FDA MADE EASY

November 2017

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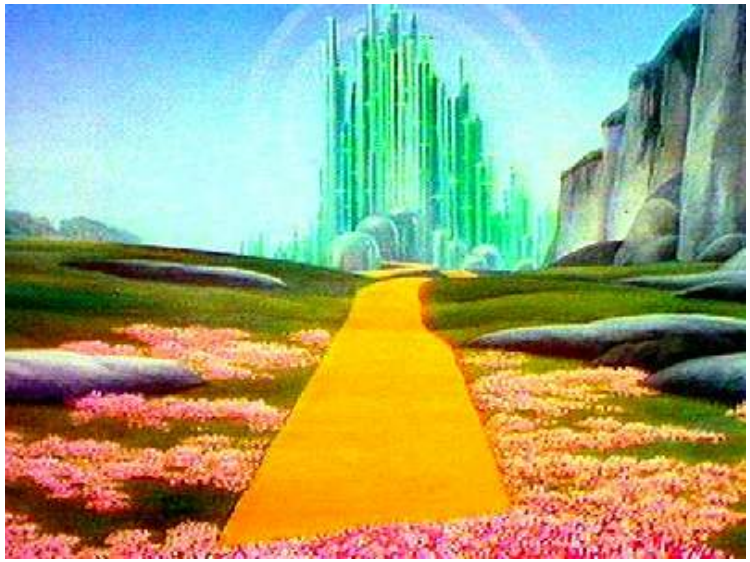
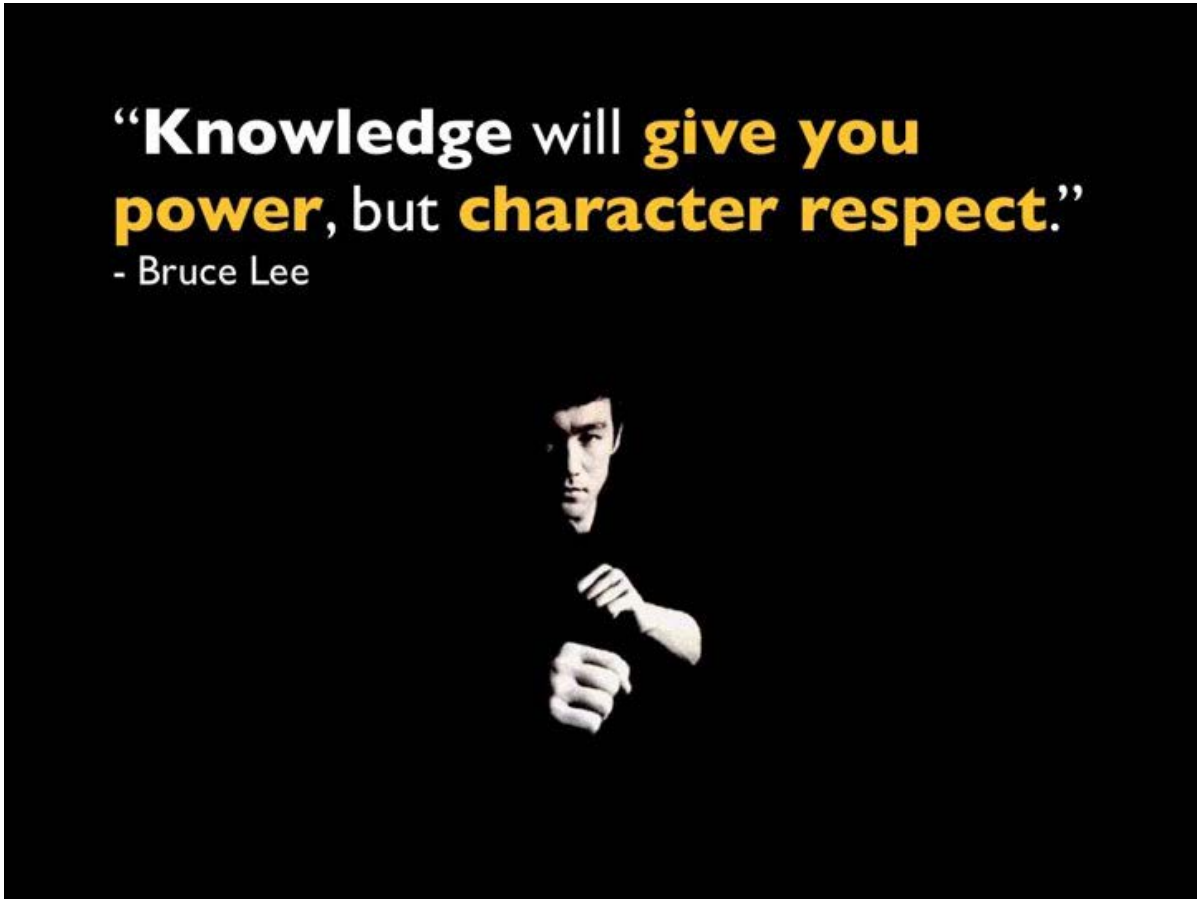
Registrar Corp

The Goal

Clear U.S. Customs and U.S. FDA without detention
Conduct Business in the USA Profitably and Competitively



First Advice



PREDICT

PREDICT establishes a risk score by analyzing shipment information according to FDA-developed risk criteria

Word to the Wise:

The Best Way to Stay Out of Trouble with FDA is To Stay Out of Trouble With FDA!

BASIC REQUIREMENTS FOR FOOD

- Facilities must be registered with FDA biennially, with Designation of “US Agent” and Consent to Inspection

- Food must be labeled properly-New Rules!!!!!

- Good Manufacturing Practices and FSMA

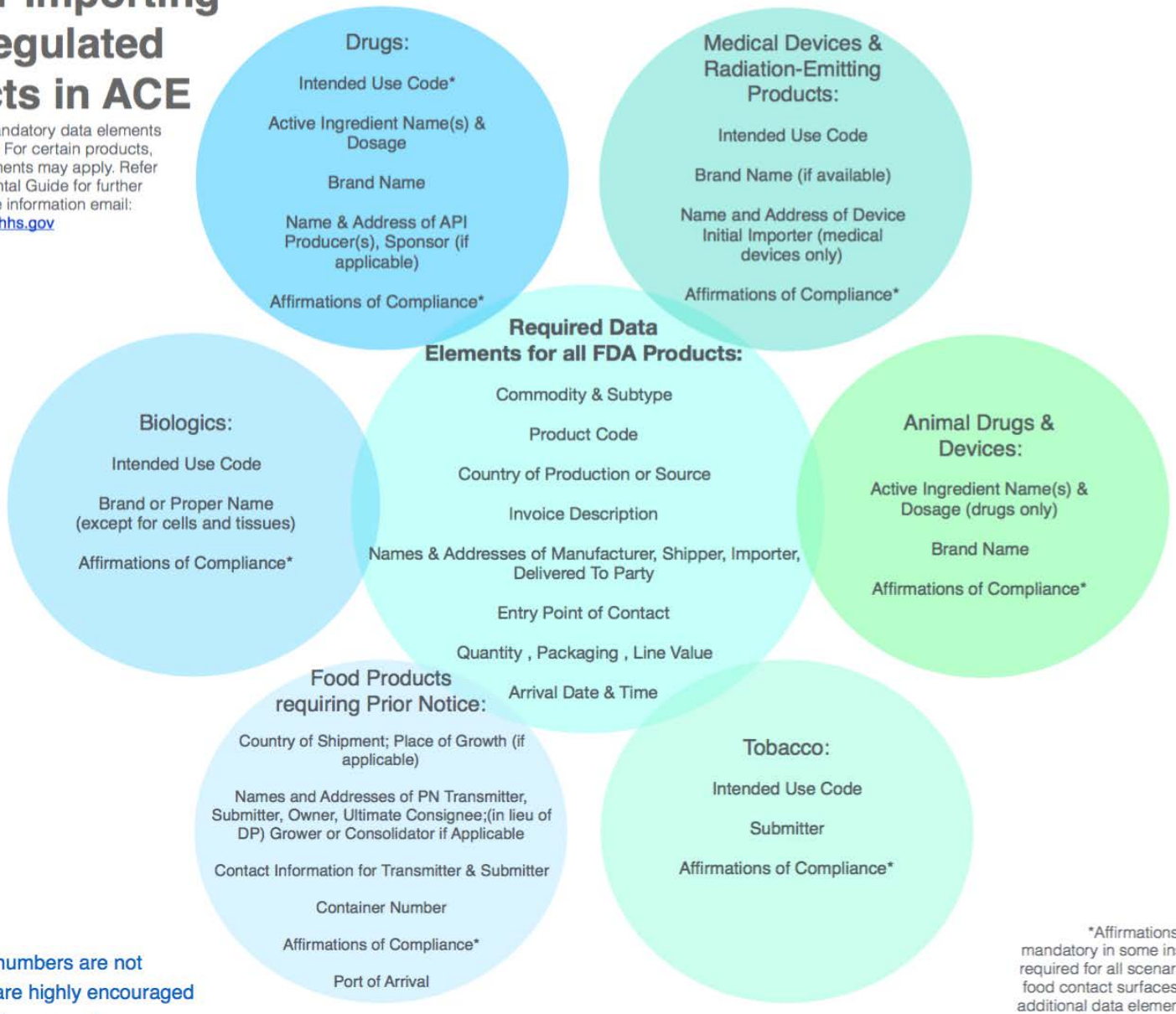
- For shelf-stable, sealed foods, “FCE” registration and process filing may be required

