Boot Camp on U.S. FDA Regulations

Presented by Registrar Corp

October 25,2016

Registrar Corp

Amendments to the Registration of Food Facilities

Presented by David Lennarz

Vice President

October 25, 2016

Registrar Corp

Overview

- The Bioterrorism Act and Food Facility Registration
- The Food Safety Modernization Act and Biennial Food Facility Registration Renewal
- The Final Rule for Food Facility Registration and the 2016 Biennial Registration Renewal Period
- Summary / Questions & Answers

To prevent, prepare for, and respond to bioterrorism and other public health emergencies.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Food Facility Registration

- Registration required under the Bioterrorism Act of 2002 for facilities that manufacture, process, pack or store food (including beverages and dietary supplements)
- Foreign facilities must designate a U.S. Agent

Food Facility Registration Exemption

- Trading companies
- Personal residences
- Transportation only
- Farms
- Retail Food Establishments
- Fishing Vessels
- USDA-regulated facilities

Food Facility Registration Information

- Facility Information (name, corporate entity type, physical location, trade names used to do business)
- Contact Information (telephone, email address, emergency contact, preferred mailing address)
- Product Information (general product categories)

Shifting the focus of federal regulators from responding to contamination to preventing it.

The Food Safety Modernization Act of 2011

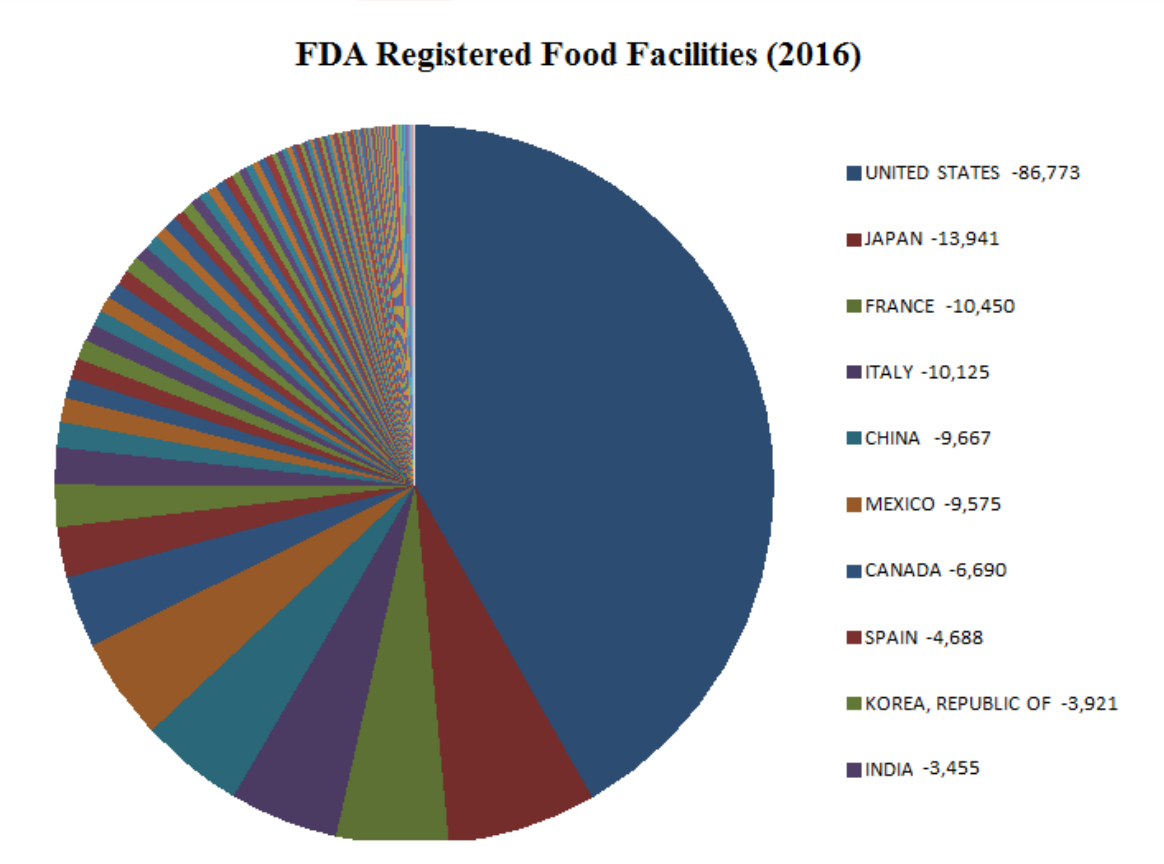
Food Facility Registration Renewal

- Every two years, on even-numbered years
- Facilities must consent to FDA inspection
- Failure to renew results in invalidated registration, is a "prohibited act"

Registrar Corp

Registration Statistics

- **FOIA Request:** 207,655 food facilities registered with FDA as of January 1, 2016
  - 120,822 of those located outside of the United States
  - See full statistics on our website.



Registration Statistics

- FDA purges its database of non-renewed registrations early the next year.
- Number of FDA registered food facilities dropped 14% from January 2014 to January 2015
  - Likely due to facilities failing to renew during the 2014 renewal period.

Registrar Corp

Final Rule for Food Facility Registration

- Unique Facility Identifier required for 2020
- Electronic submissions only in 2020
- Third Party Submission Verifications
  - If the registration submission, update, renewal or cancellation is not made by the owner, operator, or agent in charge, FDA will verify the third party was authorized to act on behalf of the registrant.
- Agent Assignment Verification
  - FDA will verify that the person designated as the U.S. Agent for foreign facilities has agreed to serve in that role.
    - FDA will not provide the facility with a registration number or confirm the registration renewal until that person confirms they agree to the designation.

Facility Food Product/Activity Categories Expanded

Human Food Product Categories and Activity Types:

- Warehouse/Holding facility will be divided into three categories:
- Ambient, Refrigerated and Frozen.
- Low Acid/Acidified Food Processor will be divided into two categories: Low Acid Food Processor and Acidified Food Processor.
- Farm "Mixed-Type" Facility will be added to the list of activities.
- Shellfish: Molluscan or Other?

Animal Food Product Categories:

- New Product Categories:

Botanicals and herbs; direct fed microbials; forage products; and technical additives.

- Old categories replaced with new ones:

Animal derived products → Animal protein products

Food processing byproducts → Human food by-products not otherwise listed

Recycled animal waste products → Processed animal waste products.

Registration and Renewal Assistance

- Registrar Corp can register and renew food facilities with U.S. FDA
- U.S. Agent Benefits
  - Registration Renewal: Registrar Corp will renew FDA registrations biennially as required by FDA
  - Mock FDA Inspection *(free of charge other than travel and lodging when FDA sets an inspection date)*
  - Certificate of Registration issued by Registrar Corp
  - Registration Updates
  - FDA Compliance Monitoring
  - Prior Notice *(three free per year)*
  - Detention Assistance
  - DUNS Assistance

Questions & Answers

Registrar Corp

Changes to Food and Dietary Supplement Labeling

Presented by Anna Benevente

Senior Regulatory Specialist

October 25, 2016

Registrar Corp

Presentation Overview

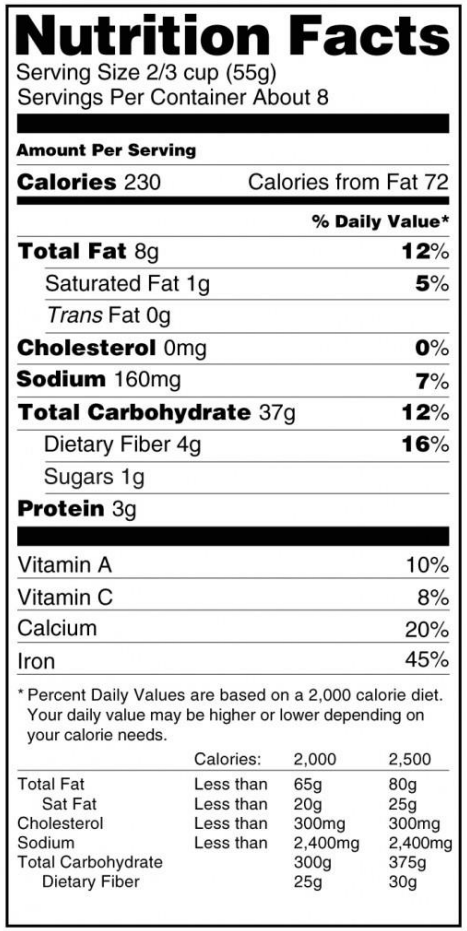
- Regulatory History
- Content Changes
- Reference Amounts and Serving Sizes
- Format Changes
- Record Keeping
- Effective and Compliance Dates
- Summary / Questions & Answers

How did we get here?

