

PREDICT and ITACS

Briefing Slides for Importers and Entry Filers

FDA Office of Regulatory Affairs
Office of Resource Management

Revised September 18, 2009

Topics

- PREDICT (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

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.

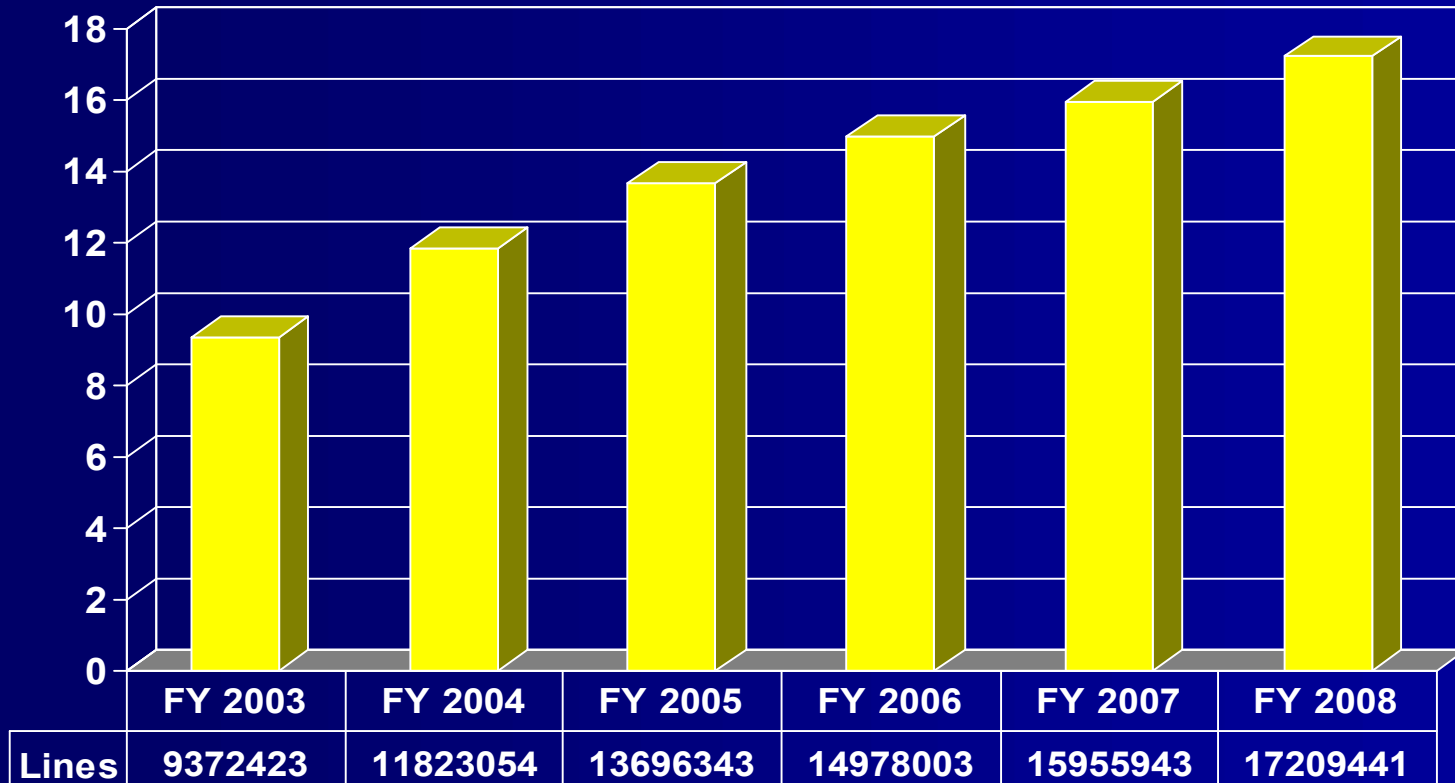
OASIS

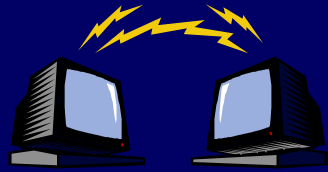
Operational and Administrative System for Import Support

