



# **U.S. Food and Drug Administration Food Safety Risk Assessment and Risk Management Activities**

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# Topics

- **Risk Analysis Framework**
- **Risk Assessments**
  - Quantitative
  - Risk Ranking and Prioritization
    - Import Sample Targeting
- **Risk Profiling**
  - Pathogens in Spices
- **Risk Management Tools**
  - Foreign Inspection Site Selection
  - Entry Admissibility/Sample Targeting – PREDICT
- **U.S FDA beyond Our Border Initiative**

# Risk Analysis

- **Adopted CODEX**
- **Described as being comprised of three components:**
  - **Risk management**
  - **Risk assessment**
  - **Risk communication**



# Risk Assessment: The Basics

- **Risk Assessment is...**

- **A process for determining the likelihood that exposure to a hazard, e.g. food borne pathogen or chemical, will result in harm or disease under various scenarios**

***Results of risk assessments are used to drive risk management, regulatory policy and risk communication decisions***



# Quantitative Risk Assessments

- ***Listeria*/smoked finfish**
- ***Listeria*/soft cheese**
  - with Health Canada
- **Avian influenza/poultry & eggs**
  - with U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS)
- ***Listeria*/Retail deli cross-contamination**
  - with USDA FSIS
- ***E coli* O157:H7/Leafy greens**
  - Research Triangle Institute (RTI) contract
- **Drug residues in milk**
  - with FDA's Center for Veterinary Medicine
- **Linking GIS with predictive risk assessment**
  - with National Aeronautics and Space Administration (NASA)



# Risk Ranking & Prioritization Projects

- **Qualitative risk ranking of food product/hazard combinations to target import sampling (FDA/CFSAN expert elicitation)**
- **Inventory and evaluation of risk ranking & risk prioritization tools & methods (RTI)**
- **Development of produce/hazard risk ranking tool (RTI)**
- **Development of iRISK methodology (RTI)**
- **Establishment of library for iRISK: 50 commodities and 20 hazards (RTI)**
- **Development of a risk prioritization framework (RTI)**

# Relative Risk Ranking of Product/Hazard Categories to Target Import Sampling

- *Relative risk ranking of import food product/hazards based on qualitative estimate of the likelihood of an adverse event occurring from consumption of the product containing the hazard and the relative severity of that hazard.*
- Where multiple hazards identified for a product, hazard with highest severity determined overall relative risk ranking of the product/hazard combination.
- Not all possible product/hazard combinations considered; only those identified as a higher concern by FDA food experts.
- Data Sources: Literature, outbreak, recalls, adverse event reports, compliance history, expert opinion, consumption data.

# Risk Profiles

- **Concept developed by Codex Alimentarius Commission 2004**
- **Science-based documents that describe current state of knowledge about a given food safety problem and relevant public health control strategies. Also identifies alternate options of control for consideration by risk managers and data gaps.**
- **FDA Risk Profiles**
  - **Norovirus/ routes of transmission**
  - **Hepatitis A virus/ produce**
  - ***Listeria monocytogenes*/ fresh-cut produce**
  - **Pathogens in cheese**
  - ***Pathogens in spices***



# Why the Focus on a Risk Profile for Domestic and Imported Spices?

- **Foodborne Outbreaks: Spices and Dried Vegetables Implicated**
  - **White Pepper**
    - *Salmonella* Rissen
  - **Commercially Prepared Ready-to-Eat Puffed Vegetable Coated Snack Food**
    - *Salmonella* Wandsworth
    - *Salmonella* Typhimurium
- **High Violation Rates for Samples of Spices Taken at the U.S. Border**
  - **Microbiological pathogens**

# Foodborne Outbreak Involving Imported White Pepper

- **Pathogen**
  - *Salmonella* Rissen
- **Related Human Illnesses/Case Count**
  - Total related Human Illnesses 72; Number Hospitalized 7; Deaths 0
  - States where cases Identified: California, Oregon, Washington, Nevada, Idaho
- **Onset Dates of Illness**
  - December 9, 2008 – April 8, 2009

