Exporting Food and Beverages to the USA? Overview of U.S. FDA Regulations & the new Food Safety Modernization Act

Presented by Beatrice Moreau, Senior Regulatory Advisor
Registrar Corp. European Office

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Seminar Overview

- U.S. FDA: Background & Jurisdiction
- Food, Drug, and Cosmetic Act
- FDA Food Safety Modernization Act
- Questions & Answers

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U.S. FDA Overview
Background and Jurisdiction

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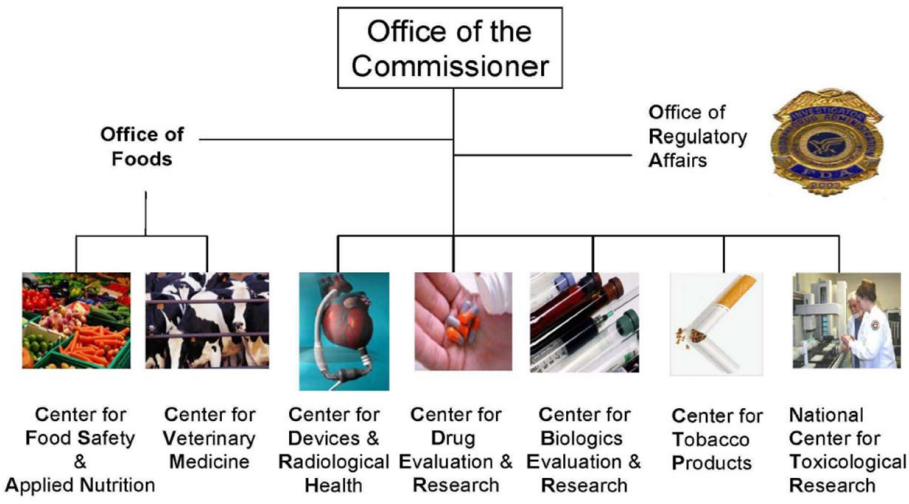
FDA Structure



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Code of Federal Regulations

- The Food, Drug, and Cosmetic Act is detailed in what we call the Code of Federal Regulations or "CFR".
- The CFR is a codification of the general and permanent rules published in the "Federal Register"
- Title 21 of the CFR is reserved for rules of the Food and Drug Administration.

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Food, Drug, and Cosmetic Act

- President Franklin D. Roosevelt signed into law the Food, Drug, Cosmetic Act in 1938.
- Remains today the principal law regulating all food, beverages, drugs, cosmetics, and medical devices in the USA.

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Food, Beverages, & Supplements

- **C**enter for **F**ood **S**afety and **A**pplied **N**utrition
  - Jurisdiction encompasses most food products (other than meat and poultry)
  - Agricultural products, processed food, canned foods, seafood, alcoholic and non-alcoholic beverages, ingredients, etc

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This table summarizes information concerning jurisdiction overlap for commercial products regulated by either or both FDA a USDA. It does not cover products made for on-site consumption such as pizza parlors, delicatessens, fast food sites, etc. Produc carrying the USDA shield are USDA jurisdiction.

FDA JURISDICTION	USDA JURISDICTION		
21 USC 392(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals and all members of the deer family including elk (wapiti) and moose)). FDA responsible for all non-specified birds including wild turkeys, wild ducks, and wild geese.	The Federal Meat Inspection Act regulates the inspection of the following amenable species: cattle, sheep, swine, goats, horses, mules or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory Inspection of Ratites and Squab (including emu) announced by USDA/FSIS April 2001	The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA. Mandatory Inspection of Ratites and Squab announced by USDA/FSIS April 2001	The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose or guinea. Voluntary grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs.)
Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass, or less than 30% fat, tallow or meat extract, alone or in combination. Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat and poultry meat (limited to less than 2%) in any combination.* Closed-face sandwiches.	Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or 30% or more fat, tallow or meat extract, alone or in combination.* Open-face sandwiches.	Products containing 2% or more cooked poultry; more than 10% cooked poultry skins, giblets, fat and poultry meat in any combination.*	Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction.
FDA is responsible for shell eggs and egg containing products that do not meet USDA's definition of "egg product." FDA also has jurisdiction in establishments not covered by USDA; e.g. restaurants, bakeries, cake mix plants, etc. Egg processing plants (egg washing, sorting, packing) are under FDA jurisdiction.			Products that meet USDA's definition of "egg product" are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction.
Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3% red meat), meat flavored spaghetti sauce with mushrooms, (2% meat), pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor	Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie	Chicken sandwich (open face), chicken noodle soup	

