# FD&C Act Section 402(a)(4)

- ❖ A food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health



# ***What are Regulations?***

Implement provisions of the law based on the authority provided by the law

Implementation of regulations must follow specific procedures that allow public notice and comment

Legally binding on industry and the agency

# Basic Food Requirements

## Good Manufacturing Practice regulations

- 21 CFR Part 110
- Maintain sanitary conditions
- Prevents adulteration

## Labeling regulations

- 21 CFR Part 101
- Helps ensure fairness and proper nutrition
- Prevents misbranding

# **Guidance Documents...**

## **...Policy Statements and Advisory Opinions**

- Serve to provide the Agency's interpretation of the law and applicable regulations**
- The preamble to a regulation has the status of an advisory opinion**
- Are not legally binding on the public or the agency**

# 21 CFR Part 110 \*

- ❖ Current Good Manufacturing Practice (GMP) in manufacturing, packing, or holding human food
- ❖ Applies to all foods



# Good Manufacturing Practice

- ❖ GMP's allow for changing technology and require manufactures to use current technology to minimize contamination, mix-ups, and errors
- ❖ GMP's are not specific "how to" documents; each manufacturer must decide the appropriate level of controls and technology to ensure that their products are safe, pure, and wholesome



# **Preventive Controls for Human Food**



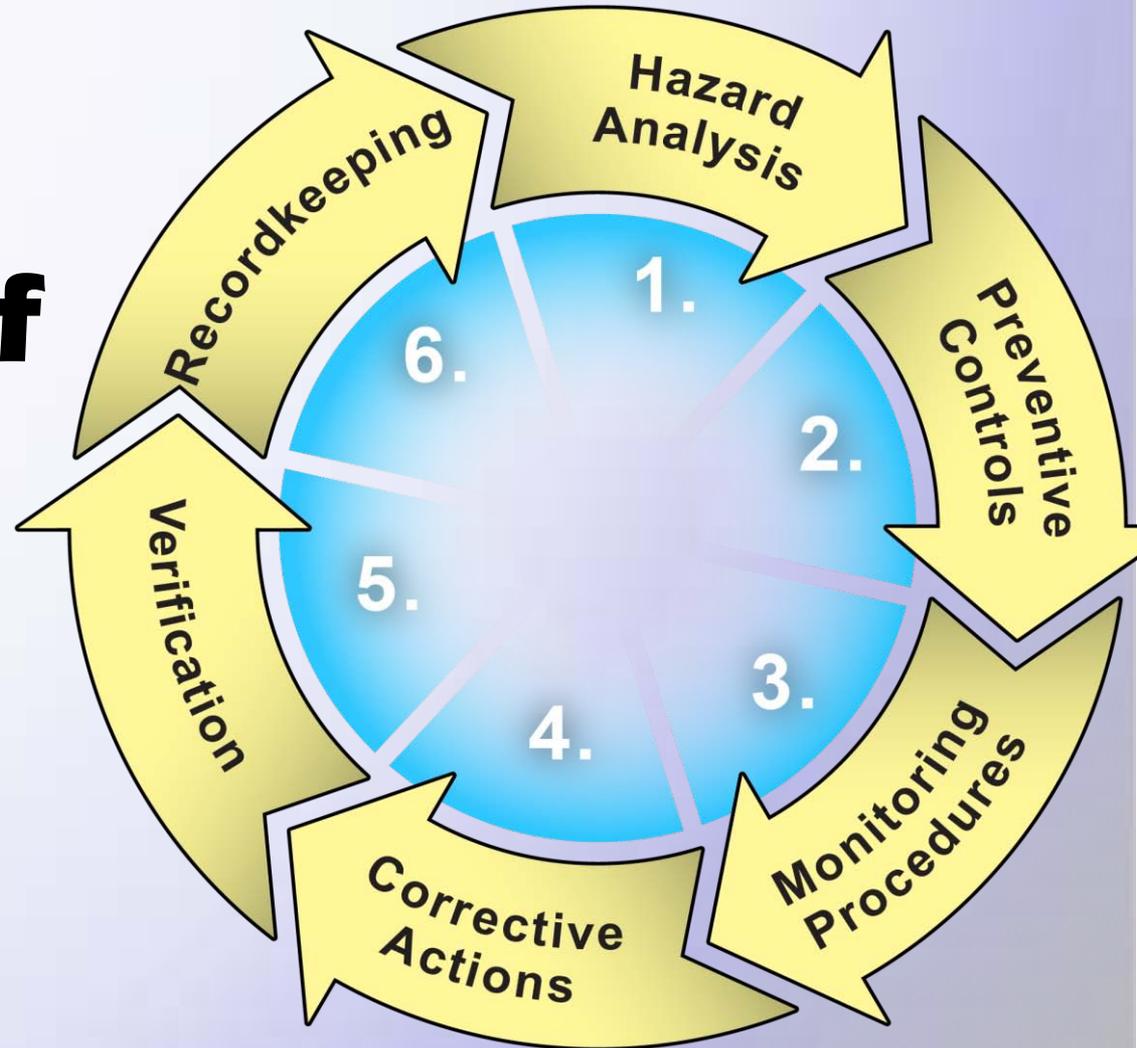
# Summary of Requirements

- ❖ Hazard Analysis and Risk-Based Preventive Controls
  - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- ❖ Updated Good Manufacturing Practices

# Who is Covered?

- ❖ Facilities that manufacture, process, pack or hold human food
- ❖ In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- ❖ Applies to domestic and imported food
- ❖ Some exemptions and modified requirements are being proposed

# Hazard Analysis of Critical Control Points



# **Preventive Controls Required**

- ❖ Process controls
- ❖ Food allergen controls
- ❖ Sanitation controls
- ❖ Recall plan
- ❖ In addition, seeking comment on supplier approval and verification program

# **Verification Required**

- ❖ Validation
- ❖ Calibration
- ❖ Review of records
- ❖ In addition, seeking comment on review of complaints, finished product and environmental testing

# Updated GMPs

- ❖ Protection against allergen cross-contact