- Prior Notice Before Each Entry of Imported Food

Tips for Importing FDA-Regulated Products in ACE

FDA Division of Compliance Systems 2016

Diagram depicts mandatory data elements by commodity-type. For certain products, additional data elements may apply. Refer to FDA's Supplemental Guide for further specificity For more information email: ACE_Support@fda.hhs.gov



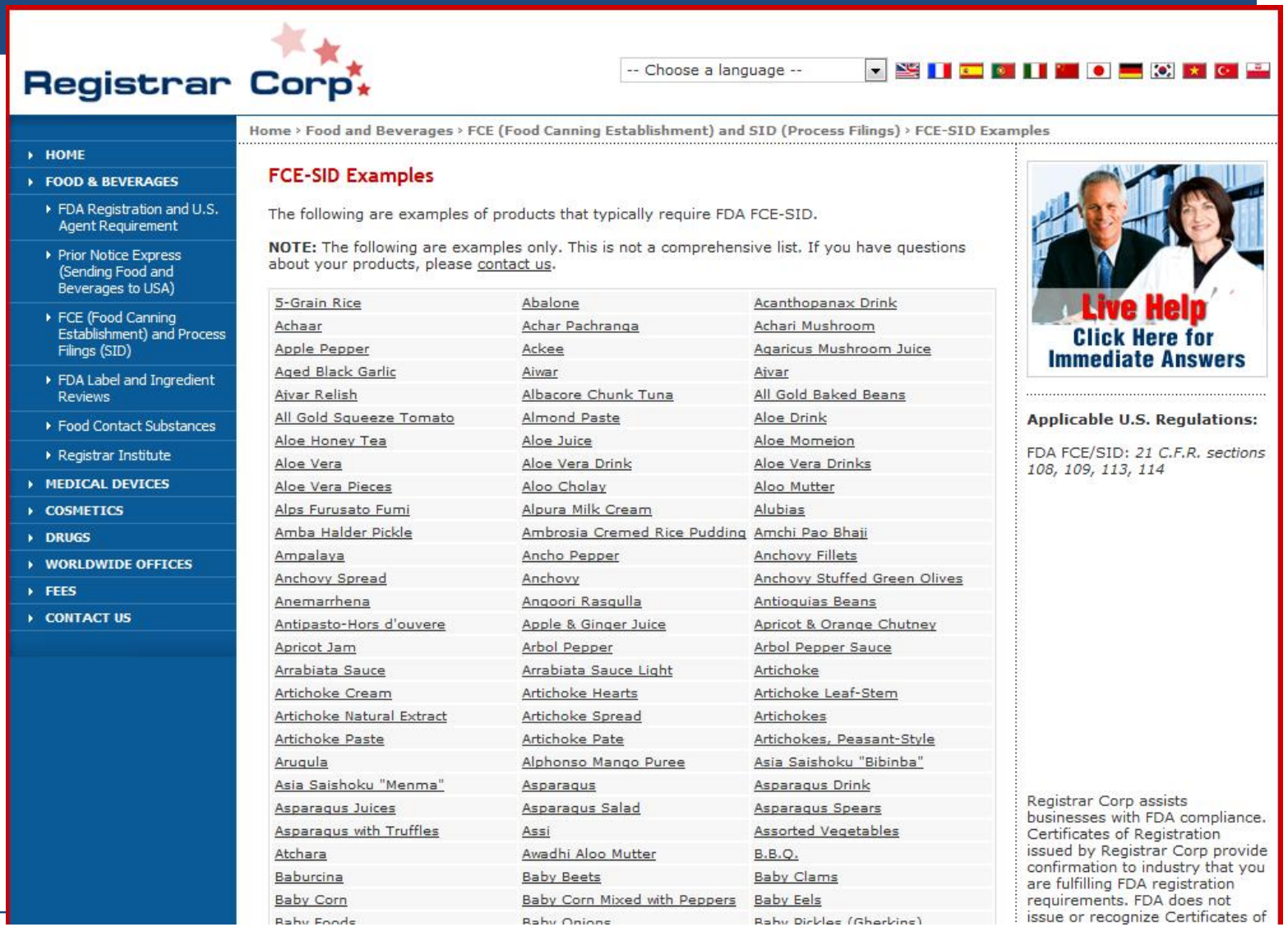
**DUNS or FEI numbers are not mandatory but are highly encouraged and may expedite processing.

*Affirmations of Compliance are mandatory in some instances but are not required for all scenarios. Cosmetics and food contact surfaces do not require any additional data elements other than those listed in the center of the diagram.

Food Canning Establishment (FCE)
Low Acid and Acidified Foods (LACF)

Rule of thumb...

If it must be refrigerated after opening, it probably requires a process filing.



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-- Choose a language --

- HOME
- FOOD & BEVERAGES
  - FDA Registration and U.S. Agent Requirement
  - Prior Notice Express (Sending Food and Beverages to USA)
  - FCE (Food Canning Establishment) and Process Filings (SID)
  - FDA Label and Ingredient Reviews
  - Food Contact Substances
  - Registrar Institute
- MEDICAL DEVICES
- COSMETICS
- DRUGS
- WORLDWIDE OFFICES
- FEES
- CONTACT US

Home › Food and Beverages › FCE (Food Canning Establishment) and SID (Process Filings) › FCE-SID Examples

FCE-SID Examples

The following are examples of products that typically require FDA FCE-SID.

NOTE: The following are examples only. This is not a comprehensive list. If you have questions about your products, please contact us.

