How to Prepare for a Foreign FDA Food Facility Inspection

Presented by Rick Barham

Food Safety Specialist

October 25, 2016

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About Rick Barham

Food Safety Specialist

- Rick Barham holds a Bachelor of Science degree in Animal Science from Virginia Tech and a Bachelor of Science degree in Accounting from Christopher Newport University. Mr. Barham has over 31 years of experience in the Food Safety profession. He acted as Regional Manager for the Virginia Department of Agriculture's Food Safety Program, and has been honored with numerous awards. Mr. Barham is based at Registrar Corp's headquarters in Hampton, Virginia. He conducts mock FDA inspections in food facilities around the world as well as creates and reviews Food Safety Plans for compliance with FDA's Preventive Controls Rules under FSMA.

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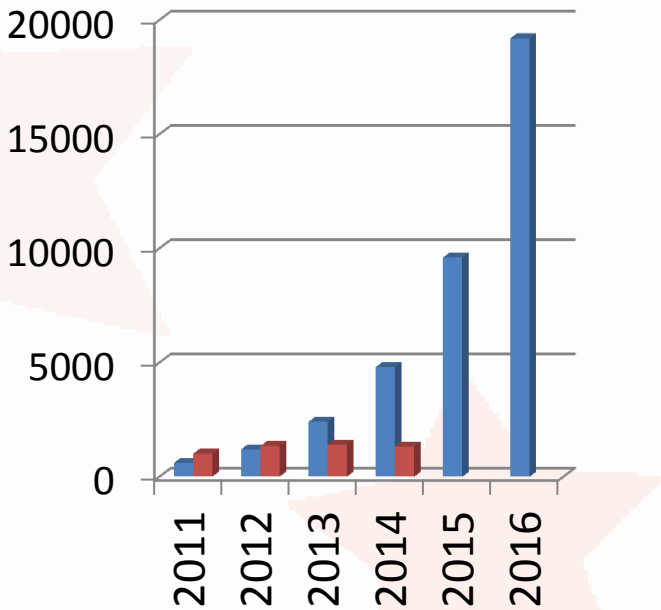
Why is FDA Conducting Foreign Inspections?

- 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

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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

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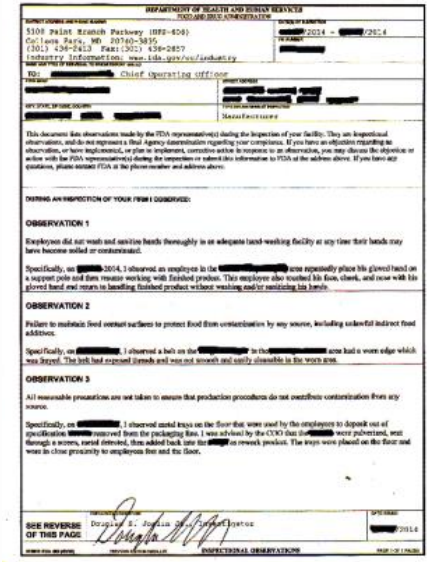
Inspection Process: Day 2

- 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/oc/industry

TO: [redacted] Chief Operating Officer

Manufacturer

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.

OBSERVATION 2

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

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE

Director

INSPECTIONAL OBSERVATIONS

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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

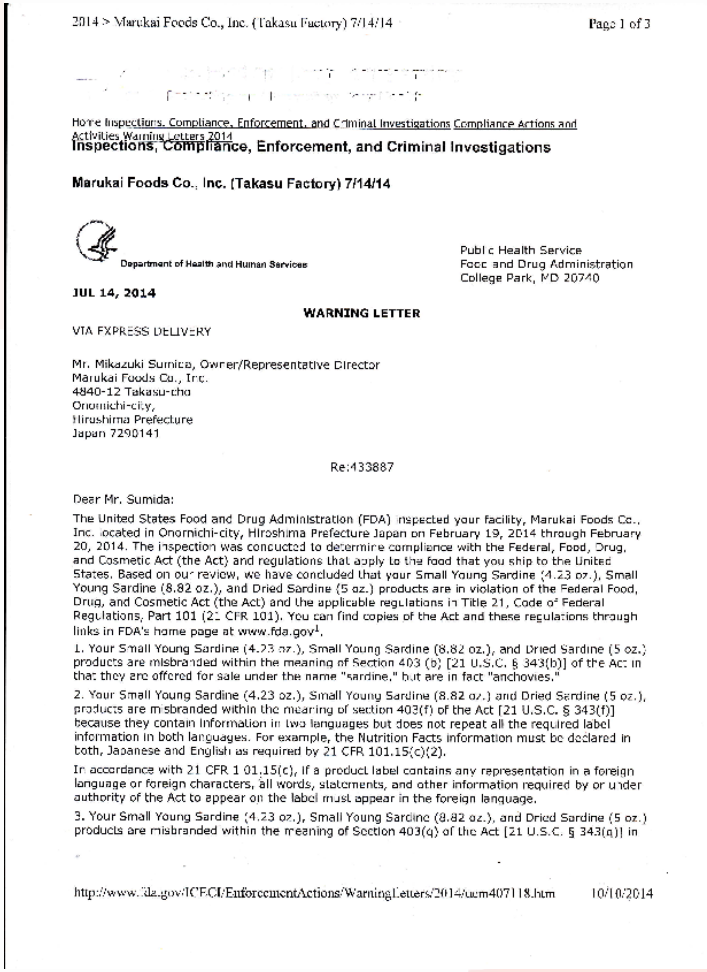
http://www.accessdata.fda.gov/scripts/inspsearch/

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



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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

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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

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