



# The United Fresh 2010 Convention April 20-23, 2010

## Import Operations Activities

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Division of Import Operations & Policy



**FDA**

U.S. Department of Health and Human Services

Food and Drug Administration



# Overview of Presentation



- ORA Import Operations Strategic Plan & Development of a National Import Program
- MARCS – Imports (PREDICT)
- Questions

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## ORA is currently developing a strategy for a new model of operations



- The job of managing imports is increasingly global and complex...
  - ✓ More outsourcing of manufacturing
  - ✓ Greater complexity in supply chains
  - ✓ Imports coming from countries with less developed regulatory systems
  - ✓ Greater opportunities for economic fraud
  
- The current model for managing imports is struggling to meet these challenges
  
- This project will address these challenges – our goals include:
  - ✓ To be more efficient, effective and uniform
  - ✓ Develop a National Import Program
  - ✓ To leverage resources across states, localities, and other federal agencies
  - ✓ To increase the authority FDA has over imports
  - ✓ To take a look at new legislation and planning for the future

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## Background & Scope of the project



### ➤ Background:

- ✓ ORA has developed a draft Import Operations Strategic Plan and associated “strawman” concept of operations. ORA proposes to analyze FDA’s National Import Operations Program to ensure that import operations operate in an increasingly **uniform, effective** and **efficient** manner.

### ➤ Scope:

- ✓ The analysis will encompass organization/people, processes, technology, physical infrastructure and performance measurement
- ✓ The analysis will take into account a number of initiatives to improve ORA operations and to enhance ORA’s ability to protect the public health of the American consumer by being more proactive in addressing potential health issues, utilizing a more priority-focused and risk-based approach across the entire life-cycle of products.

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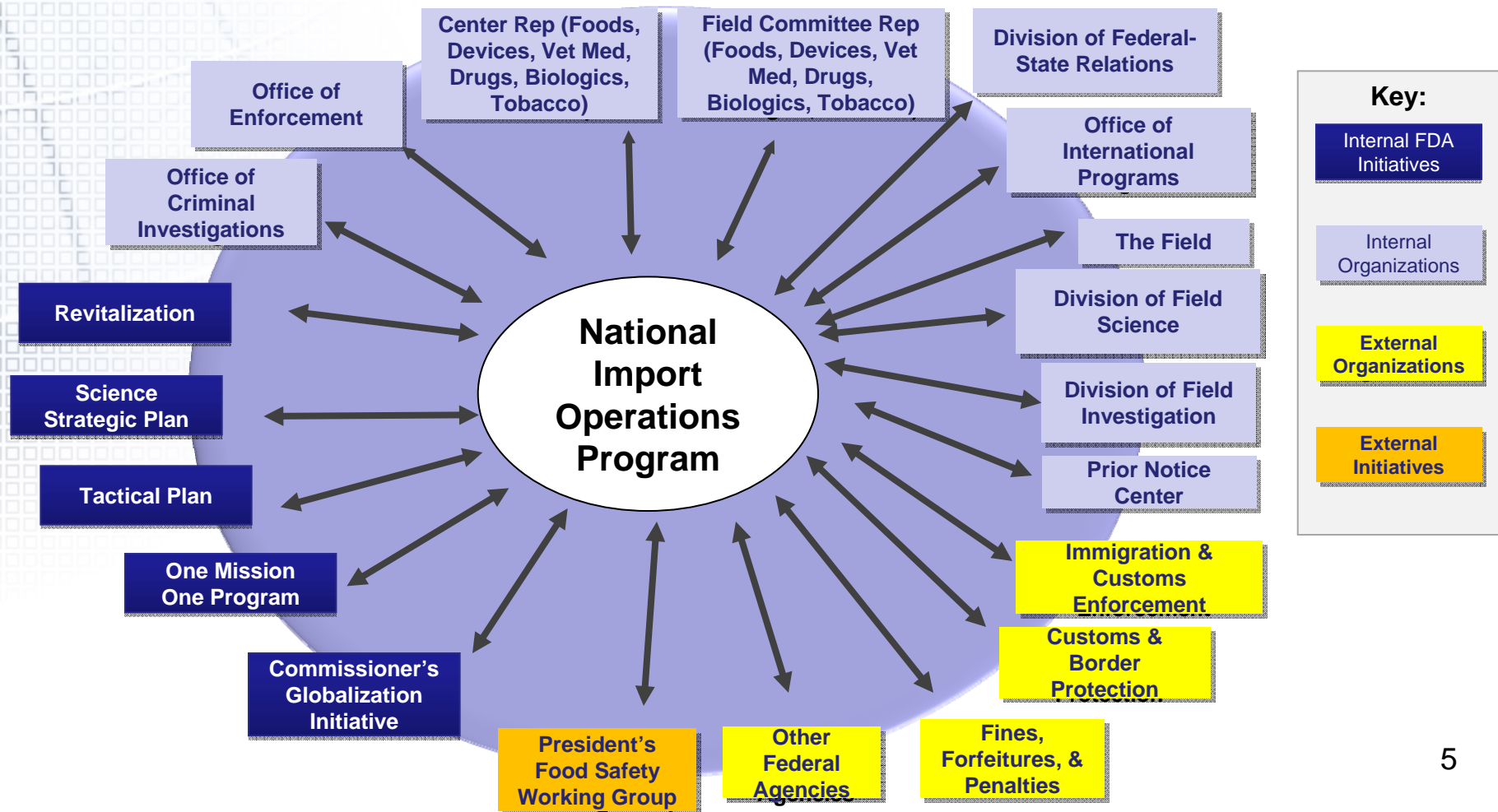