Food, Beverages, & Supplements

- **USDA: list of eligible countries** http://www.fsis.usda.gov/PDF/Countries_Products_Eligible_for_Export.pdf
- **and establishments:** http://www.fsis.usda.gov/regulations_&_policies/Eligible_Foreign_Establishments/index.asp

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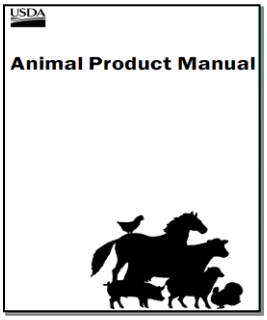
Food, Beverages, & Supplements

- **USDA**

Small amounts of eggs, meat, poultry, milk in FDA regulated products:



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Key Food Regulations

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Requirements

Food, Drug, and Cosmetic Act

- Bioterrorism Act
  - Registration, U.S. Agent, Prior Notice
- Labeling
- LACF
- Hazard Analysis and Critical Control Points (HACCP)
- Good Manufacturing Practices (GMPs)

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Bioterrorism Act of 2002

- Effective starting in October 2003
- Require companies to register if they "manufacture, process, pack, or store"
- Requires designation of a U.S. Agent for FDA communications
- Requires companies to file Prior Notice

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Bioterrorism Act of 2002

- Identification of manufacturing, packing, warehousing facilities,
- Contains contact information and details about the activities
- An eleven digits registration number is issued
- Not public – the PIN code is necessary to access your data
- Certificates; third party only
- Electronic: https://www.access.fda.gov/oaa/


CERTIFICATE OF REGISTRATION

This certifies that:

Your Company Name
Address
City, State/Region/Province
Country

is registered with the U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as currently effective on the date hereof by Registrar Corp.

U.S. FDA Registration No.: 12345678910

U.S. Registration Agent: Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to section 305 of the U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the expiration of one year from the date hereof, unless terminated after issuance of this certificate. Registrar Corp. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

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Russell R. Sheridan
Executive Director
Registrar Corp
Dated: January 1, 2012

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FDA Agent

- Must reside in the United States
- Must facilitate communications between FDA and the foreign company
- Has to be available 24/24 7/7 for FDA questions
- For routine, in case of problems, or emergency
- Always contacted in case of inspection

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Bioterrorism Act of 2002

- ONLY ONE FDA Agent per registration
- ONLY ONE registration per establishment

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Quick Numbers

- +/-449,000 facilities registered as of May 22, 2012
  - 171,000 U.S.
  - 278,000 foreign

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Registered Food Facilities

as of May 2012

China: 26,498
Mexico: 23,509
Italy: 18,199
Canada: 16,472
France: 16,026
Korea: 8,238
Vietnam: 6,594
Belgium: 1,178

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Prior Notice (Section 307)

- Notify FDA before shipments arrive in U.S. instead of after arrival
- Allows FDA to better target imports before they arrive in a U.S. port
- Allows FDA to make sure the goods come from registered companies

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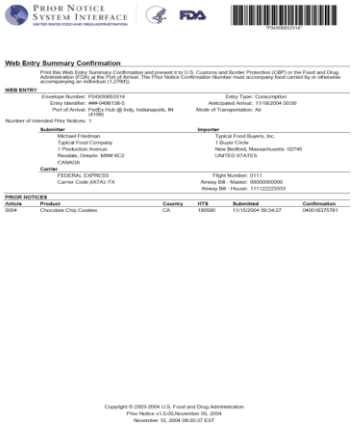
Example of a Prior Notice Confirmation

- Prior Notice is NOT an "approval" (FDA could still inspect)
- Bar-coded confirmation number issued for each product



PRIOR NOTICE SYSTEM INTERFACE

FDA

Web Entry Summary Confirmation

Print this Web Entry Summary Confirmation and present it to U.S. Customs and Border Protection (CBP) or the Food and Drug Administration (FDA) at the Port of Arrival. The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.279(f)).