5-Grain Rice	Abalone	Acanthopanax Drink
Achaar	Achar Pachranga	Achari Mushroom
Apple Pepper	Ackee	Agaricus Mushroom Juice
Aged Black Garlic	Aiwar	Ajvar
Ajvar Relish	Albacore Chunk Tuna	All Gold Baked Beans
All Gold Squeeze Tomato	Almond Paste	Aloe Drink
Aloe Honey Tea	Aloe Juice	Aloe Momejon
Aloe Vera	Aloe Vera Drink	Aloe Vera Drinks
Aloe Vera Pieces	Aloo Cholay	Aloo Mutter
Alps Furusato Fumi	Alpura Milk Cream	Alubias
Amba Halder Pickle	Ambrosia Cremed Rice Pudding	Amchi Pao Bhaji
Ampalaya	Ancho Pepper	Anchovy Fillets
Anchovy Spread	Anchovy	Anchovy Stuffed Green Olives
Anemarrhena	Angoori Rasgulla	Antioquias Beans
Antipasto-Hors d'ouvere	Apple & Ginger Juice	Apricot & Orange Chutney
Apricot Jam	Arbol Pepper	Arbol Pepper Sauce
Arrabiata Sauce	Arrabiata Sauce Light	Artichoke
Artichoke Cream	Artichoke Hearts	Artichoke Leaf-Stem
Artichoke Natural Extract	Artichoke Spread	Artichokes
Artichoke Paste	Artichoke Pate	Artichokes, Peasant-Style
Arugula	Alphonso Mango Puree	Asia Saishoku "Bibinba"
Asia Saishoku "Menma"	Asparagus	Asparagus Drink
Asparagus Juices	Asparagus Salad	Asparagus Spears
Asparagus with Truffles	Assi	Assorted Vegetables
Atchara	Awadhi Aloo Mutter	B.B.Q.
Baburcina	Baby Beets	Baby Clams
Baby Corn	Baby Corn Mixed with Peppers	Baby Eels
Baby Foods	Baby Onions	Baby Pickles (Gherkins)

Applicable U.S. Regulations:

FDA FCE/SID: *21 C.F.R. sections 108, 109, 113, 114*

Registrar Corp assists businesses with FDA compliance. Certificates of Registration issued by Registrar Corp provide confirmation to industry that you are fulfilling FDA registration requirements. FDA does not issue or recognize Certificates of

Registrar Corp

Labeling Changes

Nutrition Facts

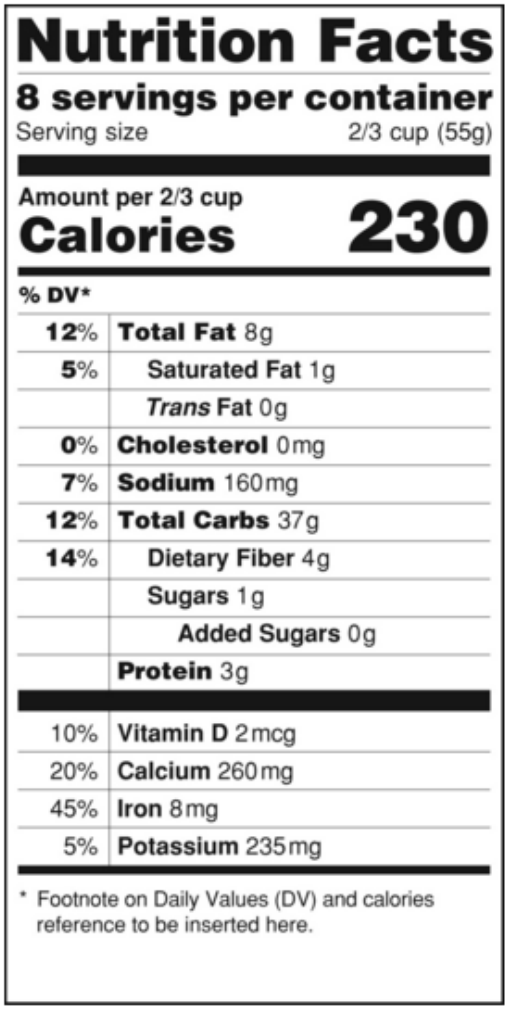
Serving Size 2/3 cup (55g)
Servings Per Container About 8

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



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.

Important: Serving Sizes Have Changed for Many Foods

FDA FOOD SAFETY MODERNIZATION ACT

Background

TIMELINE OF U.S. FOOD REGULATION

Until 1906

"The Jungle"

Background

TIMELINE OF U.S. FOOD REGULATION
1906 Meatpacking Scandal
The Pure Food and Drug Act

FDA FOOD SAFETY MODERNIZATION ACT ("FSMA")

1938

The Food, Drug and Cosmetic Act

Statutory Mandate to FDA Concerning Food:

Respond to Food Safety Violations

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

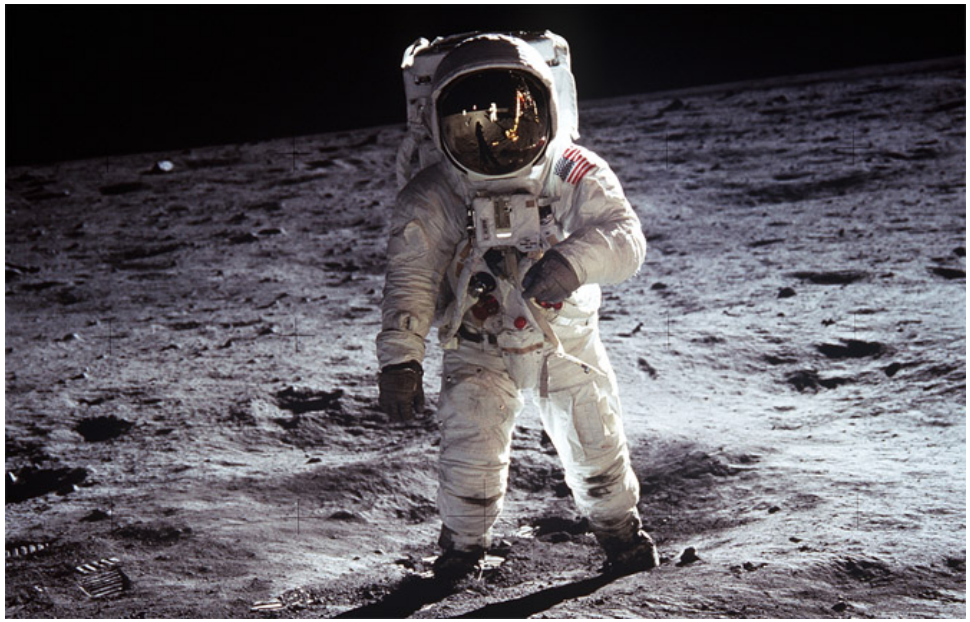
ntry Number: 000-0000000-0

Notice Number: 3

March 1, 2010

FDA Food Safety Modernization Act (FSMA)

"HACCP": Hazard Analysis and Critical Control Points



FDA Food Safety Modernization Act (FSMA)

"HACCP": Hazard Analysis and Critical Control Points

Howard Bauman

Paul Lachance

Background

FDA FOOD SAFETY MODERNIZATION ACT (“FSMA”)

Enacted by Congress and signed into law on January 4, 2011

New Mandate: Prevent Foodborne Illness

FDA Food Safety Modernization Act (FSMA)

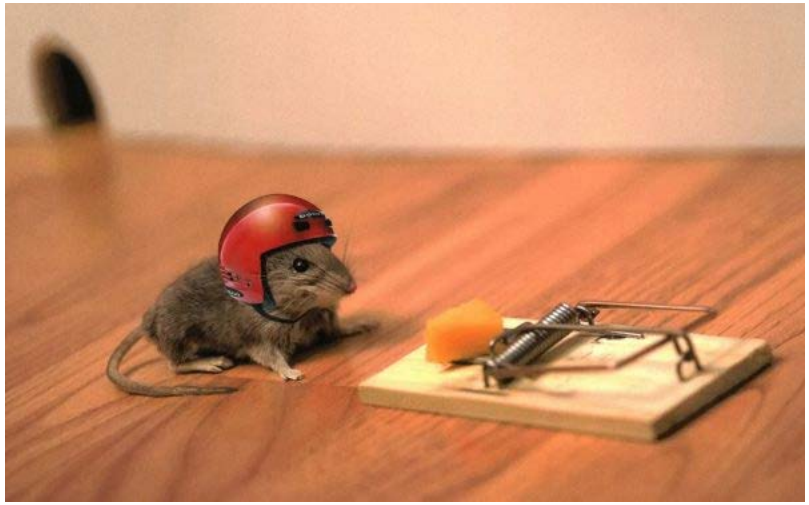
THE LAW REQUIRED FDA TO ISSUE SEVEN MAJOR SETS OF RULES

Preventive Controls for Human Food
Preventive Controls for Animal Food
Produce Safety
Foreign Supplier Verification Program
Third Party Auditor
Sanitary Transport
Intentional Adulteration