- ❖ Updated language (e.g., “must”)
- ❖ Certain provisions containing recommendations would be deleted
- ❖ Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions

# Exemptions and Modified Requirements -1

## ❖ “Qualified” facilities:

- Very small businesses (3 definitions being proposed—less than \$250,000, less than \$500,000 and less than \$1 million in total annual sales)

OR

- Food sales averaging less than \$500,000 per year during the last three years AND
- Sales to qualified end users must exceed sales to others

# **Exemptions and Modified Requirements - 2**

- ❖ Foods subject to low-acid canned food regulations (microbiological hazards only)
- ❖ Foods subject to HACCP (seafood and juice)
- ❖ Dietary supplements
- ❖ Alcoholic beverages

# **Exemptions and Modified Requirements - 3**

- ❖ Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
  - Certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records

# **Exemptions and Modified Requirements- 4**

- ❖ Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing are exempt from hazard analysis and risk-based preventive controls.
  - Also exempt with respect to CGMPs

# **Exemptions and Modified Requirements- 5**

- ❖ Facilities such as warehouses that store raw agricultural commodities that are fruits and vegetables are NOT exempt from hazard analysis and risk-based preventive controls.
  - They are exempt with respect to CGMPs



# **Farm-Related Exemptions**

- ❖ Activities within the definition of “farm,” including farm activities that are covered by the proposed produce rule
- ❖ Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods



## Effective Date:

60 days after the final rule published

## Compliance Dates:

- ❖ **Small Businesses**—a business with fewer than 500 employees would have two years after publication.
- ❖ **Very Small Businesses**—a business having less than \$250,000 (or alternatively \$500,000 or \$1 million) in total annual sales of food would have three years after publication to comply.
- ❖ **Other Businesses**—a business that does not qualify for exemptions would have one year after publication to comply.

# How to Comment on the Proposed Rules

- [www.regulations.gov](http://www.regulations.gov)
- Link to rules on [www.fda.gov/fsma](http://www.fda.gov/fsma)
- Comment period is 120 days; exact due date will be in the Federal Register
- Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together.