Regulatory History

Regulatory History

- Current Nutrition Facts Label has stayed relatively unchanged since passage of the Nutrition Labeling and Education Act (1990)



Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

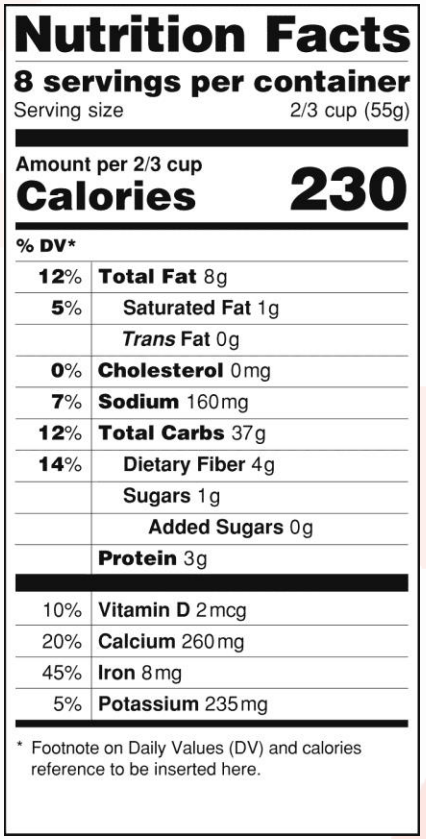
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	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

Registrar Corp

Regulatory History

- Based upon new research and nutritional data, FDA issued 2 proposed rules in 2014 to modify the current Nutrition Facts Label in content and format and requested comment
- Supplemental proposed rule issued in 2015 addressed "added sugars"



Nutrition Facts

8 servings per container

Serving size 2/3 cup (55g)

Amount per 2/3 cup	
Calories	**230**
% DV*	
12%	**Total Fat** 8g
5%	Saturated Fat 1g
	Trans Fat 0g
0%	**Cholesterol** 0mg
7%	**Sodium** 160mg
12%	**Total Carbs** 37g
14%	Dietary Fiber 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	**Vitamin D** 2mcg
20%	**Calcium** 260mg
45%	**Iron** 8mg
5%	**Potassium** 235mg

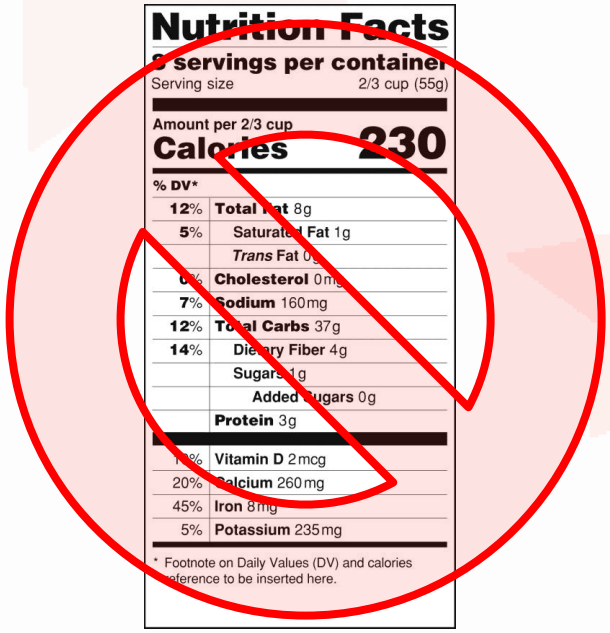
* Footnote on Daily Values (DV) and calories reference to be inserted here.

Regulatory History

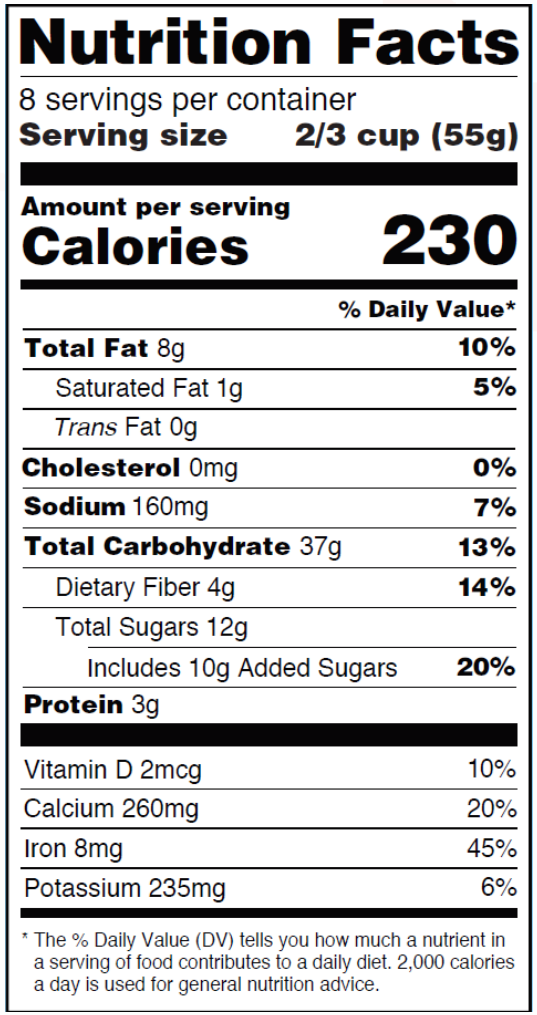
- Final Rules issued May 27, 2016:
  - Food Labeling: Revision of the Nutrition and Supplement Facts Labels
  - Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints

Regulatory History

- Final version of the Nutrition Facts Label is dramatically different than the 1990 and 2014 versions…



Final Version (Standard Format) 2016



Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Registrar Corp

What new information is FDA requiring?

Content Changes

New Content Changes

- Vitamin D and Potassium are now mandatory declarations for the label
- Vitamins A and C are now voluntary
- Calories from fat may no longer be declared
- Fluoride may now be voluntarily declared
- "Sugars" now to be declared as "Total Sugars"

New Content Changes

- Added Sugars must be declared when present at certain amounts
- Quantitative amounts for the four mandatory vitamins/minerals must be given
- Modifications to how folate and folic acid are declared
- New units for Vitamin D, Niacin, Vitamin A, Vitamin E

Dietary Fiber

- FDA has modified the definition for dietary fiber to include only those with demonstrated beneficial physiological effects
  - Nondigestible soluble and insoluble carbohydrates and lignin that are intrinsic and intact in plants, and
  - [beta]-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose
- FDA plans to review data on additional fibers and issue future guidance regarding others that may be included

Added Sugars

- Added Sugars include:
  - Those either added to the food or packaged as such
  - Sugars (free, mono- and disaccharides)
  - Syrups and honey (incl. single ingredient packages)
  - Sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type

Added Sugars

- FDA provides the following as examples:
  - Brown sugar, sugar
  - Corn syrup and high fructose corn syrup
  - Dextrose
  - Fructose
  - Invert sugar
  - Maltose
  - Trehalose

Added Sugars

- Added Sugars does **not** include:
  - Single strength or 100% fruit juices
  - fruit or vegetable juice concentrated from 100 percent juices sold to consumers (which consumer will reconstitute)
  - fruit or vegetable juice concentrates used towards the total juice percentage label declaration under § 101.30 or for Brix standardization under § 102.33(g)(2)
  - fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves
  - fruit component of fruit spreads
  - Sugar alcohols

DRV/RDI Changes

- FDA updated the Daily Reference Value ("DRV") and Reference Daily Intake ("RDI") values for many nutrients, such as:
  - Total Fat 78 g
  - Total Carb 275 g
  - Sodium 2300 mg
  - Potassium 4700 mg
  - Calcium 1300 mg
  - Dietary Fiber 28 g
- FDA established a DRV for Added Sugars at 50 g

DRV/RDI Changes

- Will impact the value of the %DV declared in the label
- Will impact whether a product can make certain nutrient content and health claims
- Updated DRV/RDI values mean products that previously could make claims such as "low sodium" or "high in fiber" may not under the new rules

How have serving sizes changed with the new rules?

Reference Amounts and Serving Sizes

RACC Values

- Serving sizes must reflect the Reference Amount Customarily Consumed (RACC) determined by FDA's review of consumer consumption data
- Reflects what consumers actually eat, not what they should eat
- Multiple RACC values have been changed to reflect new data

Notable RACC changes

- Certain beverage RACCs were increased from 240 mL to 360 mL (such as sodas)
- "All other candies" RACC value decreased from 40 g to 30 g
- Ice cream RACC increased from 1/2 to 2/3 cup
- New RACC category for "appetizers" established
- New RACC category for "after-dinner confectionary"

RACC Example

85 gram chocolate bar

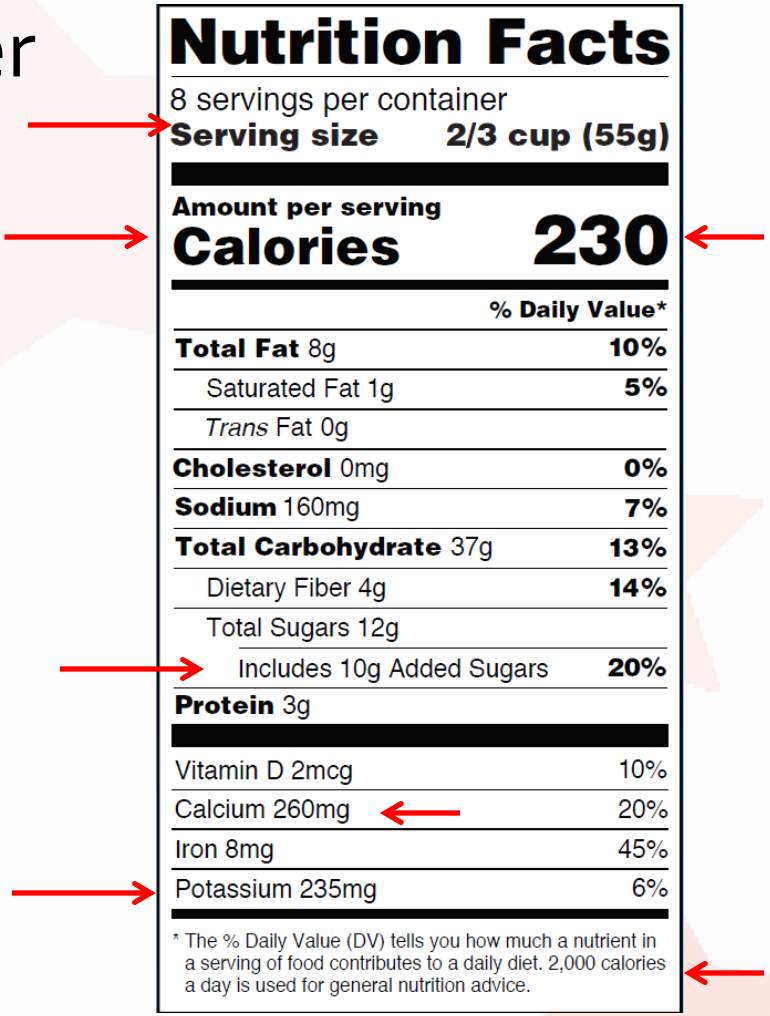
- Previous serving size based upon the 40 g RACC would result in serving size = ½ bar
- NEW serving size based upon 30 g RACC would result in serving size = 1/3 bar

How will the new label look?