FDA Food Safety Modernization Act (FSMA)

Hazard Analysis and
Risk–based
Preventive Controls

("HARPC")



Foreign Supplier Verification Program (FSVP)

"Importers" must provide adequate assurances that:

Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions

-and-

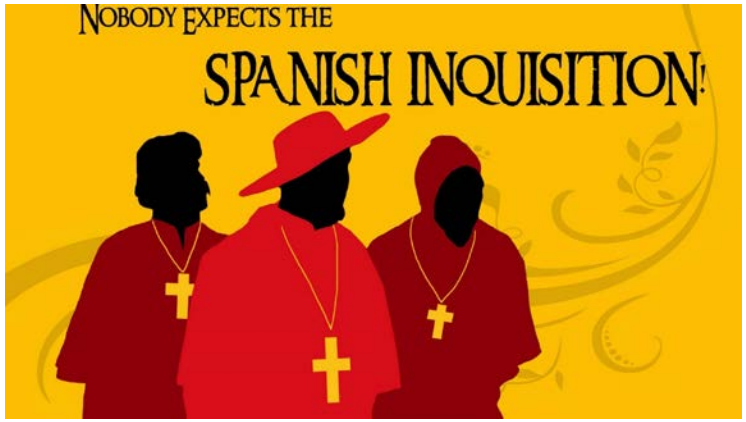
Food is not adulterated or misbranded (as to allergen labeling)

Foreign Supplier Verification Program (FSVP)

Food: Importer identification at entry

FSV, FSX, RNE
DUNS

Foreign Supplier Verification Program (FSVP)



FDA will inspect FSVP importers

"Importer" defined as US owner or consignee of food at the time of entry.

U.S. owner or consignee means the person in the United States who, at the time of U.S. entry, either **(i) owns the food, (ii) has purchased the food, or (iii) has agreed in writing to purchase the food.**

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 signed statement of consent.

FOOD SAFETY MODERNIZATION ACT FOREIGN SUPPLIER VERIFICATION PROGRAM

General Requirements of the FSVP

A "Qualified Person" Must Perform the Following:

*Hazard Analysis

* Approval and compliance status review of suppliers)

*Supplier Verification Activities, including audit if necessary

*Corrective Actions

*Periodic Reassessment of FSVP

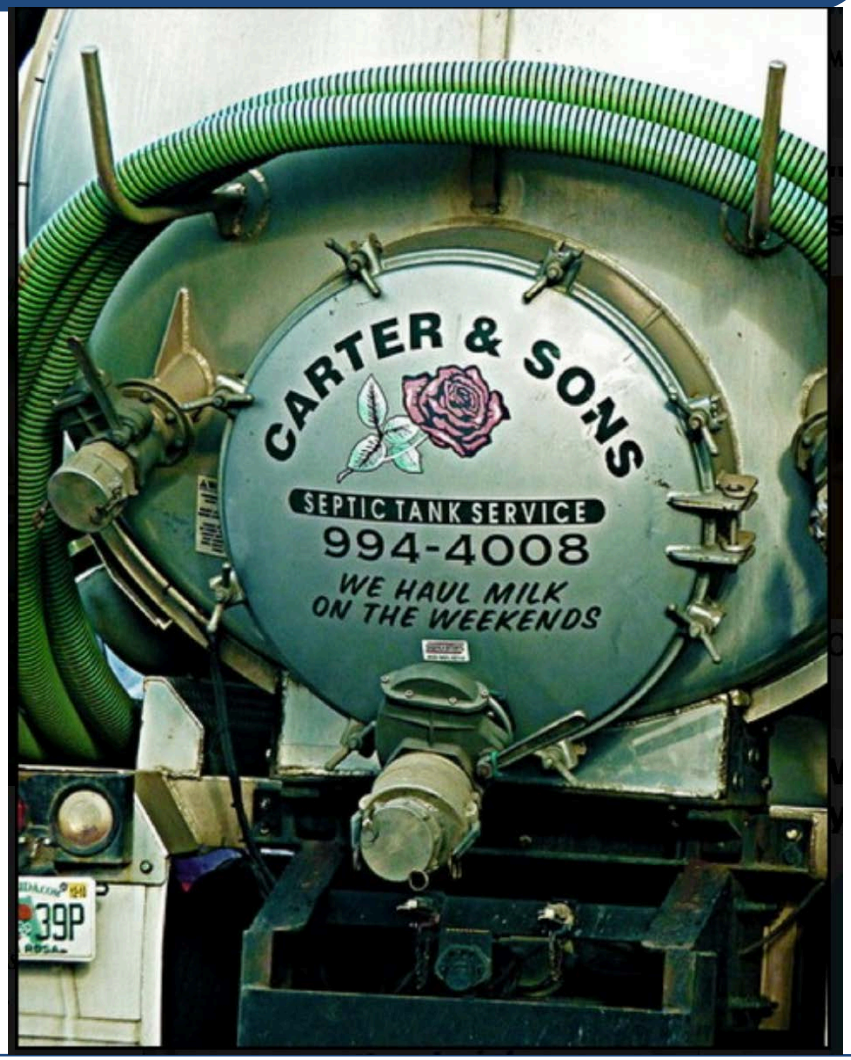
*Importer Identification at Entry

*Record-keeping

Hazard Analysis

Hazard identification must consider known or reasonably foreseeable biological, chemical and physical hazards:

- Naturally occurring
- Produced unintentionally
- Introduced intentionally for economic gain



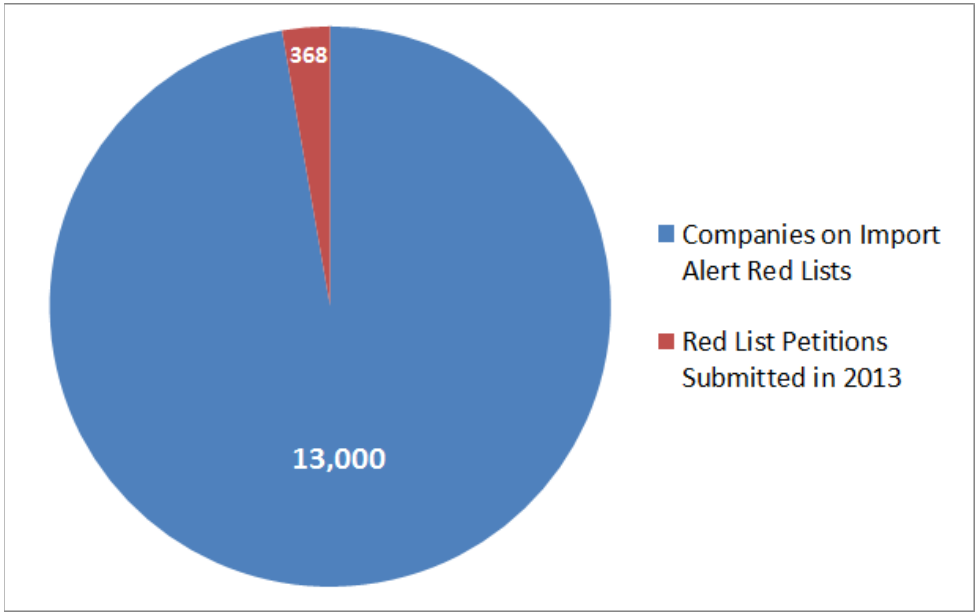
Approval and Compliance Monitoring of Suppliers

To approve suppliers, Importers must consider:

-Risk posed by the food (hazard analysis)

-Entities controlling hazards or verifying control

-Supplier characteristics (procedures and practices; FDA compliance history, Warning Letters, Import Alerts)



Foreign Supplier Verification Program (FSVP)