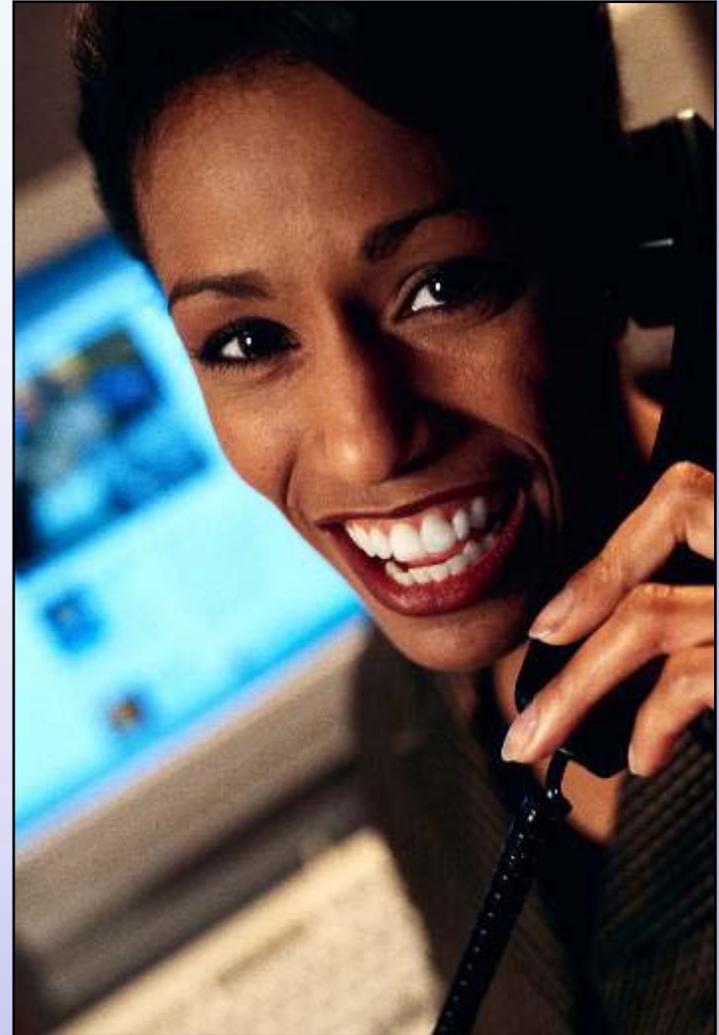
# More Information Available

- ❖ Web site:  
<http://www.fda.gov/fsma>
- ❖ Subscription feature available
- ❖ Send questions to [FSMA@fda.hhs.gov](mailto:FSMA@fda.hhs.gov)

The screenshot shows the FDA website's navigation and content for the Food Safety Modernization Act (FSMA). The top navigation bar includes the FDA logo, the agency name, and a search bar. Below the navigation bar are tabs for various categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Radiation. The 'Food' tab is selected, leading to a page titled 'Food'. The breadcrumb trail is: Home > Food > Food Safety > Food Safety Modernization Act (FSMA). A sidebar on the left lists links under 'Food Safety': Food Safety Modernization Act (FSMA), About FSMA, Full Text of the Law, Implementation & Progress, and Dockets Open for Comment. The main content area features the heading 'The New FDA Food Safety Modernization Act (FSMA)' and a text block stating: 'The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food laws in over 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the focus from responding to contamination to preventing it.' Below this text is a red envelope icon and the link 'Get FSMA Updates by E-mail'.

# ***What's in it for you?***

- ❖ Reduce customer and/or consumer complaints
- ❖ Prevent recall situations
- ❖ Promote employee commitment
- ❖ Reduce rework and waste
- ❖ Increased consumer confidence
- ❖ Peace of mind



# Reportable Food Registry

- ❖ Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007
- ❖ Published on September 2009
- ❖ <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm180761.htm>

# Recalls

- ❖ Recall means a firm's removal or correction of a marketed product(s) that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure

[21 CFR 7.3(g)]



# ***Food Defense***

## Regulations and Guidance

# **The Bioterrorism Act of 2002**

- ❖ **Registration of Food Facilities**
  - Applies to all facilities, foreign and domestic, that manufacture, process and/or hold foods for human and/or animal consumption
- ❖ **Prior Notice of Imported Food Shipments**
- ❖ **Maintenance and Inspection of Records for Foods**
- ❖ **Administrative Detention**