# Foodborne Outbreak Involving Ready-to-Eat Puffed Vegetable Coated Snack Food

## *Background*

- One U.S. firm manufactured product; implicated in two outbreaks - *Salmonella* Wandsworth and *Salmonella* Typhimirium
- Grains & other ingredients blended into a paste, baked & puffed; vegetable coating added **AFTER** heat treatment: no additional heating occurs
- *Salmonella* Wandsworth isolated from imported broccoli powder; PFGE match with clinical samples
  - First outbreak of *Salmonella* Wandsworth infection in U.S.
  - Large percentage confirmed clinical cases - young children

# Foodborne Outbreak Involving Ready-to-Eat Puffed Vegetable Coated Snack Food

	<i>Salmonella</i> Wandsworth Outbreak	<i>Salmonella</i> Typhimirium Outbreak
<b>Total Related Human Illnesses/ Case Count</b>	<b>69</b>	<b>18</b>
<b>Hospitalizations</b>	<b>6</b>	<b>2</b>
<b>Deaths</b>	<b>0</b>	<b>0</b>
<b>Age of Patients</b>	<b>&gt; 90% ages 10 months 3 years</b>	<b>Medium age of patients 2 years</b>
<b>Number of States with Confirmed Cases</b>	<b>23</b>	<b>9</b>
<b>Onset Dates</b>	<b>February 26 – July 4 2007</b>	<b>June 1 and September 20 2007</b>

# Food borne Outbreak Involving Ready-to-Eat Puffed Vegetable Coated Snack Food

## State and Local Health Department Samples; Collected Product at Patient Homes/Retail

- Isolated *Salmonella* Wandsworth; PFGE match to clinical samples
- *Salmonella* serotypes Typhimirium, Kentucky, and Haifa also isolated
- Led to identification of outbreak related cluster of *Salmonella* Typhimirium illnesses

# Food borne Outbreak Involving Ready-to-Eat Puffed Vegetable Coated Snack Food

## U.S. FDA Environmental/ Finished Product Samples; Collected at Manufacturing Site

- ***No environmental samples taken from facility were Salmonella positive***
- ***Salmonella* Wandsworth, *Salmonella* Typhimurium & *Salmonella* Haifa detected in finished product samples**
- **Samples of seasoning mix yielded the outbreak strain of *Salmonella* Wandsworth**
- **Individual ingredients of seasoning mix tested; imported broccoli powdered yielded *Salmonella* Wandsworth outbreak strain; parsley powder contained *Salmonella* Mbandaka**

# U.S. Border Sampling Results for Imported Spices

Industry Code	Industry Code Description	Micro Adverse Findings Summary from Imported Foods General Program <sup>1</sup>			
		FY04 Adverse Findings Rate	FY05 Adverse Findings Rate	FY06 Adverse Findings Rate	FY07 Adverse Findings Rate
02	Whole Grains	1.4	0	1.6	2.9
17	FDA-Regulated Meats (eg., wild game)	25.0	20.0	14.3	50.0
21	Fruits- Subtropical, Tropical	6.6	1.3	2.7	1.2
23	Nuts & Edible Seeds- includes sesame seed	7.4	6.3	8.3	3.8
24	Vegetables- including leaf & stem	2.7	5.3	1.8	2.8
<b>28</b>	<b>Spices</b>	<b>10.4</b>	<b>8.2</b>	<b>9.0</b>	<b>6.5</b>
31	Coffee & Tea	5.6	6.3	23.8	3.4
54	Dietary Supplements- including botanicals	14.0	8.5	1.6	9.2
All Covered <sup>1</sup> Products Combined		Average <sup>2</sup> : 2.23	Average <sup>2</sup> : 1.99	Average <sup>2</sup> : 2.60	Average <sup>2</sup> : 6.5

<sup>1</sup>no seafood, cheese, infant formula, medical food, special assignments