- 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

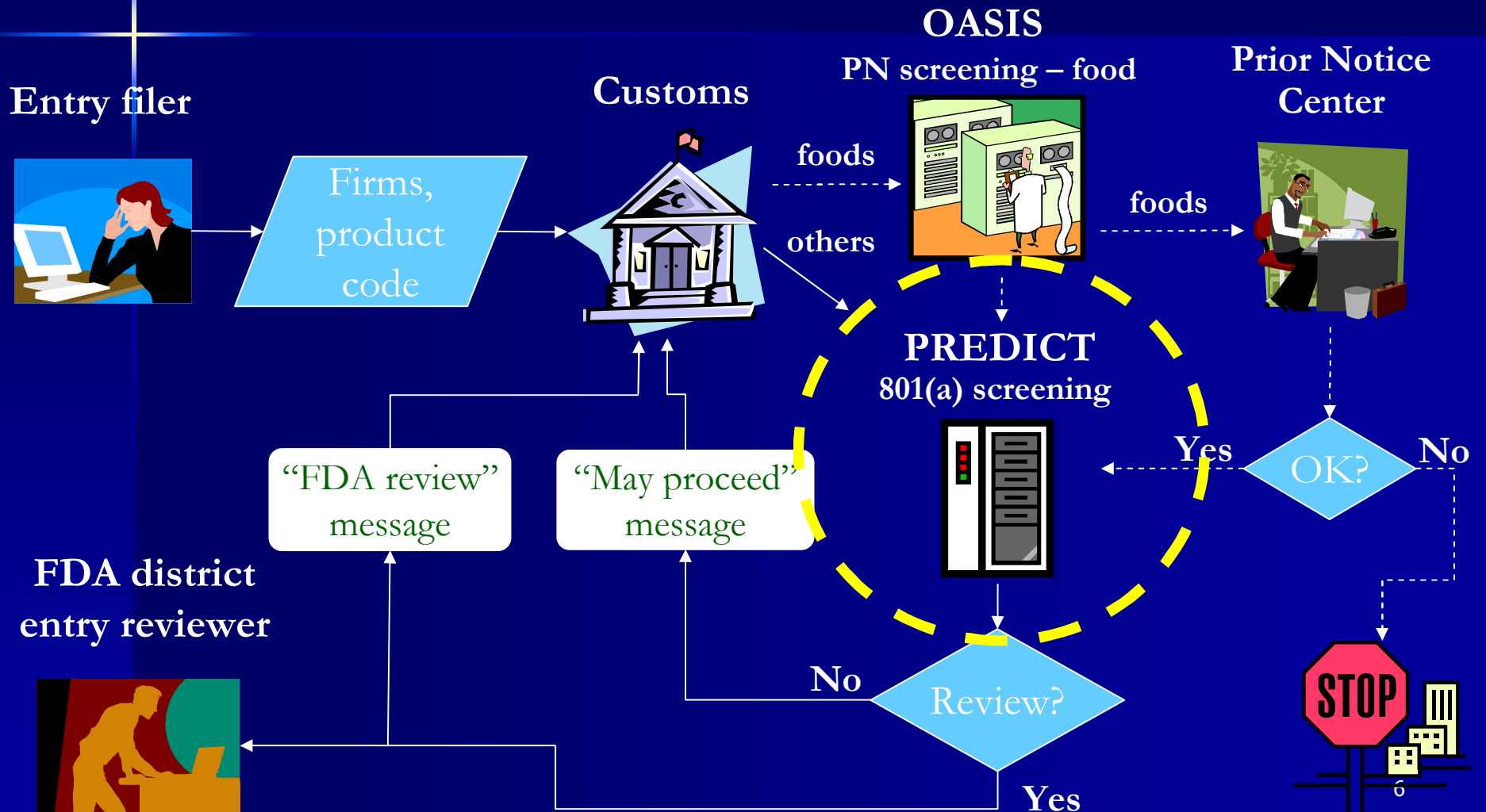
**Workload: Import entry lines, in millions
(excluding mail and baggage)**