# High level stakeholder and initiative map



- Many stakeholders and initiatives with roles in import operations need to be considered and/or addressed





## Considerations for external stakeholders



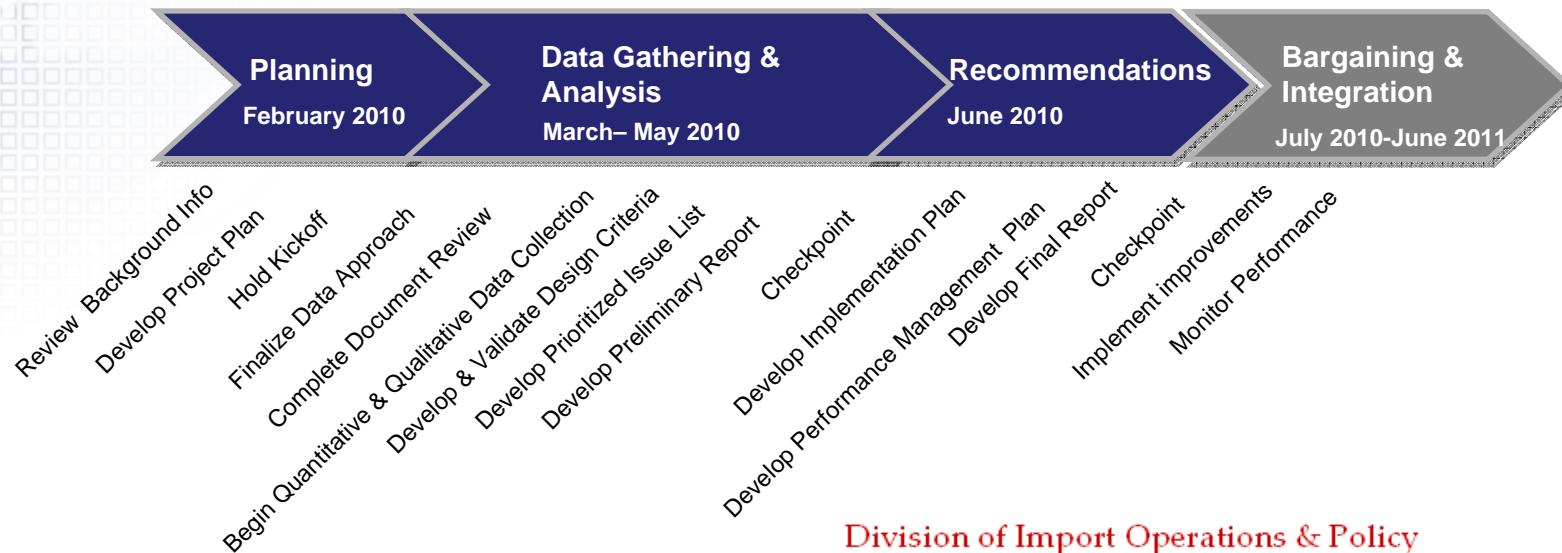
- What would you want to see changed?
- What would you not want changed?
- What performance measures are most important to you?
- What do you think would be a change that can be implemented quickly?



# The project approach



- We are using the phased approach shown below
- We are on an aggressive timeline
- We have identified three key sources of information and participation:
  - ✓ Subject matter experts
  - ✓ Data systems and key documents for analysis
  - ✓ Participation of key stakeholders (ORA, Centers, USDA, CBP, Other Federal Agencies, States and Localities, Industry)