Format Changes

Standard Label Changes

- Changes made to the order of nutrients
- Changes made to the footnote
- Changes made to the font sizes of the declarations
- Quantitative amounts of certain vitamins/minerals required



Simplified Label Changes

- "Simplified" label is permitted when the product meets FDA requirements related to nutritional content

Nutrition Facts

64 servings per container

Serving size **1 tbsp (14g)**

Amount per serving

Calories **130**

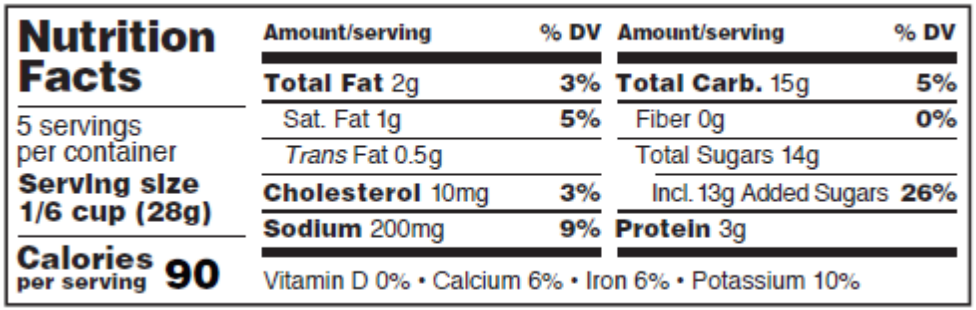
	% DV*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 2g	
Polyunsaturated Fat 4g	
Monounsaturated Fat 6g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium

* %DV = %Daily Value

Tabular Label Changes

- "Tabular" label is permitted when product packaging is below a certain size



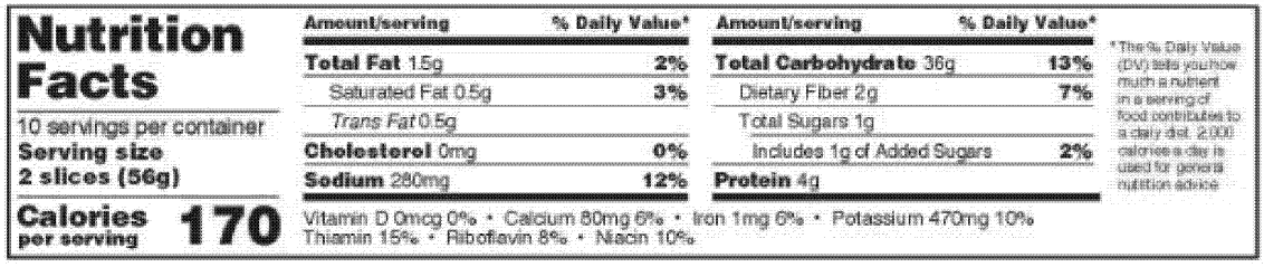
Nutrition Facts

5 servings per container
Serving size 1/6 cup (28g)

Calories per serving 90

Amount/serving	% DV	Amount/serving	% DV
Total Fat 2g	**3%**	**Total Carb.** 15g	**5%**
Sat. Fat 1g	**5%**	Fiber 0g	**0%**
Trans Fat 0.5g		Total Sugars 14g	
Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Sodium 200mg	**9%**	**Protein** 3g	

Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%



Nutrition Facts

10 servings per container
Serving size 2 slices (56g)

Calories per serving 170

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**	**Total Carbohydrate** 36g	**13%**
Saturated Fat 0.5g	**3%**	Dietary Fiber 2g	**7%**
Trans Fat 0.5g		Total Sugars 1g	
Cholesterol 0mg	**0%**	Includes 1g of Added Sugars	**2%**
Sodium 280mg	**12%**	**Protein** 4g	

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%
Thiamin 15% • Riboflavin 8% • Niacin 10%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Linear Label Changes

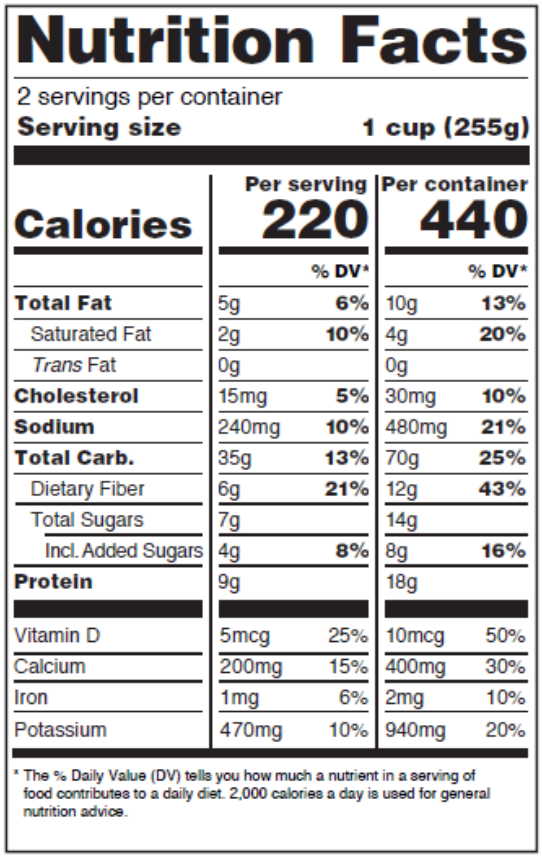
- "Linear" label is only permitted when a tabular chart will not fit on the product packaging


Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**
Amount per serving: **Calories 5,** **Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (5% DV).

Dual Column Labels

- FDA has mandated "dual column" labels for certain products
- For products in packaging that is 200-300% of the RACC
- For products that are discrete units that are 200-300% of the RACC

Dual Column Label Examples



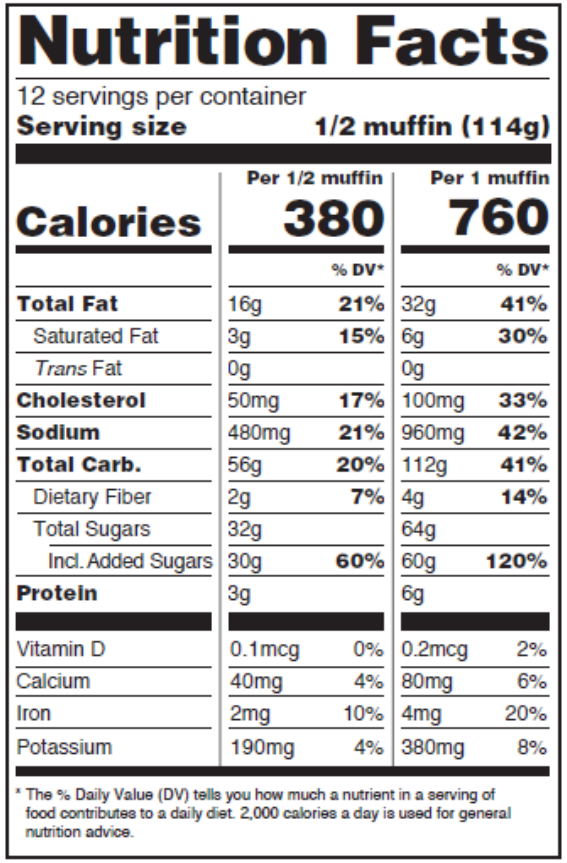
Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		**% DV***
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



Nutrition Facts

12 servings per container

Serving size **1/2 muffin (114g)**

	Per 1/2 muffin		Per 1 muffin	
Calories	**380**		**760**	
		% DV*		**% DV***
Total Fat	16g	**21%**	32g	**41%**
Saturated Fat	3g	**15%**	6g	**30%**
Trans Fat	0g		0g	
Cholesterol	50mg	**17%**	100mg	**33%**
Sodium	480mg	**21%**	960mg	**42%**
Total Carb.	56g	**20%**	112g	**41%**
Dietary Fiber	2g	**7%**	4g	**14%**
Total Sugars	32g		64g	
Incl. Added Sugars	30g	**60%**	60g	**120%**
Protein	3g		6g	
Vitamin D	0.1mcg	0%	0.2mcg	2%
Calcium	40mg	4%	80mg	6%
Iron	2mg	10%	4mg	20%
Potassium	190mg	4%	380mg	8%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Is there any data that must be kept?