WEB ENTRY

Envelope Number: FDA00660314
Entry Identifier: ###-0498138-5
Port of Arrival: FedEx Hub @ Indy, Indianapolis, IN (4199)
Entry Type: Consumption
Anticipated Arrival: 11/18/2004 00:00
Mode of Transportation: Air

Number of Intended Prior Notices: 1

Submitter
Michael Friedman
Typical Food Company
1 Production Avenue
Reedale, Ontario M8W 9C2
CANADA

Importer
Typical Food Buyers, Inc.
1 Buyer Circle
New Bedford, Massachusetts 02745
UNITED STATES

Carrier
FEDERAL EXPRESS
Carrier Code (IATA): FX
Flight Number: 0111
Airway Bill - Master: 00000000000
Airway Bill - House: 1111222225555

PRIOR NOTICES

Article	Product	Country	HTS	Submitted	Confirmation
0004	Chocolate Chip Cookies	CA	190590	11/15/2004 09:34:27	040016375781

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Food Labeling & Ingredients

- A top reason product is detained: Incorrect labeling, unapproved ingredients, prohibited health claims
- Common errors in trying to avoid problems:
  - Copy other wrong labels
  - Only follow part of the regulations

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Examples of Products Recently Detained due to Labeling Violations

- Cookies
- Noodles
- Sauces
- Canned seafood
- Energy drinks
- Food supplements





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Bulk Pack versus Retail

- FDA Inspectors are given significant freedom in deciding what should appear on "Bulk Pack" formats
  - Common name of the product
  - Latin name if applicable
  - Gross Weight / Net Weight
  - Country of Origin
  - Name/Address of Manufacturer
  - Lot or Tracking Number

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Labels for Retail

- Will consumers see your product label?

If so, then retail labeling rules apply:

- Basic Panels
  - Principal Display Panel (PDP)
  - Information Panel (IP)

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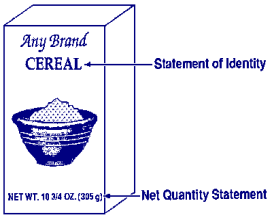
Principal Display Panel (PDP)

- Two required elements
  - **Statement of Identity**

    (name of food – can be strictly regulated by FDA)
  - **Net Contents Declaration**

    (place, size, US metric system)



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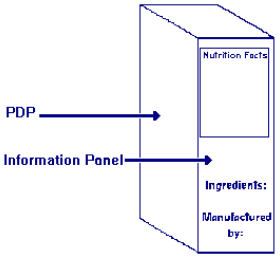
Information Panel (IP)

- Required elements
  - Nutrition Facts Chart/
  - Supplement Facts Chart
  - Ingredients List
  - Allergens
  - Manufacturer Identity
  - Made in



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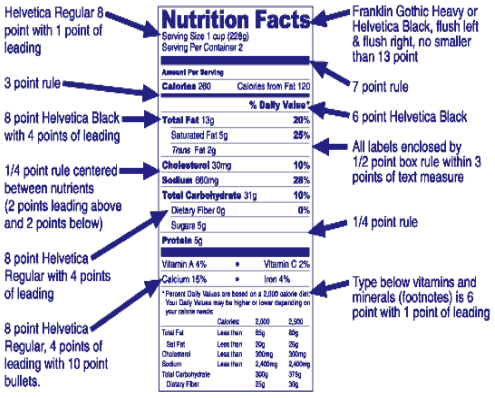
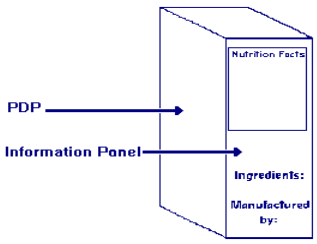
Nutrition Facts Chart





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Examples of Other Formats

Nutrition Facts
Serving Size 1 can

Amount Per Serving
Calories 140

	% Daily Value
Total Fat 0g	**0%**
Sodium 20mg	**1%**
Total Carbohydrate 36g	**12%**
Sugars 36g	
Protein 0g	

*Percent Daily Values are based on a 2,000 calorie diet.