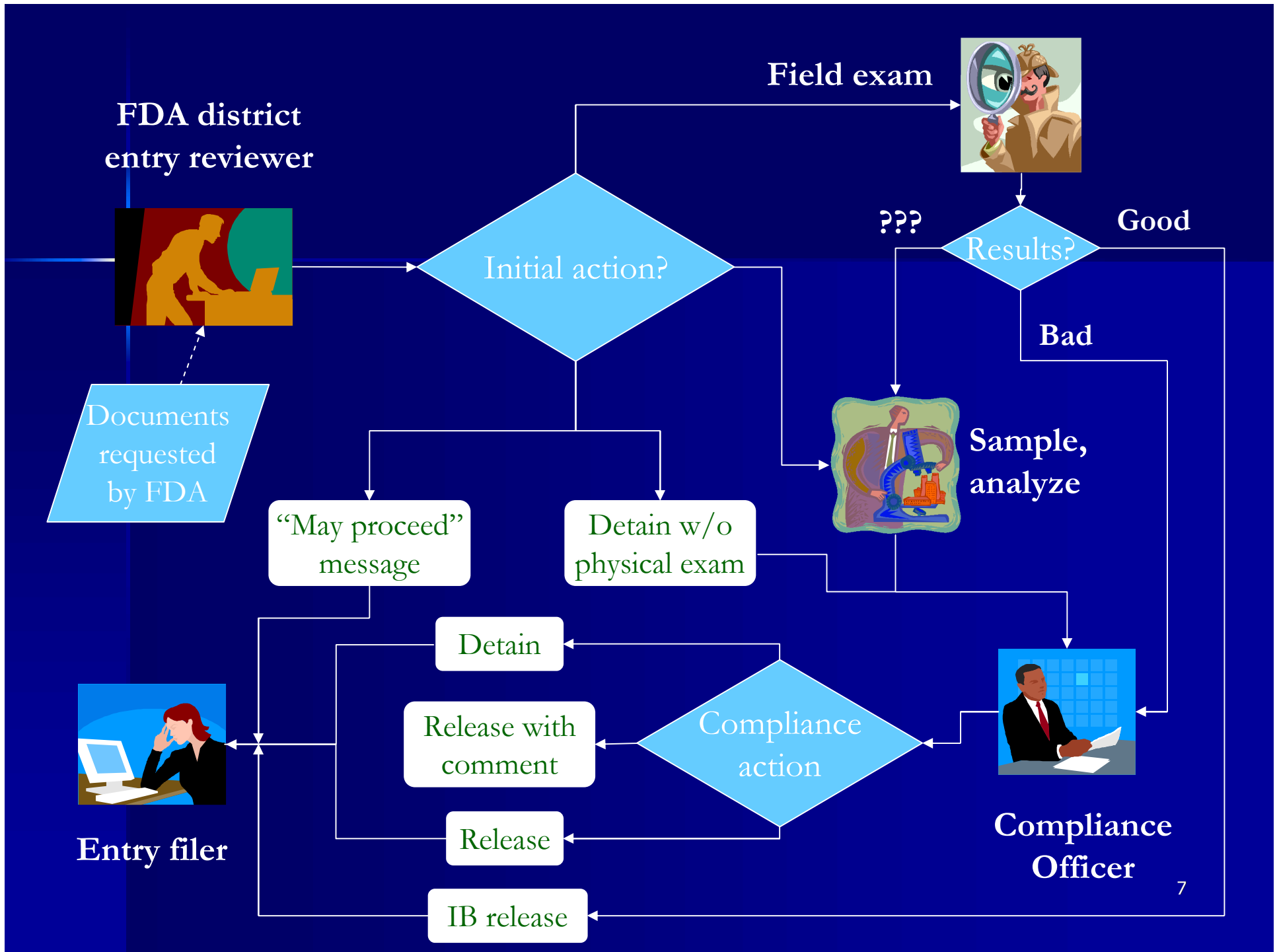
Millions





Electronic Transactions Import Entry Lines





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 various factors
 - Increase the number of automated, real-time, “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

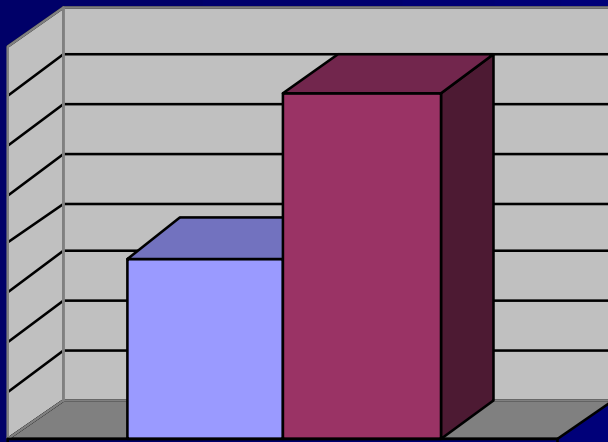
- Data anomalies within the current entry
- Admissibility history with respect to the manufacturer, exporter, importer, and consignee for the current product (at industry and more specific levels)
- Open source intelligence pertaining to the manufacturer, foreign locale, product, etc.