Recordkeeping

Records for Nutrient Declarations

- Generally must be kept for nutrients for which analytical methods are not available
- Records may be analyses of databases, recipes, formulations, batch records

Records for Nutrient Declarations

- Records must show how the nutrient values were determined, when product:
  - Has a mixture of fibers that meet and don't meet the definition of "dietary fiber"
  - Has a mixture of naturally occurring sugars and those that would be considered "added sugars"
  - Is subjected to non-enzymatic browning that results in reduction of "added sugars"
  - Has a mixture of all rac-α-tocopherol and RRR-α-tocopherol (vitamin E)
  - Has a mixture of folic acid and folate

Are dietary supplements affected by the new rule?

Changes to the Dietary Supplement Label

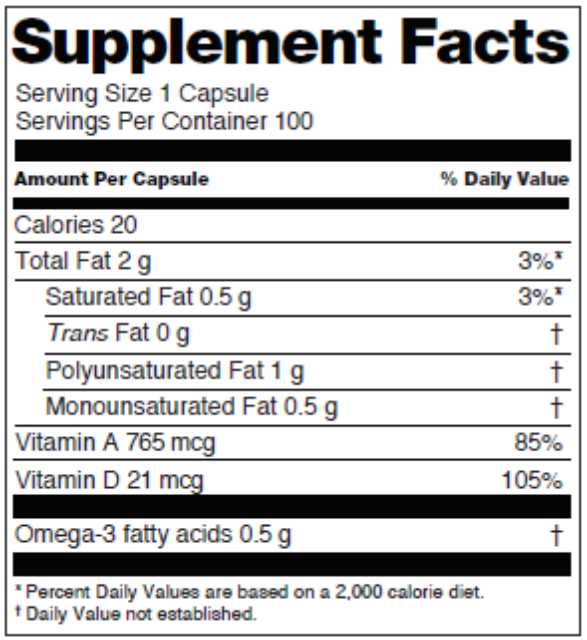
Content Changes

- List of mandatory nutrients no longer includes vitamins A and C
  - Replaced with potassium and vitamin D
  - "Calories from Fat" no longer permitted
- "Added Sugars" and "Total Sugars" must be declared if present
- Changes/additions to regulatory definitions for nutrients in Nutrition Facts Label also apply

Format Changes

- Relatively minor compared to the Nutrition Facts Label
- Size of Calorie declaration will not increase – FDA states that the final rule was in error and will be corrected in a technical amendment
- New disclaimer for supplements intended for children 1-3 years of age:
  - "*Percent Daily Values are based on a 1,000 calorie diet."

Label Examples



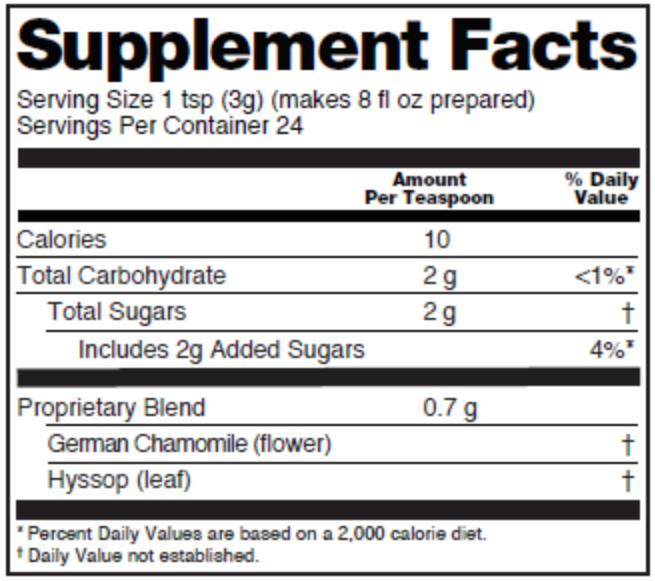
Supplement Facts

Serving Size 1 Capsule
Servings Per Container 100

Amount Per Capsule	% Daily Value
Calories 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Trans Fat 0 g	†
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 765 mcg	85%
Vitamin D 21 mcg	105%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.



Supplement Facts

Serving Size 1 tsp (3g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	<1%*
Total Sugars	2 g	†
Includes 2g Added Sugars		4%*
Proprietary Blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaf)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

How much time do I have to change my labels?

Effective and Compliance Dates

Effective Date

- Effective Date: July 26, 2016
  - New regulations went into effect
  - Replaced the former regulations found in the Code of Federal Regulations

Compliance Dates

- Compliance Dates
  - FDA allows industry time to incorporate the new rules into their packaging
  - Based upon the annual food sales of the manufacturer
  - Sales > $10 Million: July 26, 2018
  - Sales < $10 Million: July 26, 2019

Labeling and Ingredient Review

- Registrar Corp can review food labeling and ingredients for FDA compliance.
- Service includes:
  - A detailed report (typically 40-50 pages) prepared by our team of Regulatory Specialists who scrutinize every element of the food labeling
  - Update to FDA's new labeling format
  - A print-ready graphic file of the revised food label which incorporates our recommended changes.

Questions & Answers

U.S. FDA Import Alerts

Presented by Sarah Gurganus
Senior Regulatory Specialist
October 25, 2016

Registrar Corp

Presentation Overview

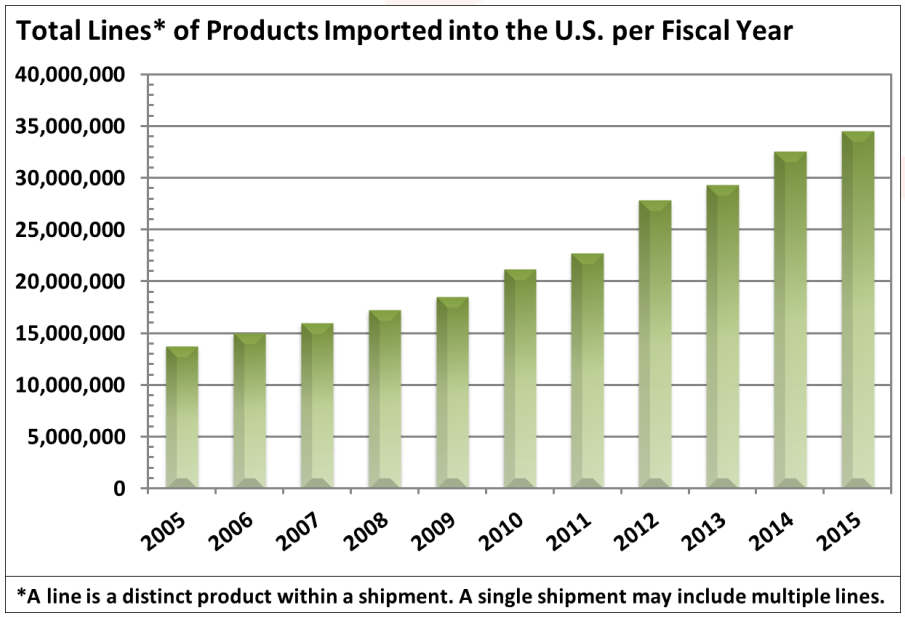
- FDA Resource Management
- What is an Import Alert?
- Detention Without Physical Examination (DWPE)
- Format of Import Alerts
- Removal or Exemption from DWPE
- Registrar Corp's Solutions
- Questions & Answers

FDA's Solution to Handle Millions of Entries

FDA Resource Management

FDA Resource Management

- Nearly 35 million entries of FDA regulated products in FY 2015.
- Over 300 possible ports of entry.



http://www.fda.gov/ForIndustry/ImportProgram/default.htm

FDA Resource Management

- In 2013, FDA was able to physically inspect only 1.9% of all food products entering the United States.

- FDA has developed systems that allow the agency to use the minimum amount of its limited resources to identify and detain products that are expected to be non-compliant.

FDA's Solution to Handle Millions of Entries

Import Alerts

What is an Import Alert?

- Notice to all entry ports that certain products from specific areas or manufacturers may be violative.
- Created whenever FDA discovers a pattern of violation that creates a reason to believe that future shipments may be similarly violative.
- Instructs FDA compliance officers to detain these products.

More than 250 active Import Alerts

What is an Import Alert?

Types of Import Alerts

Types of Import Alerts

- Green List Import Alerts:
  - Subject to the alert unless you're on the Green List.

- Red List Import Alerts:
  - Only subject to the alert if you are on the Red List.

Green List Import Alerts

- Green List Import Alerts:
  - Inherently risky products from anywhere in the world.
    - 16-20: Puffer Fish (Tetrodotoxin)
  - Violations common or widespread in certain regions.
    - 16-07: Dried or Pickled Finfish from Thailand (Filth)
    - 99-29: Vegetable Protein products from China (melamine)

Red List Import Alerts

- Red List Import Alerts:
  - Based on the nature of the violation or history of the company.
    - 16-04: Misbranded Seafood
    - 45-02: Foods Containing Illegal and/or Undeclared Colors
    - 99-19: Food Products due to Salmonella

Import Alerts

Detention Without Physical Examination (DWPE)

Detention Without Physical Examination (DWPE)

- Shipment will be detained without an inspector even looking at it.
- Works under the premise that the products *appear* violative based on a history of violation.
- NOT an *automatic refusal.*
  - The manufacturer or importer must present evidence to FDA that the product is NOT violative in order to get a shipment released from detention.
  - This process will repeat for ALL shipments for as long as the Import Alert is in effect.