Nutrition Facts Serv. Size: 1 package, Amount Per Serving: **Calories** 45, Fat Cal. 10, **Total Fat** 1g (2% DV), Sat. Fat 0.5g (3% DV), *Trans* Fat 0.5g, **Cholest.** 0mg (0% DV), **Sodium** 50mg (2% DV), **Total Carb.** 8g (3% DV), Fiber 1g (4% DV), Sugars 4g, **Protein** 1g, Vitamin A (8% DV), Vitamin C (8% DV), Calcium (0% DV), Iron (2% DV). Percent Daily Values (DV) are based on a 2,000 calorie diet.

Nutrition Facts
Serving Size 2 slices (56g)
Servings per container 10
Calories 140
Calories from Fat 15

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	2%	**Total Carbohydrate** 26g	9%
Saturated Fat 0.5g	3%	Dietary Fiber 2g	8%
Trans Fat 0.5g		Sugars 1g	
Cholesterol 0mg	0%	**Protein** 4g	
Sodium 280mg	12%		

Vitamin A 0% • Vitamin C 0% • Calcium 6% • Iron 6%
Thiamin 15% • Riboflavin 8% • Niacin 10%

* Percent Daily Values are based on a 2,000 calorie diet. 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	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

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Other Regulated Elements

- Serving Sizes
- Ingredients: GRAS? Colors, additives, new dietary ingredient
- Imports alerts by product, ingredient
- Specific warnings/ specific foods
- Claims
- FDA publishes guidances: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm

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Product Claims

- 3 types
  - Nutrient claims
  - Structure/Function Claim
  - Health Claims

- Unapproved new drug or dietary supplement?
  - Exporters of dietary supplements often encounter claim-related detentions

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Bilingual Labeling

- All labels must be in English but may also be in additional languages;

Nutrition Facts/Datos De Nutricion
Serving Size/Tamano por Racion 1 cup/1 taza (228g)
Servings Per Container/Raciones por Envase 2

Amount Per Serving/Cantidad por Racion

Calories/Calorias 260 Calories from Fat/Calorias de Grasa 120

	% Daily Value*/% Valor Diario*
Total Fat/Grasa Total 0g	**20%**
Saturated Fat/Grasa Saturada 5g	**25%**
Cholesterol/Colesterol 30mg	**10%**
Sodium/Sodio 660mg	**28%**
Total Carbohydrate/Carbohidrato Total 31g	**11%**
Dietary Fiber/Fibra Dietetica 0g	**0%**
Sugars/Azucares 5g	
Protein/Proteinas 5g	

Vitamin/ Vitamina A 4% • Vitamin/ Vitamina C 2%

Calcium/ Calcio 15% • Iron/ Hierro 4%

*Percent Daily Values are based on a 2,000 calorie diet. *Your daily values may be higher or lower depending on your calorie needs:

*Los porcentajes de Valores Diarios estan basados en una dieta de 2,000 calorias. Sus valores diarios pueden ser mayores o menores dependiendo de sus necesidades calóricas:

	Calories/Calorias:	2,000	2,500
Total Fat/ Grasa Total	Less than/Menos de	65g	80g
Saturated Fat/ Grasa Saturada	Less than/Menos de	20g	25g
Cholesterol/ Colesterol	Less than/Menos de	300mg	300mg
Sodium/ Sodio	Less than/Menos de	2,400mg	2,400mg
Total Carbohydrate/ Carbohidratos Total		300g	375g
Dietary Fiber/ Fibra Dietetica		25g	30g

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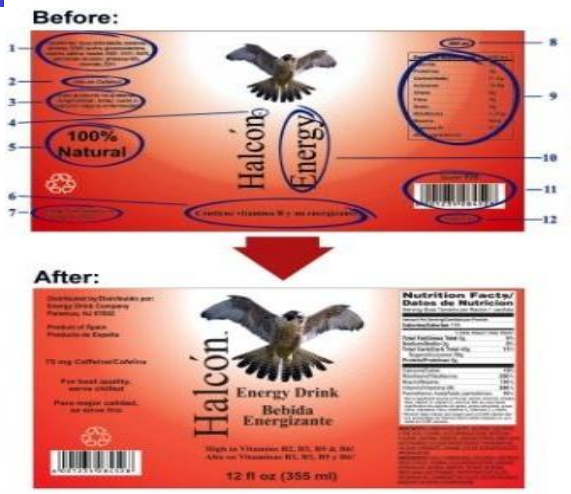
Before & After