<sup>2</sup>unweighted



# Pathogens in Spices Risk Profile Background

- **Why Now?**

- **Recent outbreaks associated with spices & dried vegetables have raised concerns re. efficacy of control measures to prevent/reduce consumption of microbiologically contaminated spices in the U.S.**
- **Imported and domestically cultivated spices consumed widely in the U.S.; domestic production accounts for 40% and foreign production 60% of total U.S. spice consumption**
- **U.S. leading supplier of dehydrated onions, garlic, paprika, chili peppers, mustard seed; must assure these products are safe**
- **The number of facilities “handling” spices in the U.S. has increased over the years and currently numbers over 500 hundred; many of these are relatively small businesses**



# Pathogens in Spices Risk Profile

## SCOPE

- **Spices**
  - Aromatic plant parts used for flavoring; whole broken or in powder form
  - As listed in 21 CFR 182.10; Appendix 1
  - Includes sesame seed, dried dill weed, dehydrated garlic, dehydrated onion, dried celery
- **Imported and domestic cultivating/processing methods and control strategies**
- **Salmonella spp. and other pathogens as determined by literature search**



# **Pathogens in Spices Risk Profile Objectives**

- **Describe nature/extent of public health risk by identifying most commonly occurring microbial hazard/spice combinations**
- **Describe/evaluate current mitigation and control options**
- **Identify other mitigation or control options**
- **Identify research needs and data gaps**



# **Pathogens in Spices Risk Profile**

## **Specific Questions to be Addressed**

- **What is known about the frequency and levels of pathogen contamination of spices throughout the supply chain (e.g., growing, harvesting, processing, manufacture, distribution, importation, retail sale/use, consumer/home/handling?)**
- **What is known about differences in production and contamination of imported versus domestic spices?**
- **What is known about the efficacy, cost, and practicality of currently available and potential future interventions to prevent human illness associated with pathogen contamination of spices (e.g., technology to reduce/prevent contamination, surveillance/inspection/import strategies or guidance etc.?)**



# **Risk Management: Risk Informed Targeting of Import Activities**

## **Risk Management Tools Developed/Implemented**

- *Foreign Inspection Site Selection Model*
- *The Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)*

## **New Initiatives Driving Risk Management Decisions**

- *Reportable Food Registry*
- *Risk Control Review Process*
- *Open Source Intelligence Data Mining*