Format of Import Alerts

Format of Import Alerts

- Available on the FDA website.
- All alerts follow the same format:
  - Identifying Information
  - Reason For Alert
  - Guidance
  - Product Description
  - Charge
  - [If country specific, the list of countries and products affected]
  - The appropriate list of facilities (red or green)

Format of Import Alerts

Import Alert # 16-124
Published Date: 09/12/2016
Type: DWPE
Import Alert Name:
"Detention Without Physical Examination Of Aquaculture Seafood Products Due To Unapproved Drugs"

Reason for Alert:
There has been an extensive commercialization and an increased consumption rate of aquaculture seafood products. As this industry grows, the use of unapproved new animal drugs and the misuse of approved new animal drugs in seafood raised through aquaculture also grows. The use of unapproved new animal drugs will have an impact on the safety of aquaculture products for consumers.

Guidance:
Districts may detain, without physical examination, the products from the firms identified in the attachmnet for this alert.

Contact the Division of Field Science at 301 796-6600 for questions or issues concerning science, science policy, analysis, preparation, or analytical methodology.

All requests for removal from detention without physical examination should be address to DIOP 301-796-0356.

Product Description:
Aquaculture seafood

Charge:
"The article is subject to refusal of admission pursuant to on 801(a)(3) in that it appears to be adulterated in that it or contains a new animal drug (or conversion product of) that is unsafe within the meaning of Section 512, which violation of Section 402(a)(2)(C)(ii)."

OASIS charge code - VETDRUGRES

List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

Format of Import Alerts

CHILE

Comercial y Servicios Sur Austral, Ltda. — **Date Published : 08/10/2016**
Ruta 5 Sur 7 , Chamiza , Puerto Montt, Los Lagos CHILE

16 X - - 03 Salmon, all, Aquaculture Harvested Fishery/Seafood Products — Date Published: 08/10/2016
Desc:Salmon; Atlantic Coho- Farmed
Notes:Problem: Isoeugenol

CHINA

BEIHAI ANBANG SEAFOOD CO.,LTD — **Date Published : 09/09/2013**
INDUSTRIAL SECTION,CHINESE OVERSEAS , &DEVELOPMENT ZONE,BEIHAI,GUANGXI,CHINA , Beihai, Yanxizhuangzuzizhiqu CHINA

16 A - - 58 Tilapia — Date Published: 09/09/2013
Desc:Tilapia
Problems: MALACHITE GREEN;

16 X - - 06 Tilapia, Aquaculture Harvested Fishery/Seafood Products — Date Published: 09/09/2013
Desc:Tilapia
Problems: MALACHITE GREEN;

BEIHAI EVERGREEN AQUATIC PRODUCT SCI.&TECH. CO.,LTD. — **Date Published : 03/04/2016**
MIDDLE STATION, HEPU COUNTY,BEIHAI CITY , Beihai, Yanxizhuangzuzizhiqu CHINA

16 A - - 58 Tilapia — Date Published: 03/04/2016
Desc:Tilapia
Problems: SULFADIAZINE;

16 X - - 06 Tilapia, Aquaculture Harvested Fishery/Seafood Products — Date Published: 03/04/2016
Desc:Tilapia
Problems: SULFADIAZINE;

Import Alert Petitions

Removal or Exemption from DWPE

Removal or Exemption from DWPE

What do you do if you find yourself or your supplier subject to DWPE?

PETITION!

Removal or Exemption from DWPE

- A firm will remain subject to DWPE unless it provides evidence to FDA that it is no longer at risk.

- Evidence is provided in the form of a petition sent to Division of Import Operations (DIO) to request removal.
  - May be 100+ pages in length.
  - Requires extensive documentary evidence.

Import Alert Petitions

Petition Requirements

Petition Requirements

- **Corrective Actions:** Documentary evidence that the problem has been corrected or prevented.
  - Corrective actions will vary depending upon the circumstances:
    - HACCP plan revisions
    - Change of suppliers
    - Label revisions
    - Lab analyses of every lot
    - Etc.

Petition Requirements

- **Shipments:** A series of non-violative shipments to verify that the corrective or preventive actions are sufficient.
  - Minimum of 5-12 routine commercial shipments spaced over a reasonable period of time.
  - Submission of shipping documents.
    - US Customs Form 3461 or 7501
    - Commercial Invoice
    - Packing List
    - Bill of Lading

Import Alert Petitions

FDA Review of Petitions

FDA Review of Petitions

- Division of Import Operations (DIO) reviews petitions in the order received.
  - Review periods can take several months.
  - FDA may request additional documentation or shipments during the course of the review.

FDA Review of Petitions

- If the petition is approved:
  - FDA will issue an approval letter to the submitter and notify all FDA district offices of the change in status.
  - Entries will no longer be subject to DWPE, but will remain subject to routine inspections.

- If the petition is denied:
  - FDA will issue a denial letter to the submitter including an explanation of the reason for denial.
  - Once any deficiencies have been corrected, a new petition may be submitted to FDA for further review.
  - No "penalty" for a denied petition.

DWPE Petition Assistance

- Assist the company to identify the cause of placement on Import Alert.
- Assist in the determination and implementation of certain types of corrective actions.
  - Label reviews, HACCP reviews, FCE/SID filing, registration, color batch certification, etc.
- Assist with FDA communications for each detained shipment after implementation of corrective actions.
- Develop petition for removal from DWPE and submit to FDA.
  - Provide an administrative review of documents regarding corrective actions and cleared shipments.
- Address FDA's questions during the review period.

Questions & Answers

How to Prepare for a Foreign FDA Food Facility Inspection

Presented by Rick Barham

Food Safety Specialist

October 25, 2016

Registrar Corp

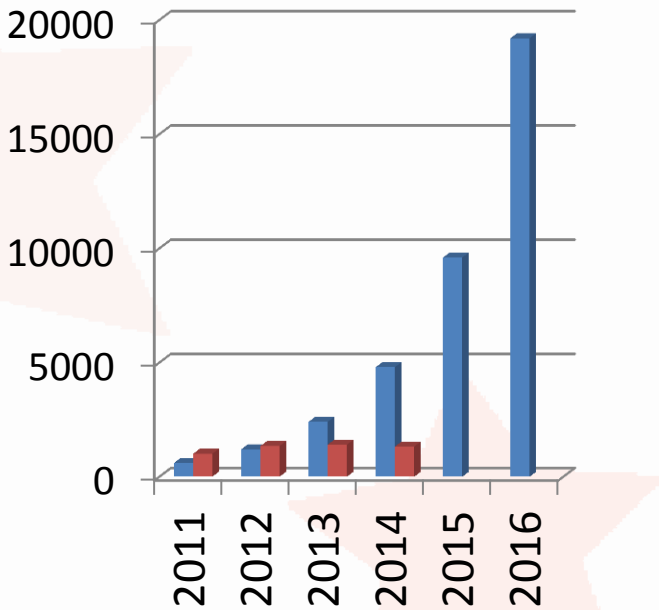
Why is FDA Conducting Foreign Inspections?

- Globalization has increased the volume of food imported into the United States and introduced a higher level of complexity for ensuring the safety of food.
- Today, about 15 percent of all food consumed in the United States is imported.
  - 80% of all seafood
  - 50% of fruits
  - 20% of vegetables

- **FSMA Mandate: Increase the number of routine inspections worldwide**

FSMA Foreign Facility Inspection Schedule

- 2011- 600 Foreign Inspections
- 2012- 1,200 Foreign Inspections
- 2013- 2,400 Foreign Inspections
- 2014- 4,800 Foreign Inspections (only completed 1,327 total in 2014)
- 2015- 9,600 Foreign Inspections (fewer than 1100 food inspections in 2015)
- 2016- 19,200 Foreign Inspections



NOTE: FDA is increasing the number of inspections globally. No one country, region, or company is being targeted for inspection.

Foreign Food Facility Inspection Selection

- Facility's risk profile:
  - Product Risk
  - Process Complexity
  - Facility compliance history (refusal rates, previous inspection results, etc.)
- New exporters shipping large volumes
- Convenience
  - typically FDA inspects 4-8 facilities on one trip

Foreign FDA Food Facility Inspections

- FDA inspections are designed to:
  - Identify food safety problems before products arrive in the U.S. or enter interstate commerce
  - Determine compliance status of facilities
  - Help FDA make admissibility decisions
  - Ensure that food products meet U.S. requirements under the FD&C Act.
- **Note:** An FDA establishment inspection is a careful, critical, official examination of a facility to determine its compliance with laws administered by FDA.

Inspection Process: "Notice of Inspection"

- Notice is sent by email to registrant's email as indicated in the food facility's FDA registration
- Notice is also sent to U.S. Agent via email
- Email will come from: @fda.hhs.gov

Inspection Process : "Notice of Inspection"

- Key Points:
  - 5 Days to Respond
  - Provide additional data
  - Refusal to respond or refusal to allow an inspection may cause "increased sampling, refusal of admission, or other regulatory action."

Inspection Process: "Factory Profile Information" Form

- Once you reply, FDA's Office of Regulatory Affairs will contact you:
  - May take days, weeks, or months (or never)
  - Coordinate inspection date
  - Ask you to complete and return a "Factory Profile Information" form to FDA
  - FDA will then come back with name of investigator, their flight info, ask you to make hotel reservations, and maybe even ask you to provide ground transportation.