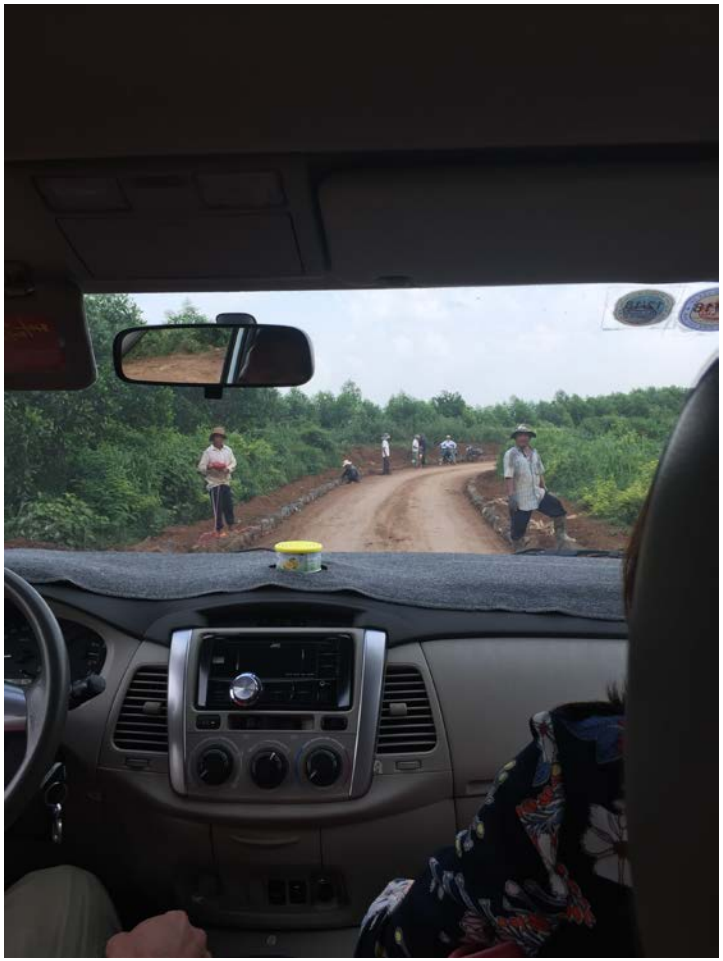
Supplier Verification Activities

- Procedures to ensure food is obtained from approved suppliers

- Determine appropriate verification activities (and frequency) based on food and supplier evaluation

- Activities may include: onsite auditing; sampling and testing; review of supplier records; other appropriate measures

Annual onsite auditing is default approach when a food has a SAHCODHA hazard (Serious Adverse Health Consequences or Death to Humans or Animals).



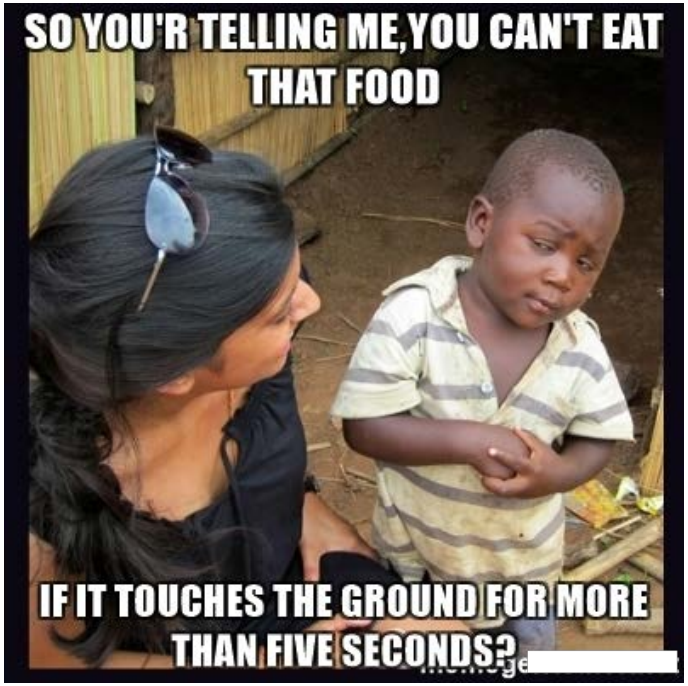
Foreign Supplier Verification Program (FSVP)

Special Circumstances

The food cannot be consumed without application of control (e.g., coffee beans)

Hazard controlled by importer's customer or subsequent entity in US distribution.

Required Extras:
Disclosure statement
Written assurance
Other system to ensure control of hazard at subsequent distribution step



Foreign Supplier Verification Program (FSVP)

Supplier Verification Activities

May rely on another entity's determination or performance of appropriate verification activities (e.g., farm audits by produce distributor, BRC, inspection by FDA)

Must review and assess results of verification activities (importer's own or others on which it relies)

Foreign Supplier Verification Program (FSVP)

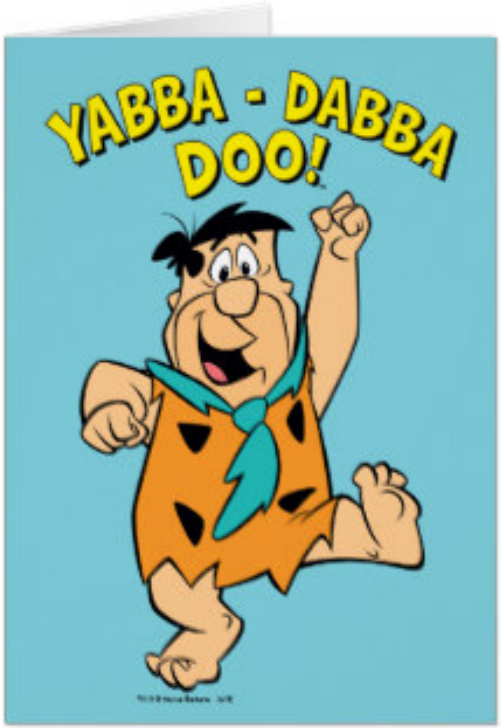
Countries With Equivalent Food Safety Systems

Importer must document that:

Foreign supplier is under oversight of comparable or equivalent food safety system.

Food is within scope of official recognition or determination.

Supplier is in good compliance standing with comparable or equivalent food safety authority.



CFIA

On 9/21/2017 11:43 AM, Owen, Tyana (CFIA/ACIA) wrote:

Dear Mr. Parr,

Thank you for your enquiry regarding Canadian exports to the U.S. under the Foreign Supplier Verification Program. The Canadian Food Inspection Agency (CFIA) is working with the United States Food and Drug Administration (US FDA) to determine how Canadian exporters can provide assurance that the food being exported to the U.S. is safe.

As you may be aware, Canada and the U.S. have a Food Safety Systems Recognition Arrangement that recognizes systems equivalence and therefore importers of food from Canadian manufacturers can benefit from modified requirements under the FSVP. This Arrangement applies to foods regulated by the US FDA including fruit and vegetables, shelled eggs, dairy (except Grade "A" milk/milk products), fish (except farmed catfish/catfish products & molluscan shellfish), maple, honey and processed products and also manufactured goods.

Until the CFIA receives clarification on this requirement, products shipped to the U.S. may be asked by their importers to provide assurances of food safety in the same manner that exporters from other countries without an Arrangement also would require.

The CFIA is waiting for further guidance on what that means to Canadian businesses, and will update the requirements on our webpages once we are aware.