# Why the Need for Risk Management of U.S. Import Activities?

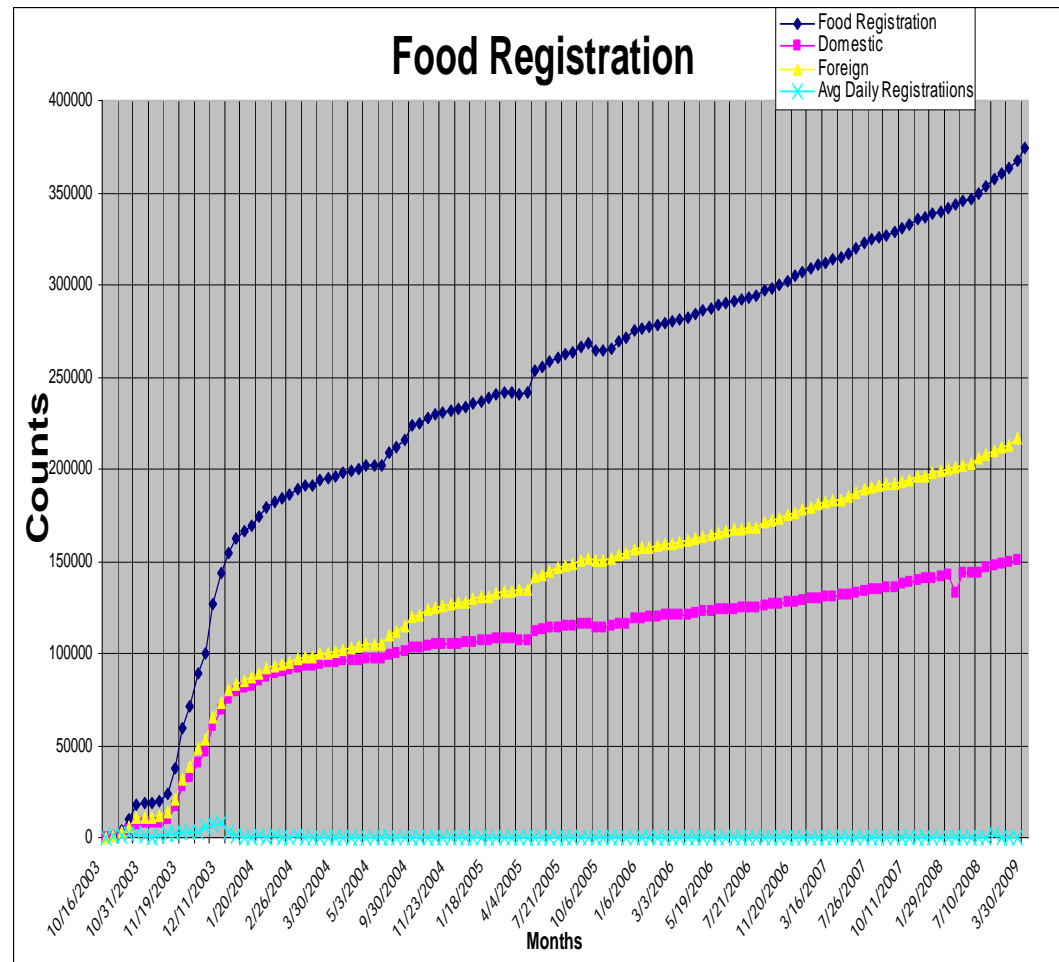
## *The Challenges of Globalization*



# U.S. Import Entry Trends Relative to Foods

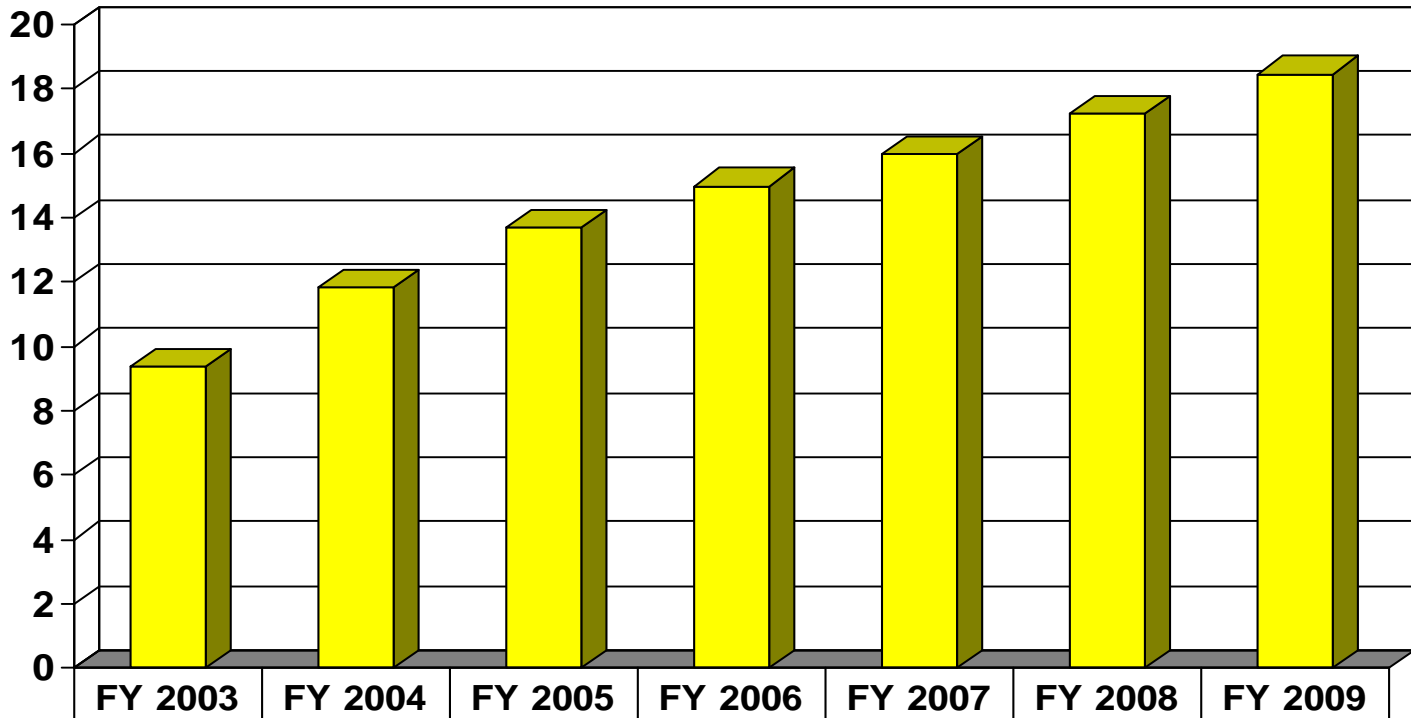
- There are over 220,000 registered foreign food facilities
- Over 200 countries/territories export to the U.S. to 300 ports
- 15 -20% of U.S. foods consumed originate from other countries
  - 80% of seafood
  - 35% of produce
  - **60% of spices**