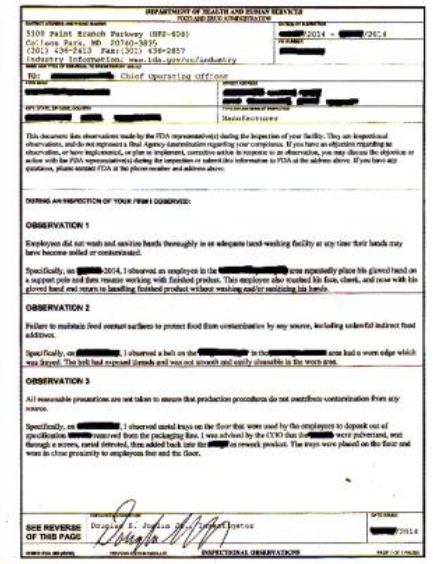
Inspection Process: Day 1

- Inspection is typically 2 days
- Day 1:
  - Introductions
  - Opening Meeting
  - Quick Tour
  - Document Review

Registrar Corp

Inspection Process: Day 2

- Day 2:
  - Most time spent in factory
  - Closing meeting with management
  - Delivery of form "483" "Inspectional Observations"



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

5100 Paint Branch Parkway (HFS-606)
College Park, MD 20740-3835
(301) 436-2413 Fax:(302) 436-2857
Industry Information: www.fda.gov/ora/industry

TO: [redacted] Chief Operating Officer

Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically, on [redacted] 2014, I observed an employee in the [redacted] area repeatedly place his gloved hand on a support pole and then resume working with finished product. This employee also touched his face, cheek, and nose with his gloved hand and return to handling finished product without washing and/or sanitizing his hands.

OBSERVATION 2

Failure to maintain food contact surfaces to protect food from contamination by any source, including unlawful indirect food additives.

Specifically, on [redacted], I observed a belt on the [redacted] in the [redacted] area had a worn edge which was frayed. The belt had exposed threads and was not smooth and easily cleanable in the worn area.

OBSERVATION 3

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically, on [redacted], I observed metal trays on the floor that were used by the employees to deposit out of specification [redacted] removed from the packaging line. I was advised by the COO that the [redacted] were pulverized, sent through a screen, metal detected, then added back into the [redacted] as rework product. The trays were placed on the floor and were in close proximity to employees feet and the floor.

SEE REVERSE OF THIS PAGE — Douglas S. Johnson, Director — [redacted] 2014

INSPECTIONAL OBSERVATIONS

Registrar Corp

Applicable FDA Regulations

- A single inspection may focus on multiple requirements
- For example, a canned tuna product may be inspected for compliance with:
  - Seafood HACCP (21 CFR 123)
  - Low Acid Canned Foods (21 CFR 113)
  - Current GMP (21 CFR 110) / **(21 CFR 117)**
  - Food Labeling (21 CFR 101)
  - Emergency Permit Control (21 CFR 108)

Preventive Controls for Human Foods

- 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
    - Not farms or retail food establishments
  - Applies to domestic and imported food
  - Some exemptions and modified requirements apply

Preventive Controls for Human Foods

- Updated the Current Good Manufacturing Practices
  - Protection against allergen cross-contact
  - Previous nonbinding provisions, such as education and training, are now binding
- Requires implementation of a food safety plan
  - Hazard Analysis
  - Prevention controls
  - Supply-chain controls
  - Recall plan
  - Procedures for monitoring
  - Corrective action procedures
  - Verification procedures
  - Recordkeeping
  - Reanalysis at least every three years

Food Safety Plan – Hazard Analysis

- Evaluation of hazards must include
  - Consideration of severity of illness/injury and probability of occurrence in absence of preventive controls
  - Evaluation of environmental pathogens for ready-to-eat foods exposed to the environment prior to packaging and the packaged does not receive a treatment or control measure to minimize significant pathogens
  - Consideration of effect of factors such as formulation, condition and design of facility and equipment, raw materials and other ingredients, transportation practices, sanitation, intended use, etc.

Food Safety Plan – Prevention Controls

- Measures required to ensure that hazards are significantly minimized or prevented. These include:
  - Process controls: maximum or minimum values, etc.
  - Food allergen controls: cross-contact, labeling, etc.
  - Sanitation controls: cleanliness of food-contact surfaces, etc.
  - Supply-chain controls: approved suppliers, verification, etc.
  - Recall plan: written procedures, public notification, etc.
- Include controls at critical control points (CCPs), if any, and controls other than those at CCPs that are appropriate for food safety

Preventive Controls for Animal Foods

- Establish Current Good Manufacturing Practices (CGMPs)
- Hazard Analysis and Risk-Based Preventive Controls
  - Each facility is required to implement a written food safety plan that focuses on preventing hazards in animal foods
- CGMPs include:
  - Personnel
  - Plant / Grounds
  - Sanitation
  - Water supply and plumbing
  - Equipment and utensils
  - Plant operations
  - Holding and Distribution
  - Holding and distribution of human food by-products for use as animal food

After the Inspection

- FDA will eventually classify the inspection:
  - No Action Indicated (NAI)
  - Voluntary Action Indicated (VAI) -
  - ***Official Action Indicated (OAI)***
- FDA discloses the final inspection classification in an online database

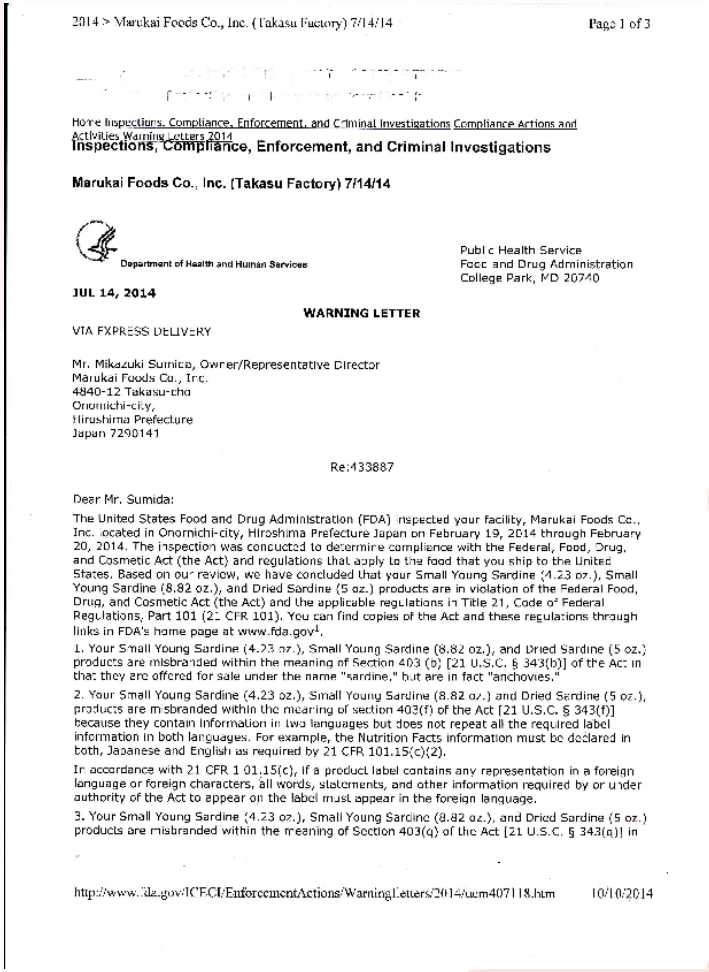
http://www.accessdata.fda.gov/scripts/inspsearch/

FDA Inspection Results

Firm Name	City	Country	Inspection End Date	Center	Project Area	Classification
Sejun Food Co., Ltd	Gwangju-si	KR	7/22/2014	CFSAN	Foodborne Biological Hazards	**OAI**
Hung Loi Manufacturing and Trading Co. Ltd.	Ho Chi Minh City	VN	4/11/2014	CFSAN	Foodborne Biological Hazards	**OAI**
TSUKEZEN SHOTEN CO.,LTD. KOBE IND.	Kobe-city	JP	7/23/2014	CFSAN	Foodborne Biological Hazards	**OAI**
BRODR. REMO AS	Fiskarstrand	NO	9/1/2014	CFSAN	Foodborne Biological Hazards	**OAI**
Maria Distribution Sarl	Dakar	SN	1/10/2014	CFSAN	Foodborne Biological Hazards	**OAI**
Inversiones Peru Pacifico S.A	Sullana	PE	2/4/2014	CFSAN	Foodborne Biological Hazards	**OAI**
Changsha Organic Herb Inc.	Changsha	CN	5/28/2014	CFSAN	Foodborne Biological Hazards	**OAI**

OAI Actions

- Warning Letter (which you could respond to) and perhaps a "Close Out Letter"
- Detentions at the port
- Registration suspension
- Re-inspection under FSMA



2014 > Marukai Foods Co., Inc. (Takasu Factory) 7/14/14 Page 1 of 3

Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters 2014

Inspections, Compliance, Enforcement, and Criminal Investigations

Marukai Foods Co., Inc. (Takasu Factory) 7/14/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

JUL 14, 2014

WARNING LETTER

VIA EXPRESS DELIVERY

Mr. Mikazuki Sumida, Owner/Representative Director
Marukai Foods Co., Inc.
4840-12 Takasu-cho
Onomichi-city,
Hiroshima Prefecture
Japan 7290141

Re:433887

Dear Mr. Sumida:

The United States Food and Drug Administration (FDA) inspected your facility, Marukai Foods Co., Inc. located in Onomichi-city, Hiroshima Prefecture Japan on February 19, 2014 through February 20, 2014. The inspection was conducted to determine compliance with the Federal, Food, Drug, and Cosmetic Act (the Act) and regulations that apply to the food that you ship to the United States. Based on our review, we have concluded that your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.), and Dried Sardine (5 oz.) products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find copies of the Act and these regulations through links in FDA's home page at www.fda.gov[1].