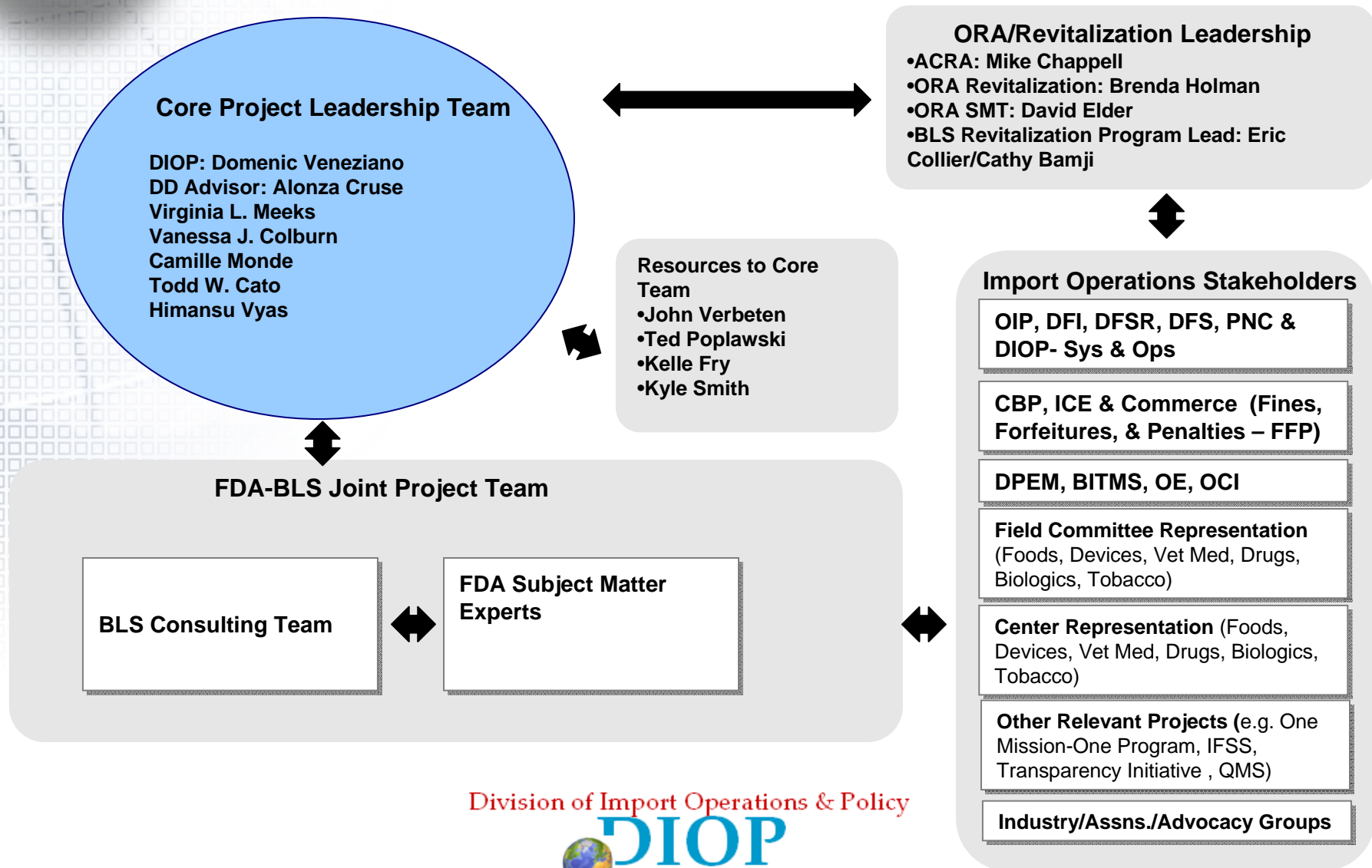


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# Import operations project team structure



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## What we will deliver by June 30, 2010



### ➤ **Recommendations:**

- ✓ **Prioritized issues list** – list of issues prioritized using criteria (e.g., impact, ease of change)
- ✓ **High level concept of operations/ process model** – graphically rich slides with key considerations and recommendations for each area of the operations process model (people, process, systems, organization/ infrastructure, performance metrics)
- ✓ **Preliminary report** – summarized findings and trends, and initial approaches for solutions



## What we will deliver by June 30, 2010



### ➤ **Recommendations:**

- ✓ **Detailed recommendations report** – detailed recommendations based on analysis of data collected, as well as detailed to-be process flows documenting current and to-be processes
- ✓ **Performance management plan** – high level approach for implementing effective performance measurements
- ✓ **Implementation plan** – high level approach for next steps in implementing operations process model

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## Work accomplished



- ✓ Presented to SMT
- ✓ Briefed One Mission One Program & Globalization Initiative
- ✓ Conducted Core Team kickoff at ORAU 3/30-3/31
- ✓ Two weekly core team calls held – 10 more scheduled before June 30, 2010
- ✓ High-level process validated with Core Team 4/12/10
- ✓ Participated in DFS call 4/14/10
- ✓ Presented to the NCBFAA Annual Conference 4/14/10
- ✓ Held meetings with multiple CBP staff 4/15
- ✓ Sites visits planned starting week of 4/19/10 (Detroit, Miami, LA, Memphis, Buffalo, New York, Philadelphia, Dallas and Washington DC)
- ✓ Planning for remote interviews and face-to-face meetings with key stakeholders underway



# **MARCS-IMPORTS PREDICT ITACS**

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# Topics



- Current IT issues
- PREDICT purpose, method, screening rules, risk types  
(Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting)
- Entry data quality, and why it really will matter with PREDICT
- ITACS (Import Trade Auxiliary Communications System)



# PREDICT



## Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting

- Purpose: Improve import screening and targeting to
- ✓ Prevent the entry of adulterated, misbranded, or otherwise violative goods
  - ✓ Expedite the entry of non-violative goods

Method: Replace the admissibility screening portion of FDA's legacy electronic system for processing import entries.