## Registered food facilities (Foreign facilities in yellow)



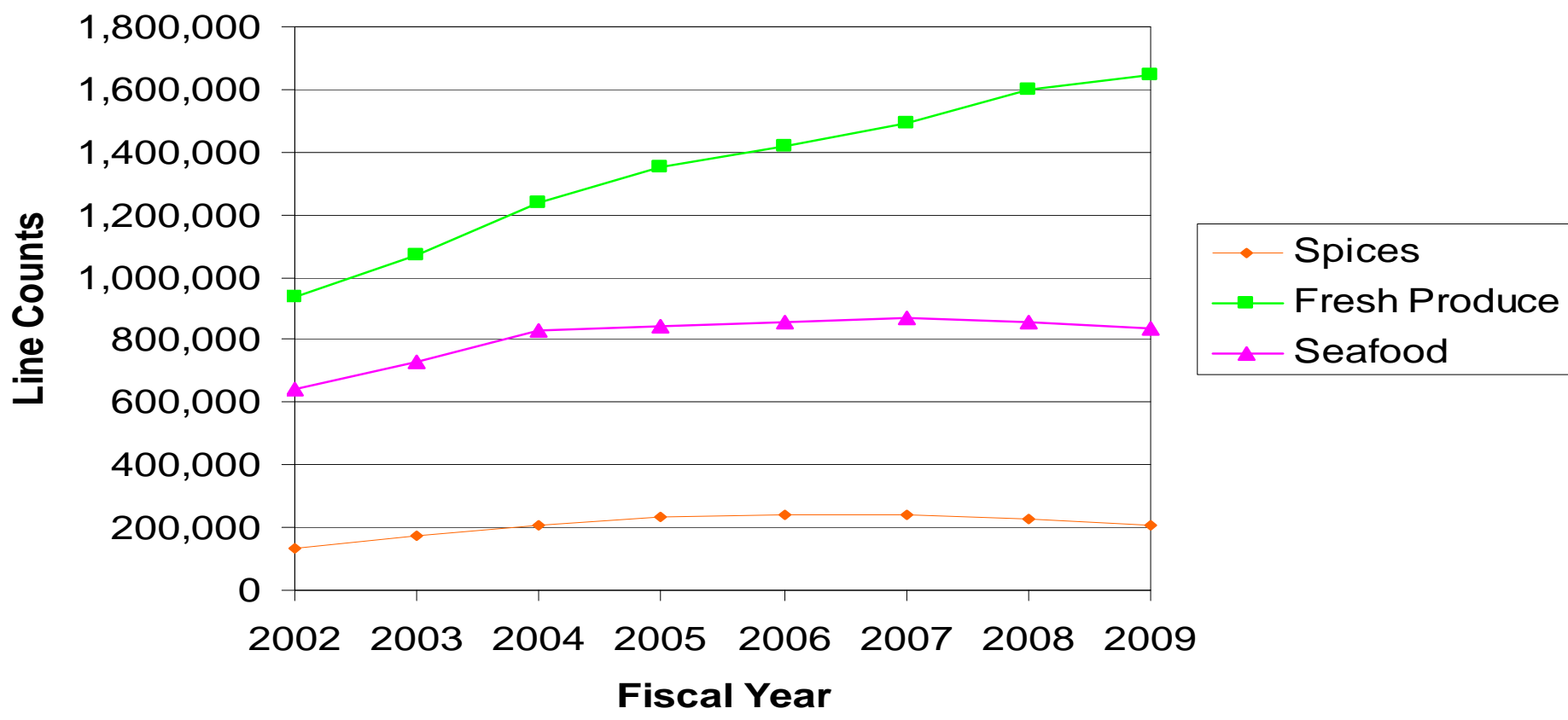
**Workload: Import entry lines, in millions  
(excluding mail and baggage)**