# What You Need to Know About ADMINISTRATIVE DETENTION OF FOOD



# What You Need to Know About PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

A Small Entity Compliance Guide



# What You Need to Know About Establishment and Maintenance of Records

FDA Food Safety and Security Information for Domestic Persons that:  
▶ Manufacture, Process, Pack, Distribute, Receive, Hold, or Import Food  
And Domestic and Foreign Persons that:  
▶ Transport Food in the U.S.



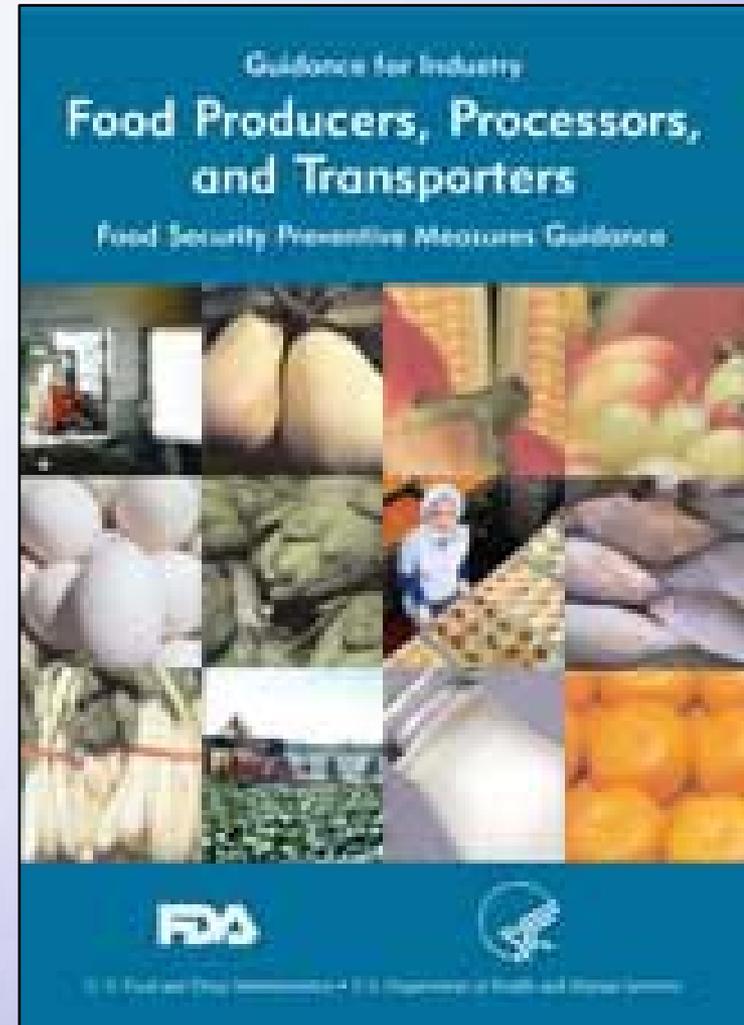
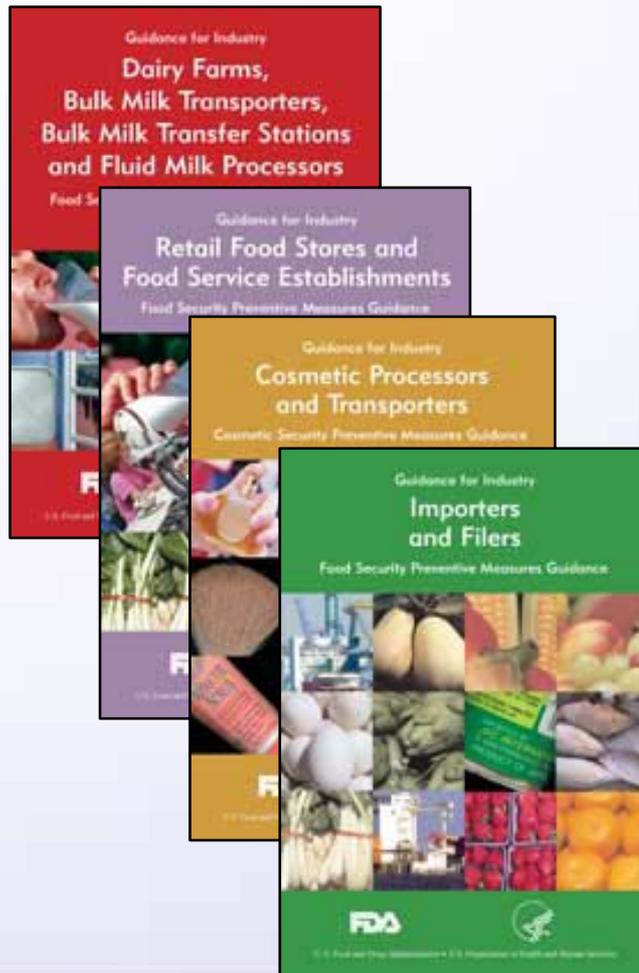
# What You Need to Know About REGISTRATION OF FOOD FACILITIES