Sincerely,
Tyana Owen
Policy Analyst, Food Import Export Division
Canadian Food Inspection Agency / Government of Canada

CFIA

From: Owen, Tyana (CFIA/ACIA) <Tyana.Owen@inspection.gc.ca>
Date: Thu, Oct 12, 2017 at 4:13 PM
Subject: RE: FW: ACTION DUE: Sep 8 | List of Canadian facilities in good standing with CFIA
To: Bracey Parr <bparr@registrarcorp.com>
Cc: "Flohr, Rick (CFIA/ACIA)" <Rick.Flohr@inspection.gc.ca>, "Hazel, Doug (CFIA/ACIA)" <Doug.Hazel@inspection.gc.ca>, "Miller, Daniel (CFIA/ACIA)" <Daniel.Miller@inspection.gc.ca>

Hi Mr. Parr,

The CFIA is still working with the USFDA to determine what meets the good standing requirements of the modified food safety systems recognition arrangement between CFIA and USFDA. The USFDA will determine the criteria for good standing rather than the CFIA, and then we will publish this information on our website once it has been confirmed.

Don’t apologise for contacting us, your patience on this matter is appreciated. Once again, please let me know if any of your exporters incur any issues at the border and we can provide assistance.

Sincerely,

Tyana Owen
Policy Analyst, Food Import Export Division
Canadian Food Inspection Agency / Government of Canada

Foreign Supplier Verification Program (FSVP)

FSVP EXEMPTIONS

Firms subject to juice or seafood HACCP regulations

Food for research or evaluation

Food for personal consumption

Alcoholic beverages and ingredients (when importer uses them to make an alcoholic beverage)

Food transshipped through U.S.

Food imported for processing and export

“U.S. food returned”

Meat, poultry, and egg products subject to USDA regulation at time of importation

Foreign Supplier Verification Program (FSVP)

Small Businesses

Very small importer (VSI)
Less than $1 million/yr. in human food sales
Less than $2.5 million/yr. in animal food sales

Food from certain small suppliers
Qualified facility (same $ as VSI)
Produce from certain small suppliers that are not covered farms
Shell egg producers with < 3,000 laying hens

Preventive Controls for Human Food

Who is Covered?

Most food facilities that are required to register with FDA
(Facilities that manufacture, process, pack or hold food)

Some exemptions and modified requirements may apply (seafood, juices, alcoholic beverages, low acid and acidified foods, storage facilities, companies with annual sales or inventory < $1M)

Farms May Be Subject to the FSMA Produce Safety Final Rule!

Food Safety Plan

Must be written by one or more “preventive controls qualified individuals” and signed by owner, operator or agent in charge

Must include:

- Hazard analysis
- Preventive controls
- Supply-chain program
- Recall plan
- Procedures for monitoring
- Corrective action procedures
- Verification procedures

“Preventive Controls Qualified Individual”

A “**preventive controls qualified individual** is a “qualified individual” who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

“**Qualified individual**” means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Reanalysis of Food Safety Plan

At least every three years

Whenever there is a significant change that creates the potential for a new hazard or a significant increase in one previously identified

When there is new information about potential hazards associated with a food

When a preventive control is ineffective

Food Safety Plan – Monitoring

The facility must have written procedures for monitoring the preventive controls

Including the frequency they are to be performed

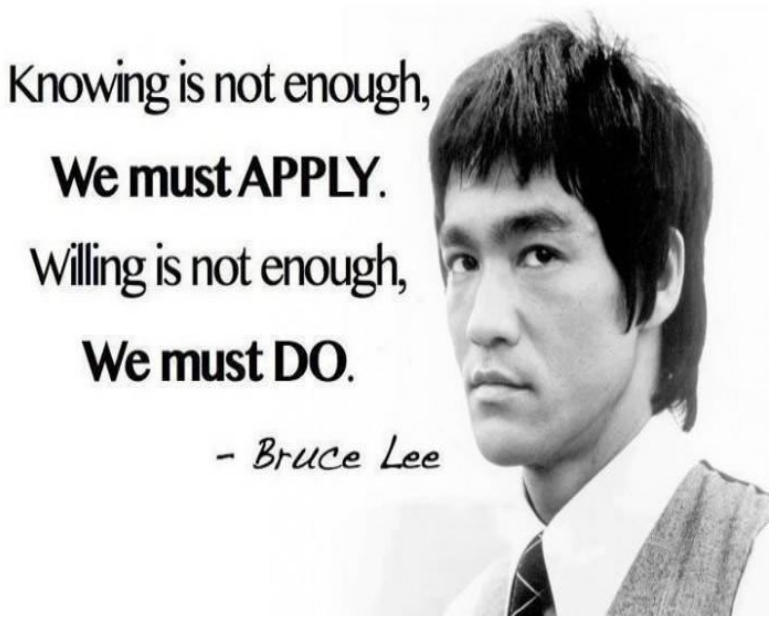
Appropriate to the nature of the preventive control

Monitoring must be documented in records and are subject to verification

Food Safety Plan - Verification

Includes (as appropriate):

- Validation of preventive controls
- Verification of monitoring and corrective actions
- Calibration of instruments
- Product testing
- Environmental monitoring
- Records review



Supply Chain Program

Manufacturing/processing facilities must have a risk-based supply-chain program to ensure control of hazards in raw materials and other ingredients when the control is applied before receipt (“supply-chain applied control”).

Supply Chain Program

- Use of approved suppliers
- Determine appropriate supplier verification activities
- Conduct and document supplier verification activities, including FDA

  compliance history
- When applicable, verify a supply-chain-applied control applied by an entity other than the facility's supplier or obtain documentation of verification by another entity

FDA Compliance Monitor

FDA COMPLIANCE MONITOR

Facility

Monitoring: On
Facility Name
Street Name
City, Province, Zipcode
India

Stop Monitoring

Compliance Status

Inspection Classification(s)

Jan 10, 2013 Official Action Indicated (OAI) for:
- Monitoring of Marketed Animal Drugs, Feed, and Devices

Request this FDA Inspection Report (FDA Form 483)

NOTE: The FDA Compliance Monitor displays classifications published after October 1, 2011.

Warning Letter(s)

Jun 07, 2015 FDA Issued an FDA Warning Letter for CGMP for Dietary Supplement/Adulterated/Misbranded

Nov 10, 2011 FDA Issued an FDA Warning Letter for CGMP/QSR/Manufacture/Packing/Storage/Installation/Adulterated
- **Jun 08, 2012** FDA Issued a Closeout Letter

NOTE: The FDA Compliance Monitor displays warning letters published after October 1, 2011.

Import Alert(s)

99-19 DWPE Detention Without Physical Examination of Food Products due to The Presence of Salmonella for Capsicums (Cayenne Chili, Hot Peppers), Ground, Cracked (Spice) Description: Chili Powder Notes: 11/23/1998

99-19 DWPE Detention Without Physical Examination of Food Products due to The Presence of Salmonella for Capsicums (Cayenne Chili, Hot Peppers), Whole (Spice) Description: Chili Powder Notes: 11/23/98 Problems: SALMONELLA

02-01 EXEMPT This company is on the Green List and therefore exempt from DWPE for Rice, Basmati, Processed (Packaged) (FDA Product Code: 02D--07)

No Import Refusals specific to this facility.

NOTE: The FDA Compliance Monitor displays refusals published after October 1, 2011.

One Simple Compliance Dashboard
Aggregates and organizes information from multiple FDA databases.

Change of Status Alerts
Receive e-mails when FDA publishes a change of compliance status.

Supports Documentation Requirements
Printable reports available 24/7 and e-mailed monthly to comply with 21 C.F.R. sec. 117.410(d)(1)(iii)(B) and 21 C.F.R. secs. 1.505(a)(iii)(B), 1.505(b).