# OASIS



## Operational and Administrative System for Import Support

- Legacy system operating 24/7 FDA-wide since 1998
- The only system in the Federal government which exchanges import admissibility data with U.S. Customs & Border Protection in real time
- Provides –
  - ✓ Electronic screening of entry lines
  - ✓ Workflow management for entry reviewers, inspectors, and compliance officers
  - ✓ Generation of notices regarding admissibility decisions

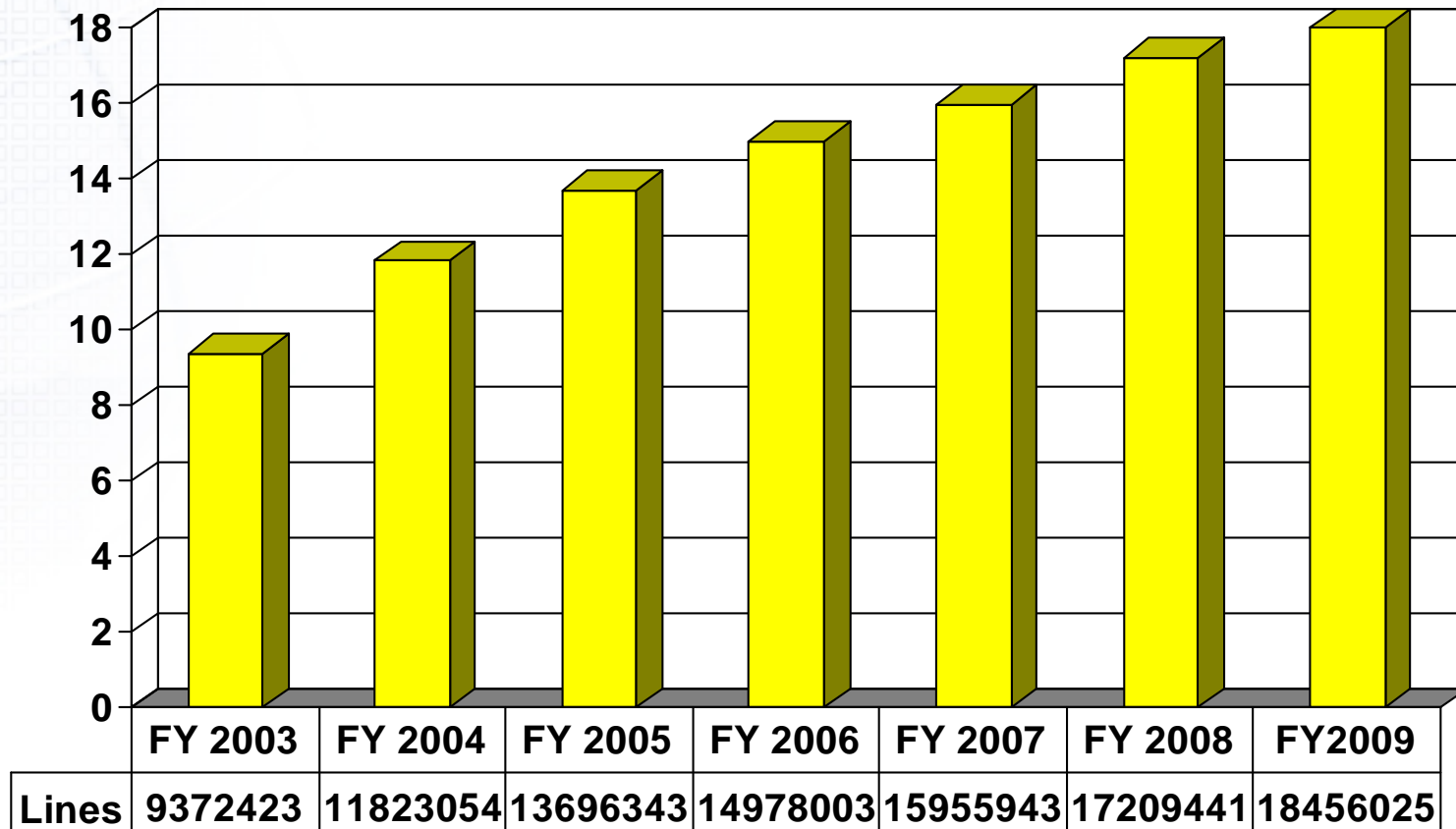


**Workload:**

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

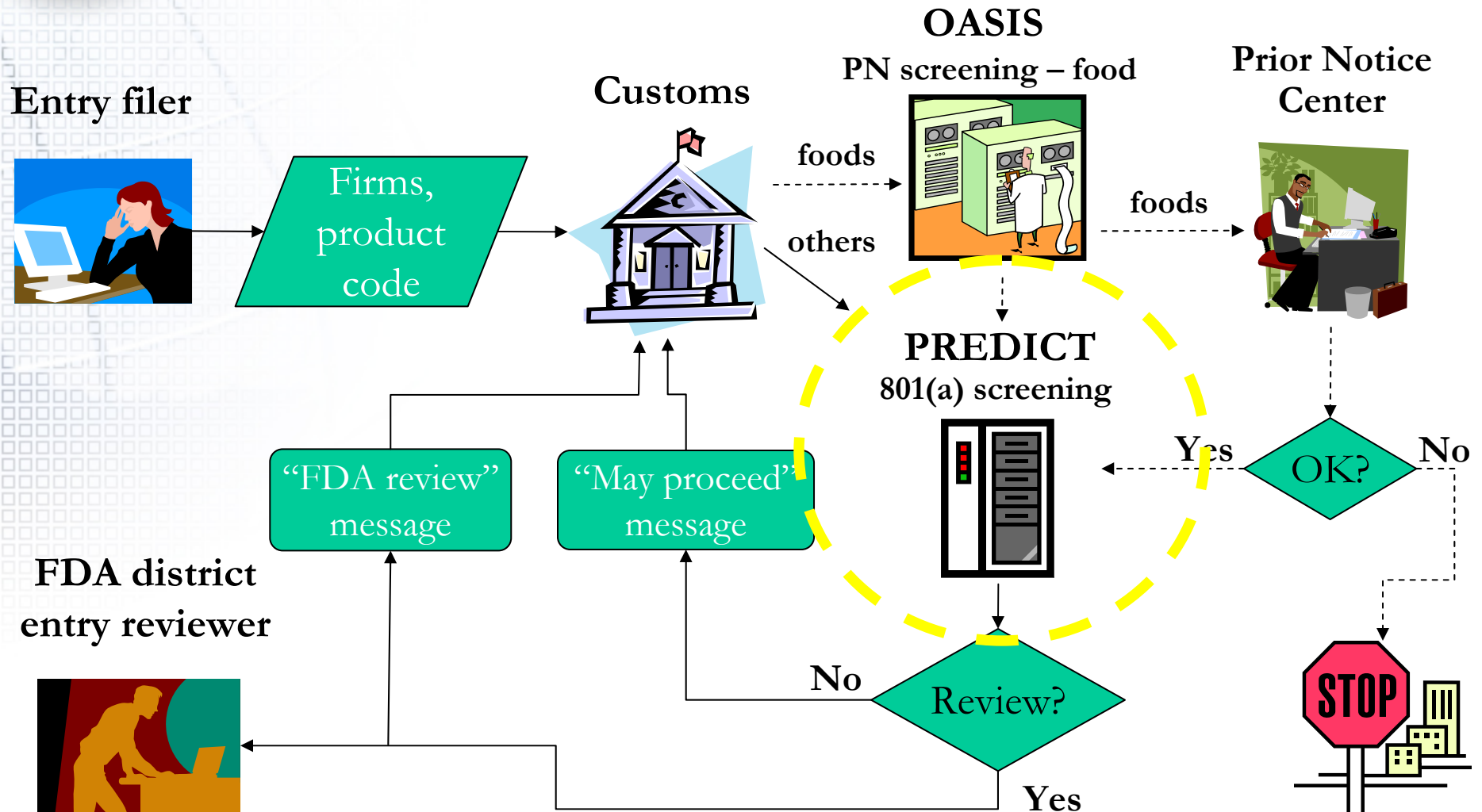


**Millions**





# Electronic Transactions Import Entry Lines

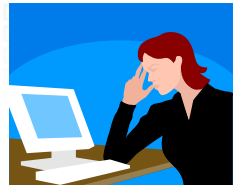




FDA district entry reviewer



Documents requested by FDA



Entry filer

Field exam

Initial action?

"May proceed" message

Detain w/o physical exam

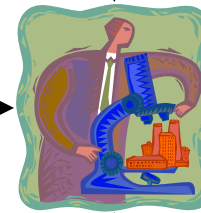
???

Results?