**Millions**



Lines	9372423	11823054	13696343	14978003	15955943	17209441	18456019
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# Line Counts for Spices, Fresh Produce & Seafood CFSAN Regulated Products





# Challenges of Globalization

**Globalization has fundamentally changed the environment for regulating food and medical products; it has created unique regulatory challenges for U.S. FDA**

- **More foreign food facilities supplying the U.S.;**
- **Increasing volume of imported food products and data;**
- **More outsourcing of food manufacturing;**
- **Greater complexity in food supply chains;**
- **Imports of food products and data coming from countries with less well developed or complete lack of regulatory systems, presenting opportunities for contamination, counterfeiting, or economic “gain” by cutting corners; and**
- **Food products could be intentionally contaminated to target a large part of the U.S. or any other country’s population**

# 21<sup>st</sup> Century Realities - Borders

- **Borders are still *jurisdictional boundaries***
- **Borders are no longer *barriers***
  - to disease
  - to information flow
  - to product acquisition
  - to the challenges of globalization
- **Borders are boundaries to our jurisdiction *but not barriers to our realm of activities***

# 21<sup>st</sup> Century Realities - Borders

- **Borders can no longer be the first line of defence against substandard products**
- **We can no longer “inspect” out bad products at the border**
- **Borders must be places where we “audit” that food safety has been built in from the farm to fork continuum**



# **Responsibility & Accountability**

**All entities involved in food production and distribution must take responsibility for assuring safe foods.**

**This includes:**

- **Foreign Governments**
- **Growers**
- **Manufacturers/Processors**
- **HOLDERS/Distributors and Transporters**
- **Importers and Consignees**

# Risk Management: FDA Foreign Inspection Program

- **Increase from 200 inspections in FY2009 to 600 in FY2010**
  - **Established Foreign Food Inspection Cadre June 2009**
  - **FY2010 High Risk Focus Areas**
    - **Produce, Seafood, LACF/AF, Dairy**
  - **FY2010 Site Selection Strategy**
    - **Inspections conducted in top 10 exporting countries by volume per high risk area**
    - **Up to 20 inspections per country per high risk area**

**Note: For-cause compliance inspections will also be performed, as warranted**



# Risk Management: Foreign Inspection Program

- **Increase from 600 foreign food inspections in FY2010 to 1000 in FY2011**
- **FY2011 Focus Areas**
  - Produce, Seafood, LACF/AF, Dairy, Low Moisture Foods/Ingredients, e.g. spices, dried vegetable seasonings etc.
- **FY2011 Site Selection Strategy**
  - Inspections will be conducted in next tier of exporting countries by volume for produce, seafood, LACF/AF and dairy and first tier of exporting countries for low moisture foods/ingredients
  - Up to 20 inspections per country per high risk area
  - Compliance follow-up inspections, as warranted

# Criteria used for Selection of Foreign LACF Firms

Specific firms chosen based on the following criteria:

- High risk product
  - Mushrooms
  - Tuna
  - Seafood
- High risk processing system
  - Steam/air
  - Water spray/cascade
- High risk containers
  - Pouch or semi rigid
- Volume of imports received from country



# FY2010/FY2011 Foreign Inspections

Information obtained through U.S. FDA foreign inspections will be used, in part, as follows:

- To expedite admissibility decisions, where appropriate
- Better target border examinations and sampling to those entries of higher risk
- To identify capacity building and educational/training needs



# PREDICT GOALS

- **Electronic entry screening/processing system that will replace current “OASIS” system by the end of this year**
- **To the maximum extent possible with available resources ---**
  - **Prevent the entry of adulterated, misbranded, or otherwise violative goods**
  - **Expedite the entry of non-violative goods**

***U.S. FDA entry reviewers will only see those entry lines which “fail” or which have high risk scores.***

# PREDICT Method

- **Uses automated data mining and pattern discovery**
- **Utilizes open-source intelligence**
- **Provides automated queries of FDA databases (e.g., registration and listing, marketing approval status, low-acid canned food scheduled processes, etc.)**

# PREDICT Method

- **Improves the “hit” rate for field exams and sampling conducted at the U.S. border by:**
  - **Scoring each entry line on the basis of risk factors and surveillance requirements**
  - **Increasing number of automated, real-time, risk-based “may proceed” decisions, giving entry reviewers more time to evaluate higher-risk lines**
  - **Providing reviewers with the line scores & reasons for scores for those lines not given an automated “may proceed”**



# Examples of Source Data for PREDICT Screening Rules

- **Product-Related Risks**
  - Inherent Risk
  - Risk of the product being the target of economic adulteration with hazardous consequences
- **Compliance Risk (Probability of Violation)**
  - Results of field exams and sample analyses of previous entries
  - Results of facility inspections, foreign and domestic

# Examples of Source Data for PREDICT Screening Rules

- **Data Anomalies within the Current Entry**
  - In combination with Product Code: Country of Origin, Shipper Country, FEI Numbers (importer, shipper, manufacturer, consignee), Carrier Type, Port of Entry
  - Tariff Code vs. Product Code
- **Admissibility History**
  - With respect to the manufacturer, exporter, importer, and consignee for the current product (at industry and more specific levels)

# Examples of Source Data for PREDICT Screening Rules

- **Open Source Intelligence**
  - Pertaining to manufacturer, foreign locale, product, natural disasters, foreign recalls, disease outbreaks, infrastructure breakdowns, etc.
- **Current OASIS Electronic Screening Rules**
  - Based Upon the Following:
    - Import Alerts
    - Import Bulletins
    - FDA Field Requests
    - FDA Headquarters Assignments, Surveys

***Note: With OASIS the need for a screening rule has to be recognized. Unlike PREDICT, there is no automated data mining or pattern recognition.***

# U.S. FDA Beyond Our Borders Initiative

- **Establishes continuous FDA presence in strategic international areas based on**
  - Volume and riskiness of exports to the U.S.
  - Opportunity for benefit of bilateral capacity building or resource leveraging activities
  - Potential for fostering relationships with FDA counterparts
- **Reflects growth of the global market in the past decade**

# U.S. FDA Beyond Our Borders Initiative

**Foreign Posts in Five Regions of the World as follows:**

- **China**
  - Beijing, Shanghai and Guangzhou
- **India**
  - New Delhi, Mumbai
- **Europe**
  - Brussels
- **Latin America**
  - San Jose, Costa Rica
  - Mexico City, Mexico
- **Middle East**
  - No physical presence overseas; presently staffed in FDA Headquarters





# **U.S. FDA Beyond Our Borders Initiative: Desired Outcomes**

- Increase our knowledge about product manufacturing and shipping**
- Respond to requests of foreign regulatory counterparts to help build their capacity to assure product safety**
- Provide information about our regulations and expectations to the industry exporting to the United States**
- Engage with sister agencies to better coordinate USG approaches to achieve synergy and leverage resources**

# THE END

*Thank you very much for your attention.*

*Direct Questions to:*

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