FDA Food Security Information for Domestic and Foreign:  
▶ Manufacturers or Processors  
▶ Packers  
▶ Holding Facilities





# Food Security Guidance Documents





# ALERT Cards

In today's world it is important to be  
**ALERT** to protect your business.

- A** How do you **ASSURE** that the supplies and ingredients you use are from safe and secure sources?
- L** How do you **LOOK** after the security of the products and ingredients in your facility?
- E** What do you know about your **EMPLOYEES** and People coming in and out of your facility?
- R** Could you provide **REPORTS** about the security of your products while under your control?
- T** What do you do and whom do you notify if you have a **THREAT** or issue at your facility, including suspicious behavior?

Can you answer these questions?

This message brought to you by the  
 U.S. Food and Drug Administration  
 U.S. Centers for Disease Control and Prevention  
 U.S. Department of Agriculture

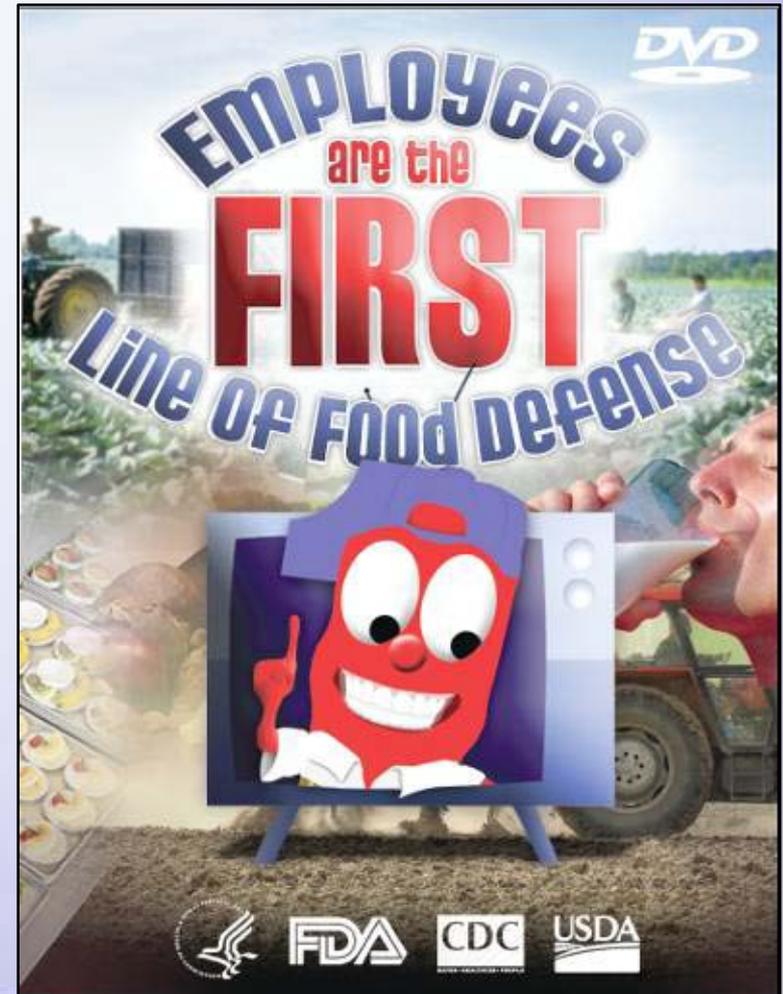


For help in answering these questions,  
check [www.fda.gov/alert](http://www.fda.gov/alert)

An **ALERT** for owners and  
operators of food establishments  
about the security of your facilities ...