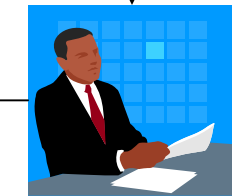
Good

Bad

Sample, analyze



Compliance action



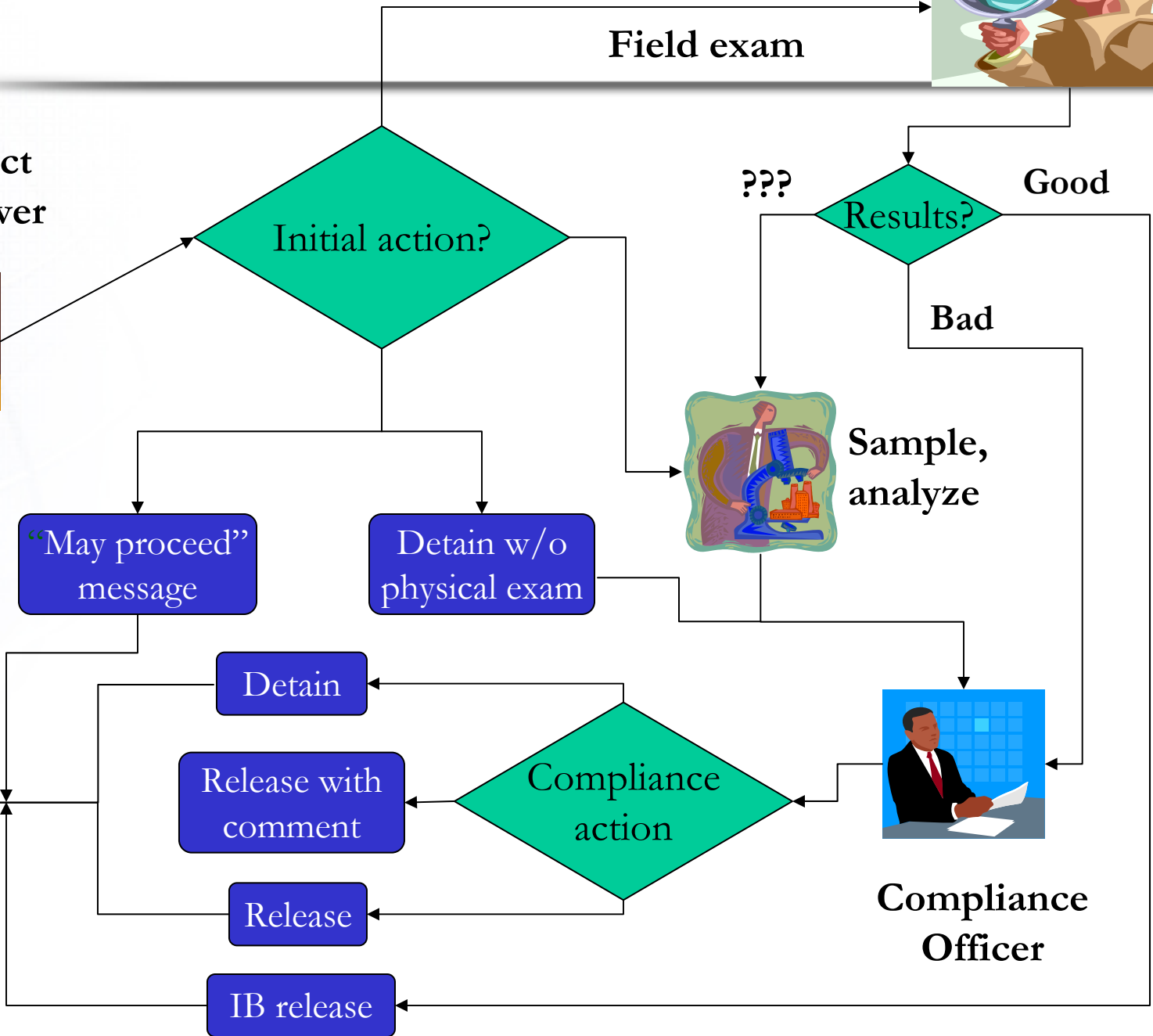
Compliance Officer

Detain

Release with comment

Release

IB release





# PREDICT method



- Use automated data mining and pattern discovery
- Utilize open-source intelligence
- Provide automated queries of Center databases where relevant (i.e., registration and listing, marketing approval status, low-acid canned food scheduled processes, etc.)



# PREDICT method



- Improve the targeting of entry lines by –
  - ✓ Scoring each entry line on the basis of risk factors and surveillance requirements
  - ✓ Increase the number of automated, real-time, risk-based “may proceed” decisions, thereby giving entry reviewers more time to evaluate higher-risk lines
  - ✓ For those lines not given an automated “may proceed,” providing reviewers with the line scores and the reasons for those scores



## Examples of source data for PREDICT screening rules



- Results of field exams and sample analyses of previous entries
- Results of facility inspections, foreign and domestic
- Ratings of inherent product risks
- Accuracy of product and facility coding by entry filers and importers