Supplier Verification Activities

- Onsite audits (annually as default for serious hazards)
- Sampling and testing
- Review of relevant food safety records
- Other as appropriate

Circumstances Where Preventive Controls Are Not Required By Processors

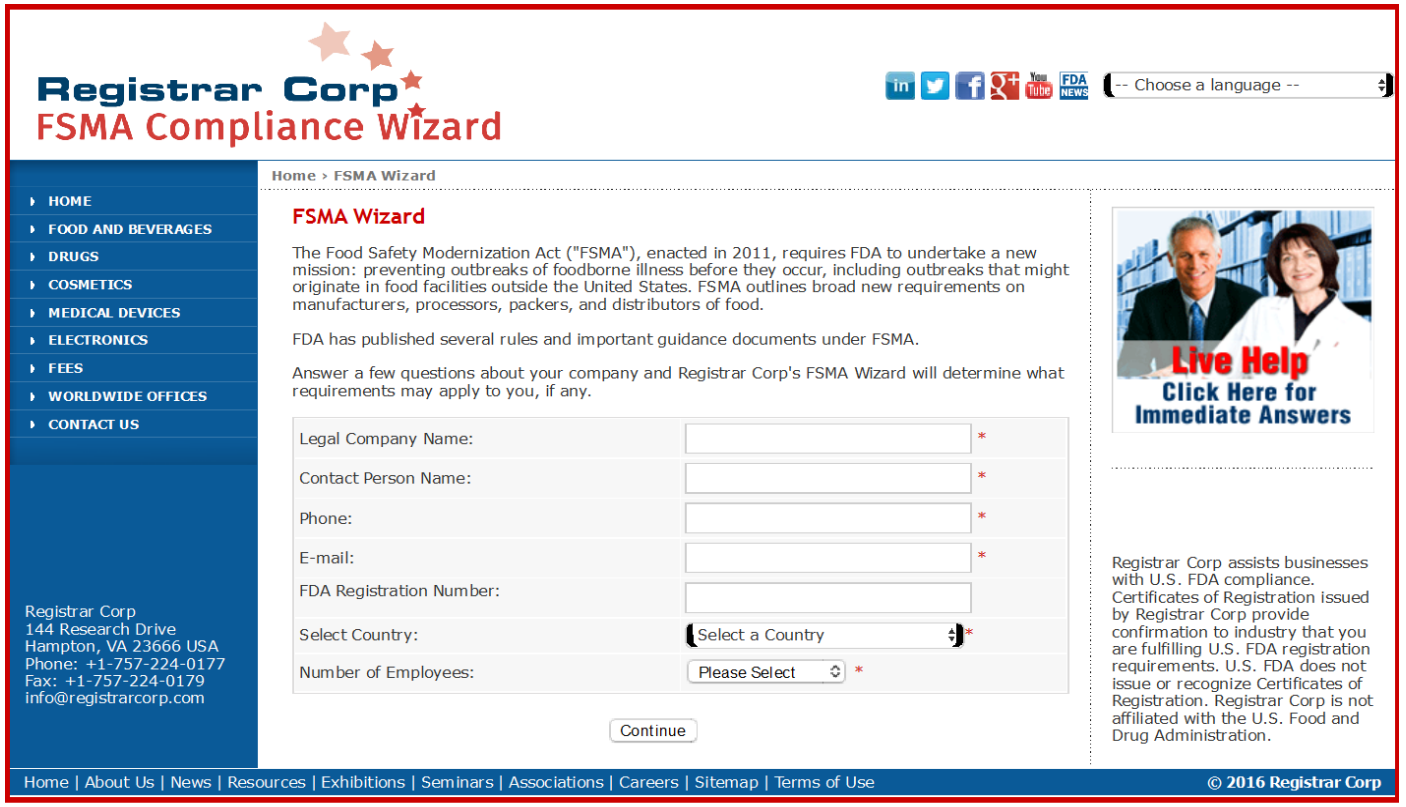
1. The processor determines and documents that the type of food could not be consumed without application of an appropriate control (e.g., cocoa beans)

Circumstances Where Preventive Controls Are Not Required By Processors

2. The hazard is controlled downstream and the manufacturer obtains annual written assurances or establishes its own downstream controls.

a) Documents accompanying the food must disclose: “not processed to control [identified hazard].”

b) Annual written assurances from customer or customer's customer that hazard is being controlled downstream and customer promises not to sell to entity that does not assure in writing .


Registrar Corp
FSMA Compliance Wizard
-- Choose a language --
HOME
FOOD AND BEVERAGES
DRUGS
COSMETICS
MEDICAL DEVICES
ELECTRONICS
FEES
WORLDWIDE OFFICES
CONTACT US
Home › FSMA Wizard
FSMA Wizard
The Food Safety Modernization Act ("FSMA"), enacted in 2011, requires FDA to undertake a new mission: preventing outbreaks of foodborne illness before they occur, including outbreaks that might originate in food facilities outside the United States. FSMA outlines broad new requirements on manufacturers, processors, packers, and distributors of food.
FDA has published several rules and important guidance documents under FSMA.
Answer a few questions about your company and Registrar Corp's FSMA Wizard will determine what requirements may apply to you, if any.
Legal Company Name:
Contact Person Name:
Phone:
E-mail:
FDA Registration Number:
Select Country:
Select a Country
Number of Employees:
Please Select
Continue
Live Help
Click Here for Immediate Answers
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FDA Food Safety Modernization Act (FSMA)

English
http://www.registrarcorp.com/fsma-wizard6/

Spanish:
http://www.registrarcorp.com/fsma-wizard6/?fromlg=en&lang=es

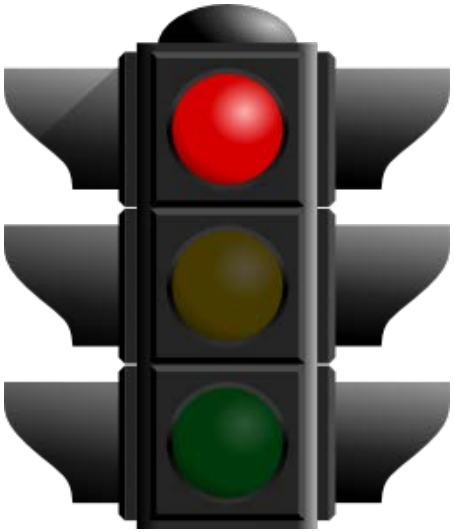
Mandarin:
http://www.registrarcorp.com/fsma-wizard6/?fromlg=es&lang=ch

IMPORT ALERTS:

- ***DETENTION WITHOUT PHYSICAL EXAMINATION***

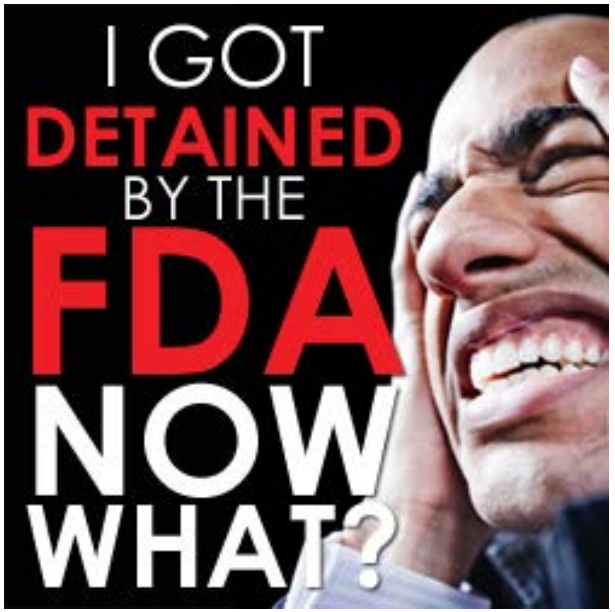
Detention without Physical Examination ("DWPE")

- Green lists
- Red lists
- Yellow Lists
- Removal from Import Alert



FDA Detention

- “Notice of Action”
- Sampling
- Opportunity to Present “Testimony”
- Reconditioning (Form 766)
- Release or Refusal
- Released “with comment”
- Re-Export or Destruction
- “Redelivery”