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Low-Acid Canned Food

- Low-Acid, Acidified, Thermally Processed Foods
- Typically produced in Cans, Bottles, Jars, or Tetra Paks
- Food Canning Establishment ("FCE") Registration required
- Process Filings ("SID") for each product, each size

http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm

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HACCP

- Focuses on the prevention of hazards
- Can be applied throughout the food chain ("from farm to table")
- Currently required for
  - Seafood (21 *CFR* 123)
  - Meat and Poultry (9 *CFR* 417)
  - Juice (21 *CFR* 120)

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cGMP – 21 CFR Part 110

- Guidelines and conditions which must be met to ensure production of safe and wholesome foods.
- GMPs required for all food, beverages, and dietary supplements
- Once new FSMA regulations are published, new GMPs will be found 21CFR part 117
- http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/default.htm

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Voluntary Certifications

FDA Food Safety Modernization Act

- "FSMA" signed by President Obama in January 2011
- Phased in over time 2011 - 2016
- Most significant update to food safety laws since 1938

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What's Next with FSMA?

- U.S. FDA must now promulgate the regulations:
  - Federal Register Notice: *Proposed Rules*
  - Comment Period
  - Final Rules

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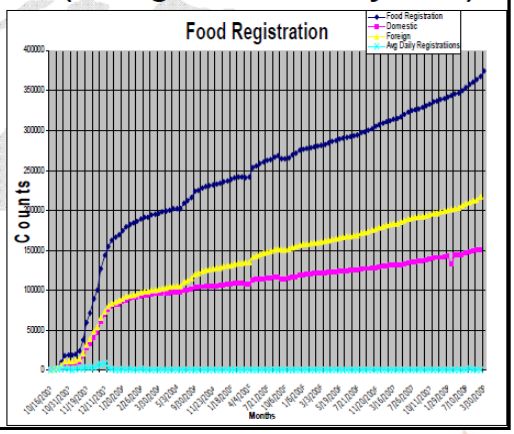
U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

U.S. Import Entry Trends Relative to Foods

- There are over 240,000 registered foreign food facilities
- Over 200 countries/territories export to the U.S. to 300 ports
- 15 -20% of U.S. foods consumed originate from other countries
  - 80% of seafood
  - 35% of produce
  - *60% of spices*

Registered food facilities
(Foreign facilities in yellow)



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Burden on Manufacturers and Importers

- Port-of-Entry inspection cannot handle increase in imported foods (9,900,000 shipments in 2010 / 27,000 per day; 796,000 inspected)
- FSMA makes Importers more responsible for quality of products from foreign manufacturers
- Accountability

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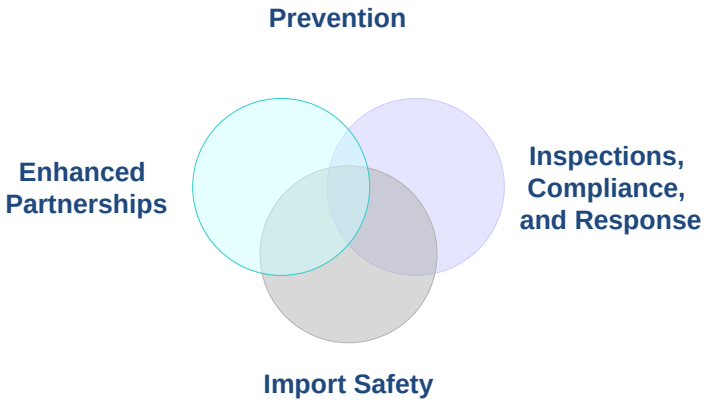
Vision of FSMA



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Key Components

1. **Prevention**
   - Mandatory preventive controls for food companies - Final rule due July 2012

   Proposed Rule published January 2013

   Comment period until May 2013
   - Mandatory Produce Safety Standards - Final rule due July 2012