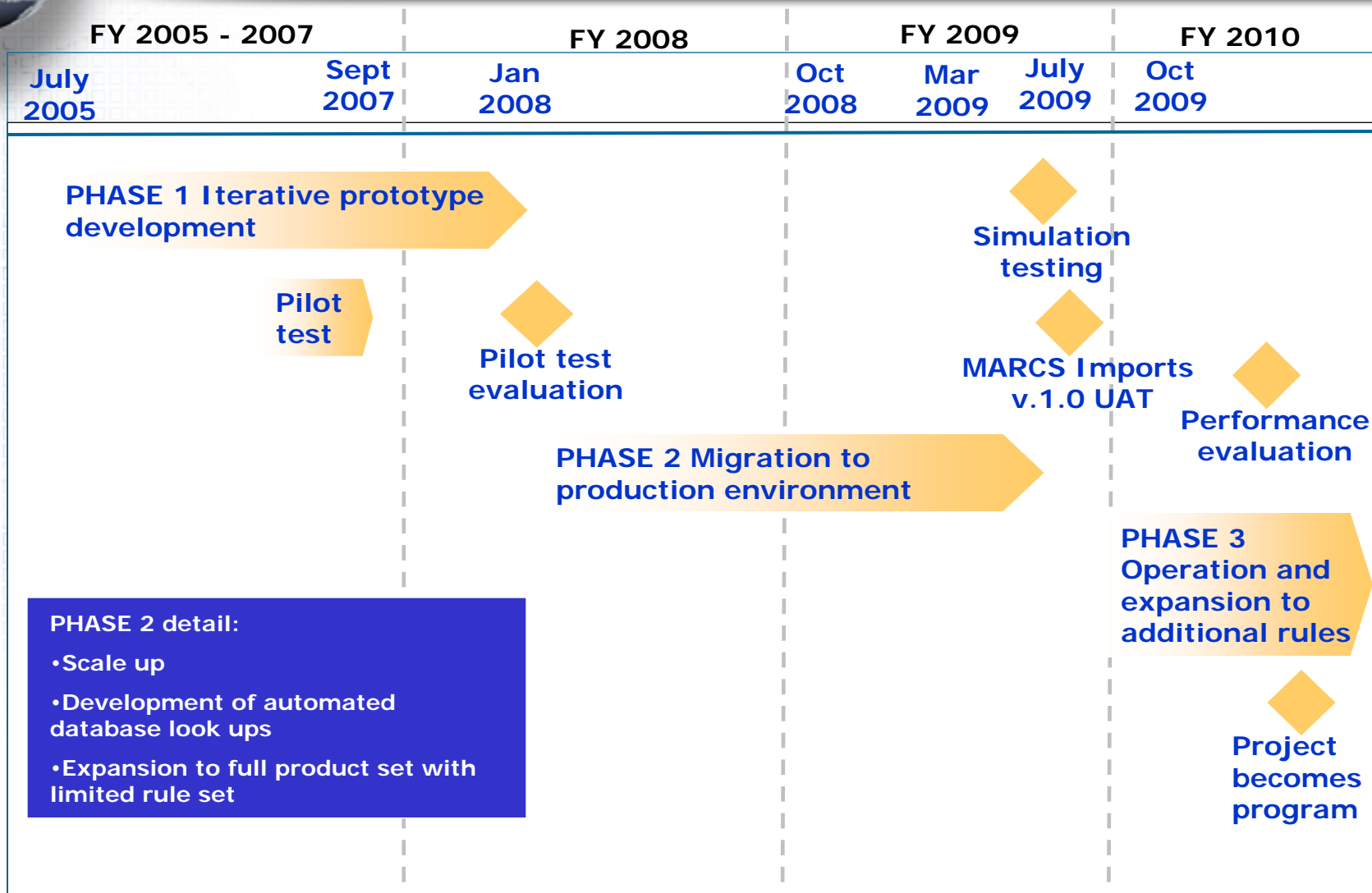
## Examples of source data for PREDICT screening rules



- Data anomalies within the current entry
- Admissibility history with respect to the manufacturer, exporter, importer, and consignee for the current product (at industry and more specific levels)
- Open source intelligence pertaining to the manufacturer, foreign locale, product, etc.



# Timeline



NOTE: Timeline is not to scale.



# Timeline



(As revised 7/28/09)

<b>July 21 – 24, 2009</b>	User acceptance testing
<b>Late September through early October</b>	Beta testing at Los Angeles
<b>Late October through early December</b>	Training of users, national implementation with limited rule set (one district at a time)



## Risk types to be included in targeting scores



- Compliance risk (probability of violation)
- Product-related
  - ✓ Inherent health risk (Type 1)
  - ✓ Incremental health risk in view of previous FDA analytical results for products of the same manufacturer (Type 2)
  - ✓ Risk of the product being the target of economic adulteration with hazardous consequences; i.e., wheat flour or milk adulterated with melamine and cyanuric acid; counterfeit drugs with missing or different inactive ingredients, etc. (Type 3)

**Note: Not all product-related risk factors will have been included by the time of initial system deployment.**



## Accurate, Consistent, Complete data



- To expedite entry screening by PREDICT, importers and entry filers must provide:
  - ✓ Consistent, accurate identifiers for firms
  - ✓ Accurate product codes
  - ✓ All of the relevant affirmations of compliance
  
- With those data PREDICT will be able to issue system 'may proceeds' quickly for low-risk, non-violative shipments
  
- OASIS tracks FDA corrections of data submission errors, and PREDICT uses these data to adjust the risk scores for future entry lines



# Affirmations of compliance



- Affirmations of compliance are data elements submitted voluntarily to FDA to expedite the entry review process. For example:
  - ✓ New drug application number
  - ✓ Device “510(k) clearance” number
  - ✓ National drug code (NDC)
  - ✓ Radiological health product report accession number



## With PREDICT: Affirmations of compliance



- With accurate and complete affirmations of compliance (NDA, ANDA, PMA, 510(k), NDC numbers, etc.), PREDICT can do the automated lookups for marketing status.