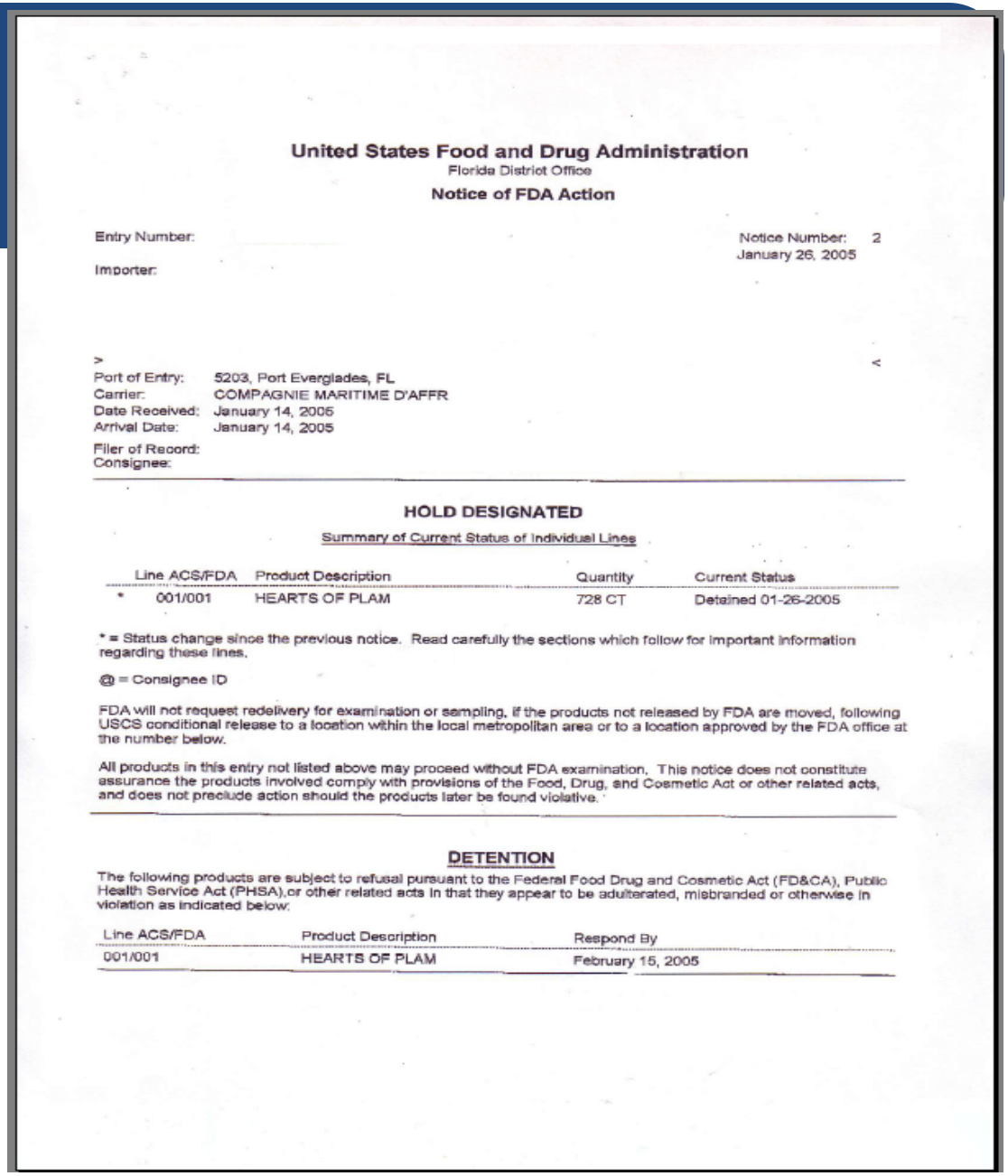


“Notice of FDA Action”

Issued by FDA and sent to two parties:

Importer of Record
Customs Broker

Time sensitive with a respond by deadline



United States Food and Drug Administration
Florida District Office
Notice of FDA Action

Entry Number:
Notice Number: 2
January 26, 2005
Importer:

>
Port of Entry: 5203, Port Everglades, FL
Carrier: COMPAGNIE MARITIME D'AFFR
Date Received: January 14, 2005
Arrival Date: January 14, 2005
Filer of Record:
Consignee:

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	HEARTS OF PLAM	728 CT	Detained 01-26-2005

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

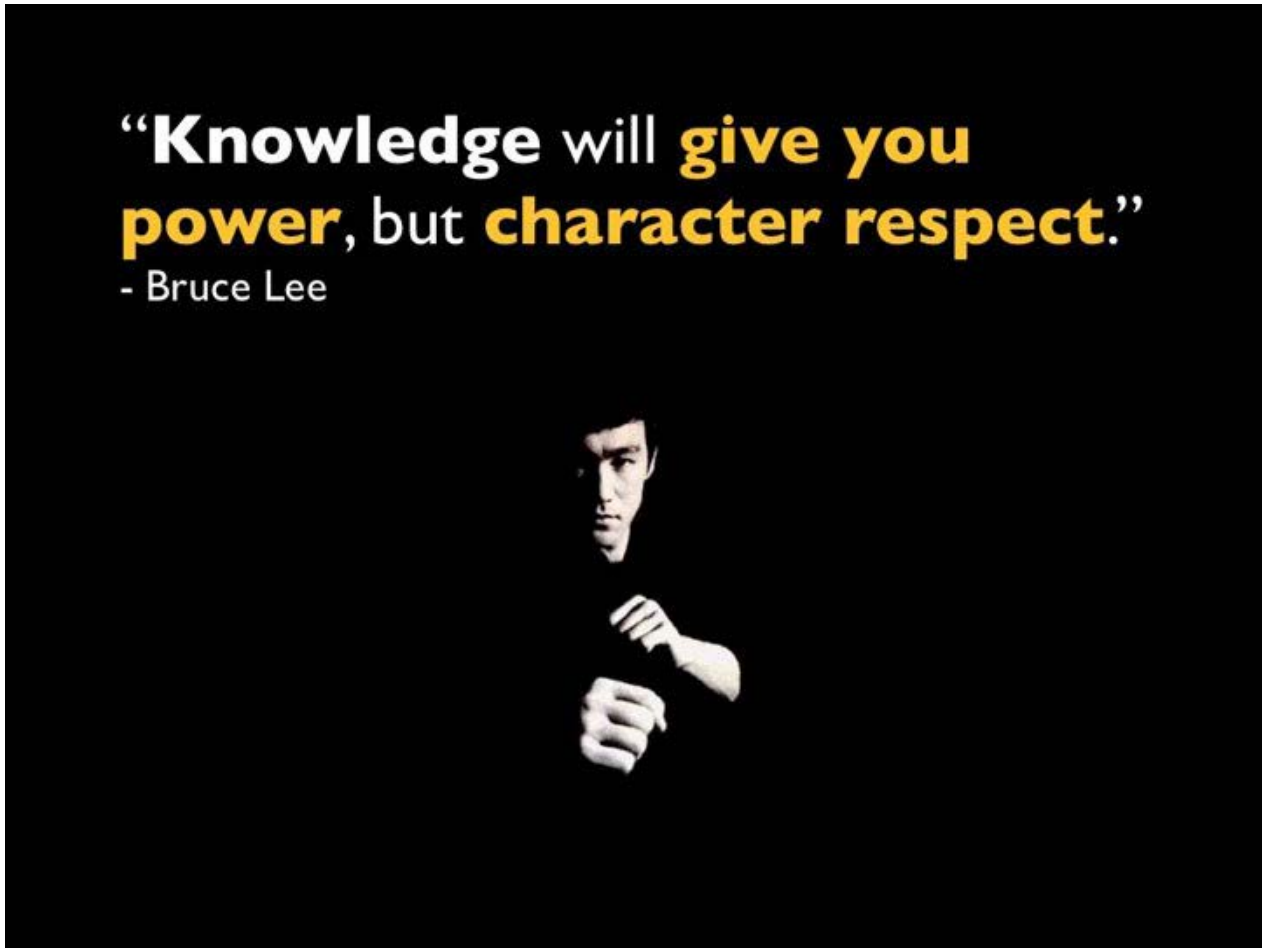
All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By
001/001	HEARTS OF PLAM	February 15, 2005

Final Advice



Questions?

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