1. Your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.), and Dried Sardine (5 oz.) products are misbranded within the meaning of Section 403 (b) [21 U.S.C. § 343(b)] of the Act in that they are offered for sale under the name "sardine," but are in fact "anchovies."

2. Your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.) and Dried Sardine (5 oz.), products are misbranded within the meaning of section 403(f) of the Act [21 U.S.C. § 343(f)] because they contain information in two languages but does not repeat all the required label information in both languages. For example, the Nutrition Facts information must be declared in both, Japanese and English as required by 21 CFR 101.15(c)(2).

In accordance with 21 CFR 101.15(c), if a product label contains any representation in a foreign language or foreign characters, all words, statements, and other information required by or under authority of the Act to appear on the label must appear in the foreign language.

3. Your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.), and Dried Sardine (5 oz.) products are misbranded within the meaning of Section 403(q) of the Act [21 U.S.C. § 343(q)] in

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm407118.htm 10/10/2014

Recommendations

- Preparedness is critical
  - Most companies think they are prepared, but they're not. Having a review by an external expert is often highly beneficial
- Address simple to correct findings during the inspection process
- Respond to the 483 with evidential solutions, not with vague answers

Mock FDA Inspection Service

- Registrar Corp will send a Food Safety Specialist trained in FDA inspections to a foreign facility to help it prepare.
  - Typically 2 days per facility
  - Helps to identify potential food safety problems in the structure, processes, procedures and documentation used in a facility's daily production.
- U.S. Agent Clients: Free of charge, other than travel and lodging expenses, when FDA schedules an inspection.

Questions & Answers

Implementation Status of the Food Safety Modernization Act

Presented by Bracey Parr

Regulatory Advisor

October 25th, 2016

Registrar Corp

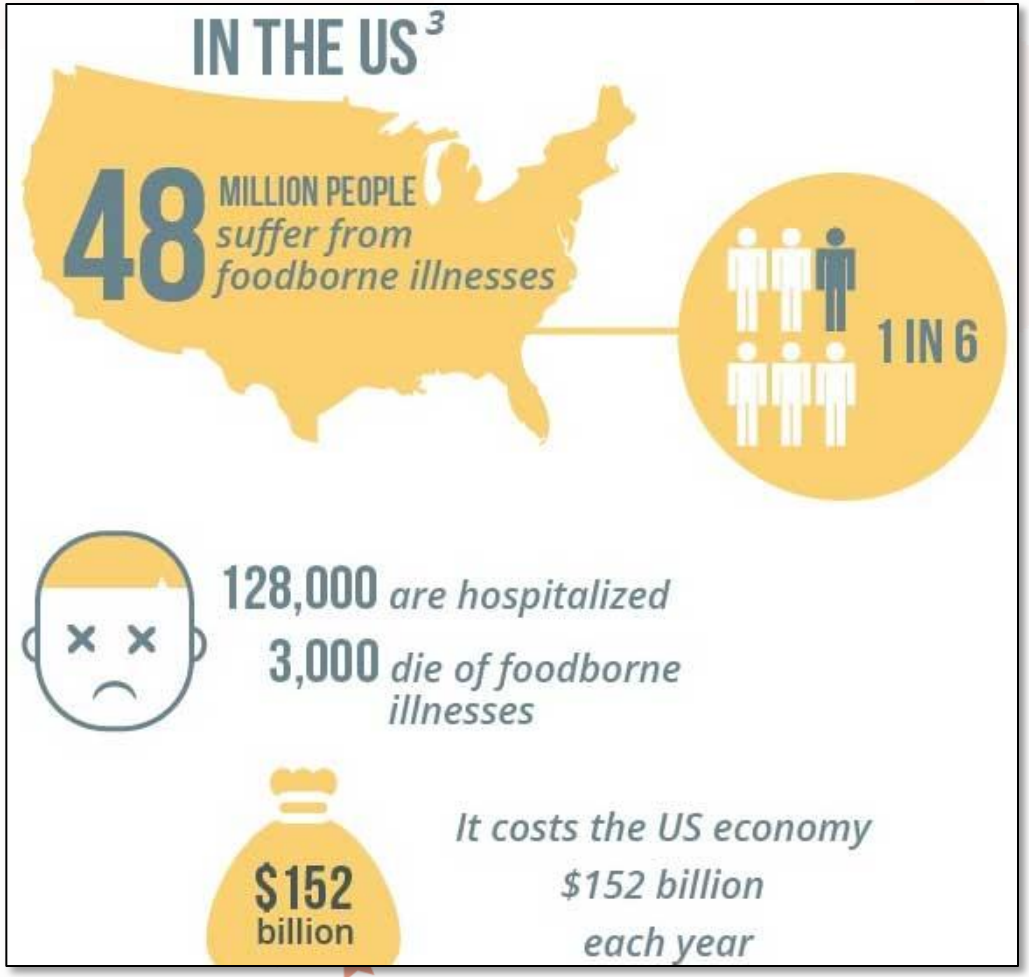
Presentation Overview

- History of FSMA
- Review of Major Rules
  - Preventive Controls for Human and Animal Food
  - Foreign Supplier Verification Program
- Current Implementation Status
- Summary / Questions & Answers

"The most sweeping reform…in 70 years"

History of FSMA

History of FSMA



History of FSMA

- June 8th, 2009 – Introduced in the House
- June 9th, 2009 – Passed by the House
- December 21st, 2010 – Passed by the Senate
- December 29th, 2010 – Resolved differences
- January 4th, 2011 – Signed by Pres. Obama
  - PL 111-353
- Sept. 17th, 2015 - First Final Rule published

PC Rules and FSVP

Review of Major Rules

Preventive Controls

Food Safety Plan

Preventive Controls

Preventive Controls

- Exemptions and modified requirements:
  - Retail establishments (restaurants and stores)
  - Qualified facilities
  - Juice and Seafood HACCP
  - Alcoholic beverages
  - Dietary supplements
  - USDA products
  - Farms
  - Unexposed, packaged food in warehouses

Preventive Controls

- Deadlines
- Food Safety Plan
  - Facilities with >500 full-time equivalent employees: September 19th, 2016
  - Small business (<500 employees): September 18th, 2017
- Qualified facility attestation
  - Qualified facilities and very small businesses: September 2018

FSVP – Written Program

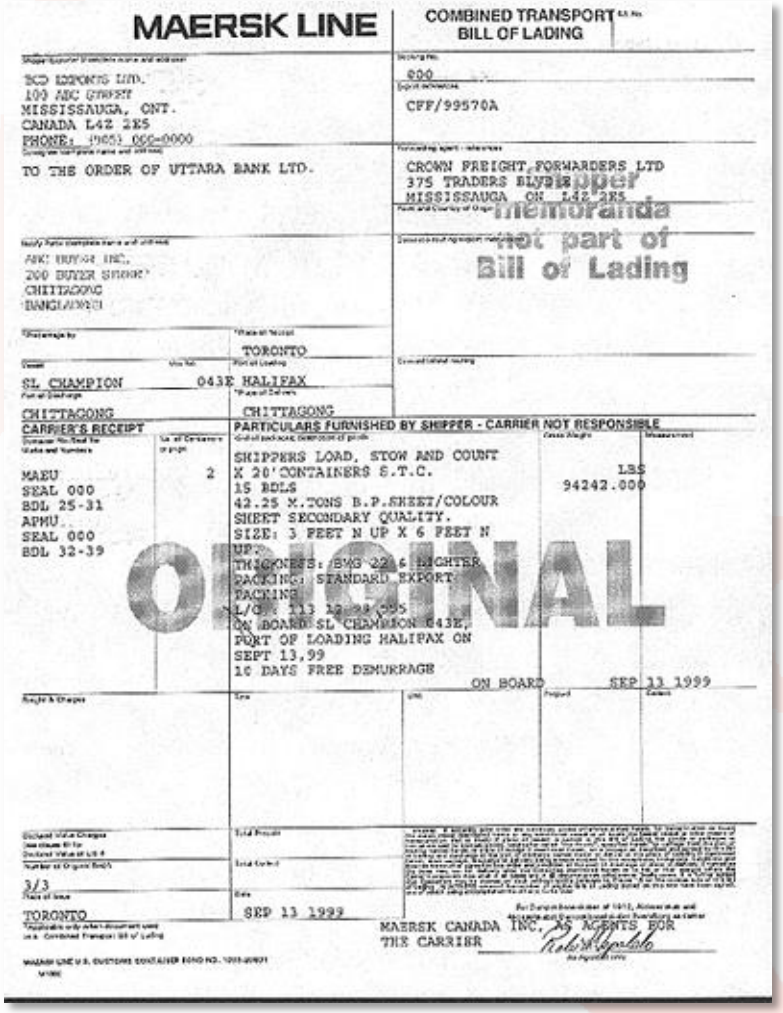
Foreign Supplier Verification Program

FSVP

- Qualified Individual

FSVP

- Who must comply?
  - "Importer": defined as owner or consignee
  - If there is no US owner or consignee, the "Importer" is the U.S. agent or representative of the foreign owner or consignee, as confirmed in a signed statement of consent.