- If an automated lookup fails, the entry line will be forwarded to a reviewer for manual processing.



# MID



## Customs' manufacturer identification

- Receiving inconsistent MIDs for the same foreign facility is a serious data quality issue for FDA.
- Current record: 75 different MIDs for one facility
- Typical case: 6 different MIDs for one facility
- Submitting a different MID for an established, site-specific facility will cause PREDICT to view the facility as new, and the entry line's targeting score will be substantially elevated.
- The long-term solution is to replace the MID with a unique, reproducible identifier such as DUNS.



## Importers and Filers



- When PREDICT comes online, the quality of the data you submit to FDA will count more than ever.
- Importers need to work closely with filers to ensure data quality.
- Poor data quality or missing data will increase the targeting scores for your subsequent entry lines (importers and filers).
- Higher risk scores increase the likelihood of examination and/or sampling by FDA.
- Data error rates will be available to the public through the Freedom of Information Act.



# ITACS



## Import Trade Auxiliary Communications System

- Internet portal for entry filers to
  - ✓ Check the status of individual entries/lines
  - ✓ Submit documents and link them to specific entries/lines
  - ✓ Provide availability information for targeted shipments
  
- Submitted documents will be readily available to entry reviewers
  
- To be pilot tested in Los Angeles concurrently with PREDICT beta testing



# ITACS



## screenshot examples

- Entry line status
- Document submission
- Availability of product for inspection



# Entry line status



## Status and Actions

### Results

Entered Information: Entry: 275-1368174-5 Entry Level Status: CBP Line Number: FDA Line Number:

Select	Entry/CBP-FDA[Suffix]	Product	Product Code	Quantity	Country Name	Status	Status Date	ITACS Status
<input type="checkbox"/>	275-1368174-5/1-1	WHITE SHRIMP	16X--21	Total: 14528 Kilograms (14528 Kilograms)	Thailand	Documents Required	04/21/2009	

[Select All Lines](#) [Clear Selected](#)

### Actions



If an action needs to be taken for the lines selected above, please choose the appropriate action option and press the Take Action button. The action taken will be applied to all of the selected lines.

- Input Line Availability for the selected items(s)
- Submit Documents for the selected item(s)

TAKE ACTION

FINISHED




# Document submission



## Document Submission

Entry/Doc-Line [Suffix]	Product	Product Code	Quantity	Country Name	Status	Status Date	ITACS Status
082-0306370-9/1-1	FRZ_COOKED SHRIMP WONTON WITH CONCENTRATED SOUP	16W--18	Total: 1204 Carton (1204 Carton, 6 Box, 6 Cup, 145 Grams)	Thailand	Updated Line Availability	Apr 20, 2009	Updated Line Availability

### Submit Document

 To associate a PDF file to the selected lines, please press the Browse button to locate and identify a PDF file from your local machine. Once you have identified the appropriate PDF file, please press the Attach button. To scan a file from your scanner, please press the Scan button. Up to 5 files can be identified for upload at a time.

**Note:** All documents identified will be associated with all selected lines.  
\* are required fields

Submitter Name: \*

Submitter Firm Name: \*

Submitter Phone Number: \* (xxx-xxx-xxxx)

Additional Information:



# Availability of product for inspection



## Input Line Availability

Entry/Doc-Line[Suffix]	Product	Product Code	Quantity	Country Name	Status	Status Date	ITACS Status
082-0306370-9/1-1	FRZ. COOKED SHRIMP WONTON WITH CONCENTRATED SOUP	16W--18	Total: 1204 Carton (1204 Carton, 6 Box, 6 Cup, 145 Grams)	Thailand			

### Availability Information

To indicate Line Availability, please start by selecting the Line Availability option in the Goods location section that best describes the type of Line Availability information you are attempting to provide. Next enter the Submitter information in the appropriate fields. Lastly, please enter in the necessary information for the Facility Information section and then press the Submit button.

\* are required fields

#### Goods Location

- Goods for the selected lines are available at the Consignee address as filed
- Goods for the selected lines are available at the Consignee address as filed with extra information as provided below
- Provide an updated location for the selected lines

#### Submitter Information

Submitter Name: \*  Submitter Phone Number: \* (xxx-xxx-xxxx)

Submitter Firm Name \*

#### Facility Information

Facility Name:  Contact Phone Number:(xxx-xxx-xxxx)

Contact Name:  Warehouse/Pier Lot Number:

Street Address:  Hours Of Operation:

City:  State:  Zip Code:

Additional Information:



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# QUESTIONS?



# FY 2009 Data Fresh Produce



⌚ Total number of lines =	1,647,191
⌚ Total # of samples collected =	3,578
⌚ % of lines sampled =	0.22 %
⌚ Total number refused =	130
⌚ % of lines violative based on refusal =	3.63 %
⌚ Total number reconditioned =	8
⌚ Total number released with comment =	102
⌚ Total number of actual violations =	240
⌚ % of violative shipments =	6.70 %
⌚ Ave time between sample collection & final disposition =	11 days