# Employees **FIRST** DVD Training

- ❖ For management to incorporate into food defense training program for first-line employees
- ❖ 12-minute DVD in English and Spanish
- ❖ Includes double-sided poster in English and Spanish
- ❖ Comes together in a mailer





# Contact Information

❖ Devin Koontz

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– 303.236.3020



# **Labeling**

## Regulations

# **Principal Display Panel**

- ❖ That part of the label most likely to be seen by the consumer at the time of purchase
- ❖ Must include:
  - Statement of identity
  - Net quantity of contents

(21 CFR 101.1)

# Information Panel

- ❖ That part of the label immediately contiguous and to the right of the PDP
- ❖ Includes:
  - Nutrition labeling
  - Ingredient statement
  - Name and place of business of the manufacturer, packer or distributor

(21 CFR 101.2)

# Nutrition Facts

Helvetica Regular 8 point with 1 point of leading

3 point rule

8 point Helvetica Black with 4 points of leading

1/4 point rule centered between nutrients (2 points leading above and 2 points below)

8 point Helvetica Regular with 4 points of leading

8 point Helvetica Regular, 4 points of leading with 10 point bullets.

<b>Nutrition Facts</b>			
Serving Size 1 cup (226g)			
Serving Per Container 2			
Amount Per Serving			
<b>Calories</b> 280	Calories from Fat 120		
		% Daily Value*	
<b>Total Fat</b> 13g		20%	
Saturated Fat 5g		25%	
Trans Fat 2g			
<b>Cholesterol</b> 30mg		10%	
<b>Sodium</b> 680mg		28%	
<b>Total Carbohydrate</b> 31g		10%	
Dietary Fiber 0g		0%	
Sugars 5g			
<b>Protein</b> 5g			
Vitamin A 4%	•	Vitamin C 2%	
Calcium 15%	•	Iron 4%	
*Percent Daily Values are based on a diet of 2,000 calories a day. Your Daily Values may be higher or lower depending on your calorie needs.			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	30g	35g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Franklin Gothic Heavy or Helvetica Black, flush left & flush right, no smaller than 13 point

7 point rule

6 point Helvetica Black

All labels enclosed by 1/2 point box rule within 3 points of text measure

1/4 point rule

Type below vitamins and minerals (footnotes) is 6 point with 1 point of leading



# **Voluntary Nutrient Content Claims**

- ❖ Free and Low Claims
- ❖ Relative and Comparative Claims
- ❖ Percent and Amount Claims
- ❖ Implied Claims
- ❖ Modified Standardized Foods (21 CFR 130.10)
- ❖ Claim Based on an Authoritative Statement

# **Voluntary Health Claims**

- ❖ **Unqualified**
  - NLEA
- ❖ **Structure/Function**
  - DSHEA
- ❖ **Qualified**
  - Interim procedures, 9/1/03
  - ANPR pending
- ❖ **Dietary guidance statements**
  - ANPR 11/25/03

# Evaluation of Potential Health Claims

- ❖ FDA evaluates potential health claims based on the scientific evidence that exists on the subject
- ❖ Scientific agreement and conclusiveness determines the outcome

**Health Claims Report Card**



<b>A</b>	<b>High</b> Significant scientific agreement	<b>1</b>
<b>B</b>	<b>Moderate</b> Evidence is not conclusive	<b>2</b>
<b>C</b>	<b>Low</b> Evidence is limited and not conclusive	<b>3</b>
<b>D</b>	<b>Extremely Low</b> Little scientific evidence supporting this claim	<b>4</b>