   Proposed Rule published January 2013

   Comment period until May 2013

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Key Components

2. **Inspections, Compliance, and Response**
   - Mandated inspection frequency - Effective October 2011
   - Records access – Effective October 2011
   - Each food facility must renew its U.S. FDA registration every two years (4th quarter of every even-numbered year). First period October 2012
   - Mandatory recall – Effective October 2011
   - Expanded administrative detention - Effective July 2011
   - Suspension of registration - Effective June 2011

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Key Components

4. **Import Safety**

   - Voluntary Qualified Importer Program - Implementation due June 2012
   - Foreign Supplier Verification Program

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Key Components

5. **Enhanced Partnerships**

   - Reliance on inspections by other agencies, including foreign governments
   - Third Party certification - System due January 2013

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New User Fees

- New FDA User Fees: 10/01/2011
- FDA Hourly Rates:
  - $221 per hour, domestic
  - $289 per hour, foreign travel
- Charged for
  - DWPE Petition Review
  - Reconditioning
  - Re-Inspections

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New User Fees

- Reinspection Fees
  - Will be charged to the facility's U.S. Agent listed in Section 7 of the food facility registration module
  - That could be your importer who you listed in your registration as your U.S. Agent
  - The person or company listed might be unwilling to continue to serve as your U.S. Agent for FDA communications

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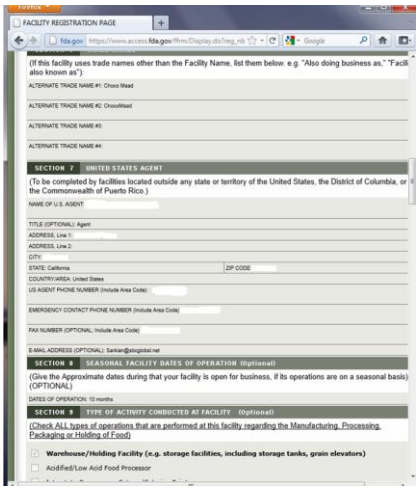
U.S. Agent Responsibilities



- US Agent is designated in Section 7, FFRM
- US Agent must:
  - Reside in USA
  - Be available 24/7
  - Answer questions as though they are answering for registrant
  - Should know how to deal with FDA.

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New User Fees

- Reinspection Fees include:
  - Traveling to and from the facility
  - Preparing reports
  - Analyzing samples
  - Examining labels

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Registration Suspension

- FDA may suspend a food facility's registration. Effectively stops any foreign manufacturer from exporting to the U.S.
- Registration may be held in suspension until FDA determines the cause to be rectified and that no further health consequences exist.

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Administrative Detention

- Allows FDA to proactively detain food for 30 days if suspected of adulteration or misbranding at the border instead of being required to wait for a proven health concern.

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Inspections and Detentions

- FDA's inspection or reinspection of a facility, or detention of a shipment, can have serious impact on business
  - Warning Letters
  - DWPE
  - OASIS

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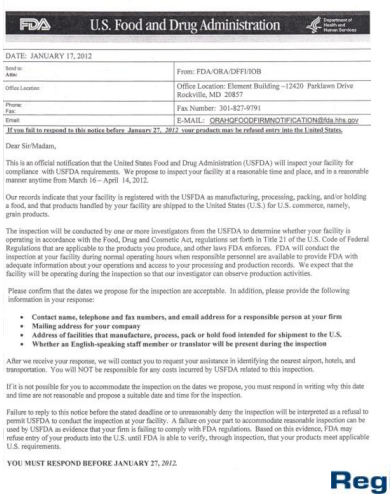
FDA Inspection Notice

- Notice of inspection is sent by email to the U.S. Agent listed in the FFRM



FDA U.S. Food and Drug Administration — Department of Health and Human Services

DATE: JANUARY 17, 2012

Send to: Attn:	From: FDA/ORA/DFFI/IOB
Office Location:	Office Location: Element Building –12420 Parklawn Drive Rockville, MD 20857
Phone: Fax:	Fax Number: 301-827-9791
Email:	E-MAIL: ORAHQFOODFIRMINOTIFICATION@fda.hhs.gov

If you fail to respond to this notice before January 27, 2012 your products may be refused entry into the United States.

Dear Sir/Madam,

This is an official notification that the United States Food and Drug Administration (USFDA) will inspect your facility for compliance with USFDA requirements. We propose to inspect your facility at a reasonable time and place, and in a reasonable manner anytime from March 16 – April 14, 2012.