MAERSK LINE

COMBINED TRANSPORT BILL OF LADING

SCD IMPORTS LTD.
100 ABC STREET
MISSISSAUGA, ONT.
CANADA L4Z 2E5
PHONE: (905) 000-0000

000

CFF/99570A

TO THE ORDER OF UTTARA BANK LTD.

CROWN FREIGHT FORWARDERS LTD
375 TRADERS BLVD E
MISSISSAUGA ON L4Z 2E5

Shipper Memoranda
Not part of Bill of Lading

ABC IMPORT INC.
200 BUYER STREET
CHITTAGONG
BANGLADESH

TORONTO

SL CHAMPION 043E HALIFAX

CHITTAGONG

CARRIER'S RECEIPT

PARTICULARS FURNISHED BY SHIPPER - CARRIER NOT RESPONSIBLE

MAEU
SEAL 000
BDL 25-31
APMU
SEAL 000
BDL 32-39

2

SHIPPERS LOAD, STOW AND COUNT
X 20' CONTAINERS S.T.C.
15 BDLS
42.25 M.TONS B.P.SHEET/COLOUR
SHEET SECONDARY QUALITY.
SIZE: 3 FEET N UP X 6 FEET N
UP.
THICKNESS: BWG 22/26 LIGHTER
PACKING: STANDARD EXPORT
PACKING
L/C : 113 13 00 095
ON BOARD SL CHAMPION 043E,
PORT OF LOADING HALIFAX ON
SEPT 13,99
10 DAYS FREE DEMURRAGE

LBS
94242.000

ORIGINAL

ON BOARD SEP 13 1999

3/3

TORONTO

SEP 13 1999

MAERSK CANADA INC. AS AGENTS FOR
THE CARRIER

Registrar Corp

FSVP

- Exemptions
  - Firms subject to juice or seafood HACCP regulations
  - Very small importers ($1 million human/$2.5 million animal)
  - Food for research or evaluation; Food for personal consumption
  - Alcoholic beverages and ingredients
  - Food transshipped through U.S.
  - Meat, poultry, and egg products subject to USDA regulation at time of importation
  - Country with equivalent food safety system

FSVP

- When must I comply?
  - Latest of these dates
    - May 2017
    - Six months after supplier is required to become compliant
    - Date the importer must comply with those supply-chain provisions

FSVP

- New information required in the Automated Commercial Environment
  - Name of FSVP importer
  - E-mail address
  - Unique facility identifier

FSMA

Current Implementation Status

Current Implementation Status

7 MAJOR FSMA RULES	PUBLICATION DATE
Preventive Controls for Human Food	September 17th, 2015
Preventive Controls for Animal Food	September 17th, 2015
Produce Safety	November 27th, 2015
Foreign Supplier Verification Program (FSVP)	November 27th, 2015
Third Party Certification	November 27th, 2015
Voluntary Qualified Importer Program (VQIP)	Draft Guidance – June 4th, 2015
Sanitary Transport	April 6th, 2016
Intentional Adulteration	May 27th, 2016

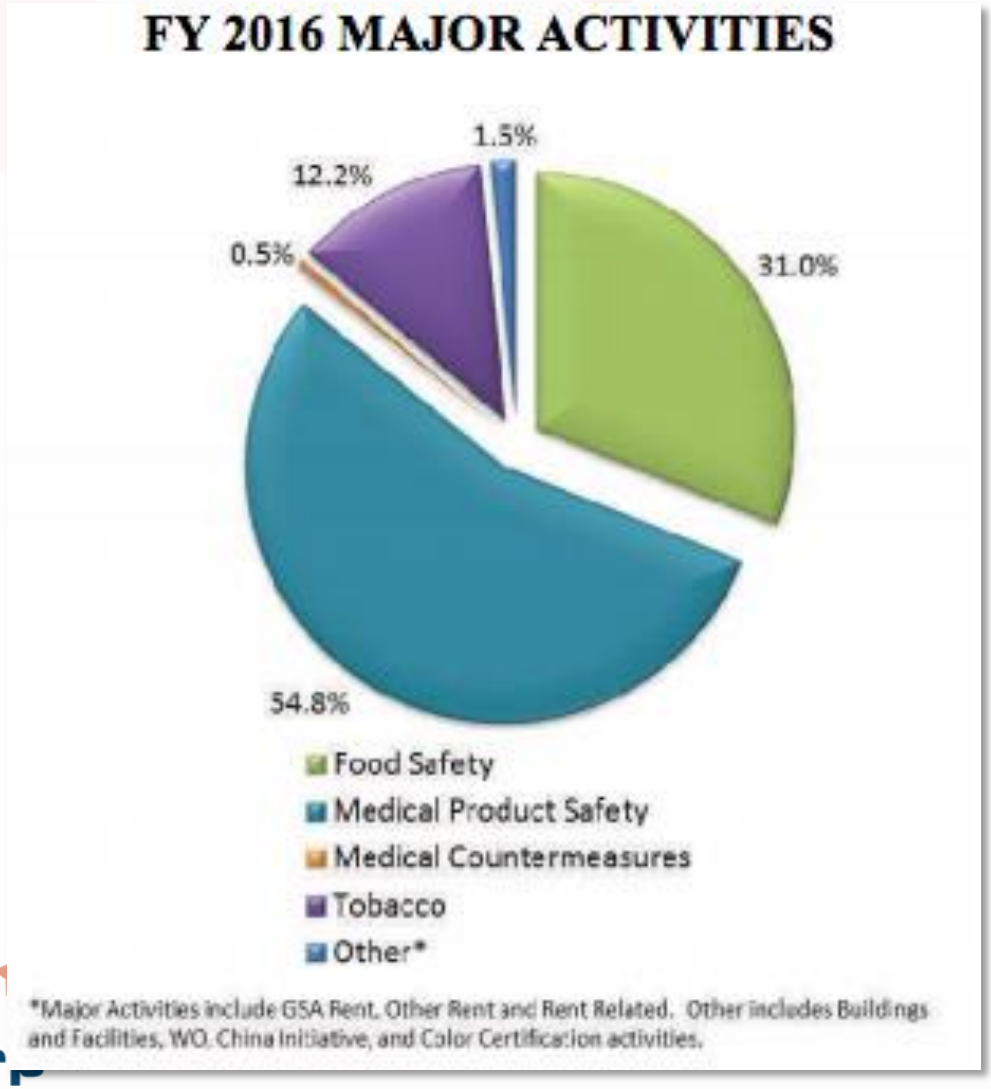
FDA FOOD SAFETY MODERNIZATION ACT

Current Implementation Status

FDA FOOD SAFETY
MODERNIZATION ACT

Registrar Corp

Current Implementation Status



Current Implementation Status

- Authority granted immediately
  - Administrative detention if "reason to believe" food may be adulterated or misbranded
  - Mandatory recall for a contaminated food
  - Changes to registration
    - Renewal
    - E-mail of contact person or US agent
    - Suspension authority

Current Implementation Status

- Authority granted immediately
  - Protections for whistle blowers at food facilities
  - Fees
    - Reinspection (2017 - $221 per hour; $285 per hour [foreign])
    - Non-compliance with a recall order (same)

Current Implementation Status

- Preventive Controls for Human Food Rule
  - Draft Rule: January 16th, 2013
  - Final Rule: Sept. 17th, 2015
  - Draft Qualified facility attestation guidance: May 16th, 2016
  - Deadline clarifications: August 24th, 2016
  - First deadline: Sept. 19th, 2016
    - Subject companies with more than 500 full-time equivalent employees

Current Implementation Status

- Foreign Supplier Verification Program
  - Draft Rule: July 29th, 2013
  - Final Rule: Nov. 27th, 2015
  - Deadline clarifications: August 24th, 2016
  - First deadline: May 30th, 2017
    - FSVPs for PC-rule subject suppliers with more than 500 full-time equivalent employees
  - Guidance: Forthcoming

Current Implementation Status

- Animal Food
  - cGMPs: Sept. 19th, 2016; PC: Sept. 18th, 2017
- Produce Safety
  - First deadline: (Sprouts) Nov. 27th, 2016
- Sanitary Transport
  - First deadline: April 26th, 2017
- Intentional Adulteration
  - First Deadline: May 28th, 2019

Current Implementation Status

- Third Party Certification
  - July 2015: Released guidance
  - Fees for Accreditation Bodies and Certification Bodies
- Voluntary Qualified Importer Program
  - June 2015: Released guidance
  - Estimated fee: $16,400 (first year)
  - Jan. 2018: Accept applications
  - Oct. 2018: Program begins

Assistance with FSMA Requirements

- FSMA Wizard: www.fsmawizard.com
  - Free tool to help identify your possible requirements
- FDA Compliance Monitor: www.fdamonitor.com
  - Monitor suppliers for Import Alerts, Warning Letters, Inspection Classifications, Import Refusals
- Food Safety Plans
- Foreign Supplier Verification Programs (FSVPs)
- Food Defense Plans

Questions & Answers

Registrar Corp's Solutions

- Registrar Corp provides a full range of fixed-fee compliance services:
  - Registration & U.S. Agent Service
  - Prior Notice Filings
  - Label, Ingredient, and Product Review
  - LACF and Food Safety Services (Mock FDA Inspections)
  - FSMA Compliance Services
  - Detention Assistance
  - DWPE Petition Submissions
  - FDA Compliance Monitor

Registrar Corp Worldwide Offices

Contact Us

Registrar Corp Headquarters

144 Research Drive

Hampton, Virginia

USA 23666

P: +1-757-224-0177

F: +1-757-224-0179

info@registrarcorp.com

www.registrarcorp.com