Our records indicate that your facility is registered with the USFDA as manufacturing, processing, packing, and/or holding a food, and that products handled by your facility are shipped to the United States (U.S.) for U.S. commerce, namely, grain products.

The inspection will be conducted by one or more investigators from the USFDA to determine whether your facility is operating in accordance with the Food, Drug and Cosmetic Act, regulations set forth in Title 21 of the U.S. Code of Federal Regulations that are applicable to the products you produce, and other laws FDA enforces. FDA will conduct the inspection at your facility during normal operating hours when responsible personnel are available to provide FDA with adequate information about your operations and access to your processing and production records. We expect that the facility will be operating during the inspection so that our investigator can observe production activities.

Please confirm that the dates we propose for the inspection are acceptable. In addition, please provide the following information in your response:

- **Contact name, telephone and fax numbers, and email address for a responsible person at your firm**
- **Mailing address for your company**
- **Address of facilities that manufacture, process, pack or hold food intended for shipment to the U.S.**
- **Whether an English-speaking staff member or translator will be present during the inspection**

After we receive your response, we will contact you to request your assistance in identifying the nearest airport, hotels, and transportation. You will NOT be responsible for any costs incurred by USFDA related to this inspection.

If it is not possible for you to accommodate the inspection on the dates we propose, you must respond in writing why this date and time are not reasonable and propose a suitable date and time for the inspection.

Failure to reply to this notice before the stated deadline or to unreasonably deny the inspection will be interpreted as a refusal to permit USFDA to conduct the inspection at your facility. A failure on your part to accommodate reasonable inspection can be used by USFDA as evidence that your firm is failing to comply with FDA regulations. Based on this evidence, FDA may refuse entry of your products into the U.S. until FDA is able to verify, through inspection, that your products meet applicable U.S. requirements.

YOU MUST RESPOND BEFORE JANUARY 27, *2012.*

Registrar Corp

Reasons for Inspection

- Routine schedule
- Response to reported problem
- Fulfillment of FSMA mandate

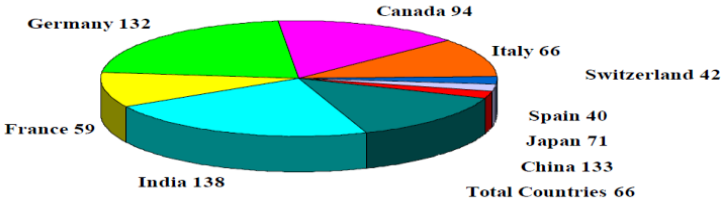
Registrar Corp

FSMA Foreign Facility Inspection Schedule

- *2011-* 600 Foreign Inspections
- 2012- 1,200 Foreign Inspections
- 2013- 2,400 Foreign Inspections
- 2014- 4,800 Foreign Inspections
- 2015- 9,600 Foreign Inspections
- 2016- 19,200 Foreign Inspections

Registrar Corp

FDA's International Inspections By Country, FY 2010



Registrar Corp

Proactive versus Reactive

- Investing in compliance is much cheaper than reacting to a failed inspection or detention in the U.S.
- Detentions mean laboratory testing fees, warehousing fees, cost to "recondition" product, return freight, possible FDA fees, and loss of a customer.

Registrar Corp

How can you prepare now?

- Do you have your 11-digit registration number and 8-character PIN?
- Verify that the information in your FDA registration is up-to-date, especially your contact details (phone, fax, email)
- Determine who is listed as your U.S. Agent in your FDA Food Facility Registration (does their email work? Are they still in business?)

Registrar Corp

How can you prepare now?

- Make sure your U.S. Agent is aware of FSMA and is a reliable communications link between FDA and you (will they forward emails from FDA? Will they answer the phone if FDA calls? Will they know how to answer an FDA question?)
- Determine if your Agent will handle the registration updates and renewals for you
- Prepare for an eventual FDA inspection

Registrar Corp

How can you prepare now?

- Verify the compliance of your products: ingredients, labeling, claims…
- Determine responsibilities between you and your clients
- Keep your archives up to date

Registrar Corp

Questions?

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