Pilot test

- Began June 4, 2007
- Covered 32,696 lines of seafood entering at five ports within Los Angeles District
- Limited electronic interface with OASIS allowed PREDICT to screen and to issue “may proceeds”
- Reviewers presented with line scores and background information in PREDICT application
- Reviewers used OASIS to enter their decisions and workflow assignments

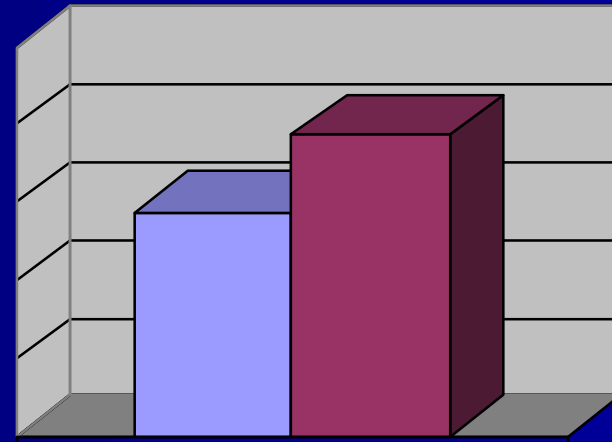
"Hit rates"

Field Exams



■ FY 2006 (OASIS)
■ PREDICT pilot test

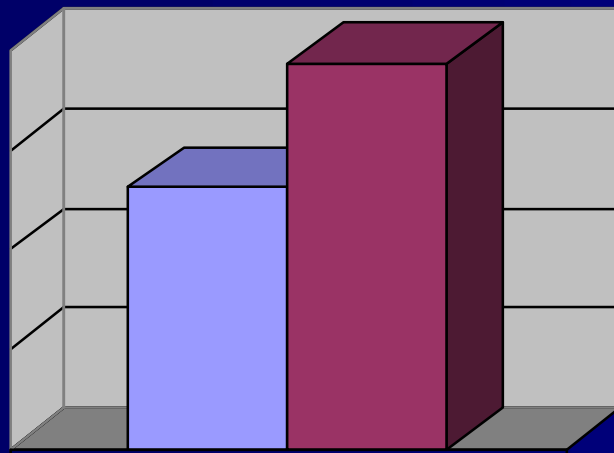
Sample Analyses



■ FY 2006 (OASIS)
■ PREDICT pilot test

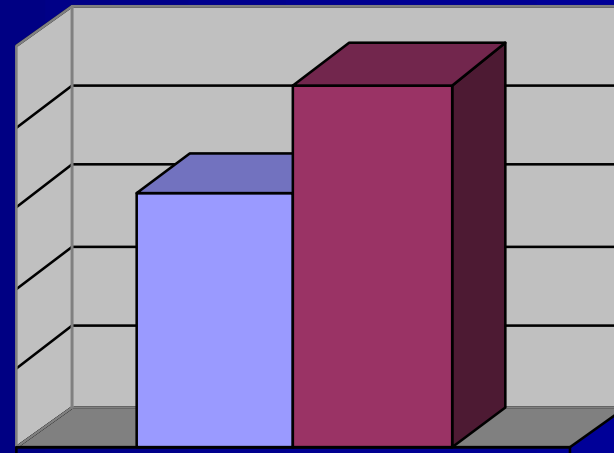
Violation Significance Index

Field Exams



■ FY 2006 (OASIS)
■ PREDICT pilot test

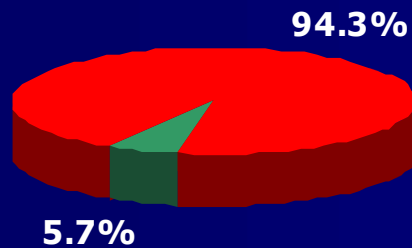
Sample Analyses



■ FY 2006 (OASIS)
■ PREDICT pilot test

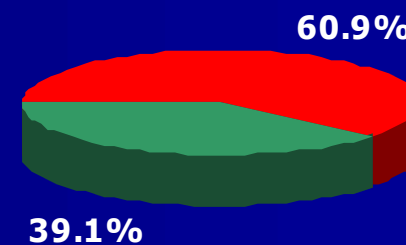
Effective rates – Automated “may proceed”

FY 2006 Control



■ "May proceed" ■ Held for review

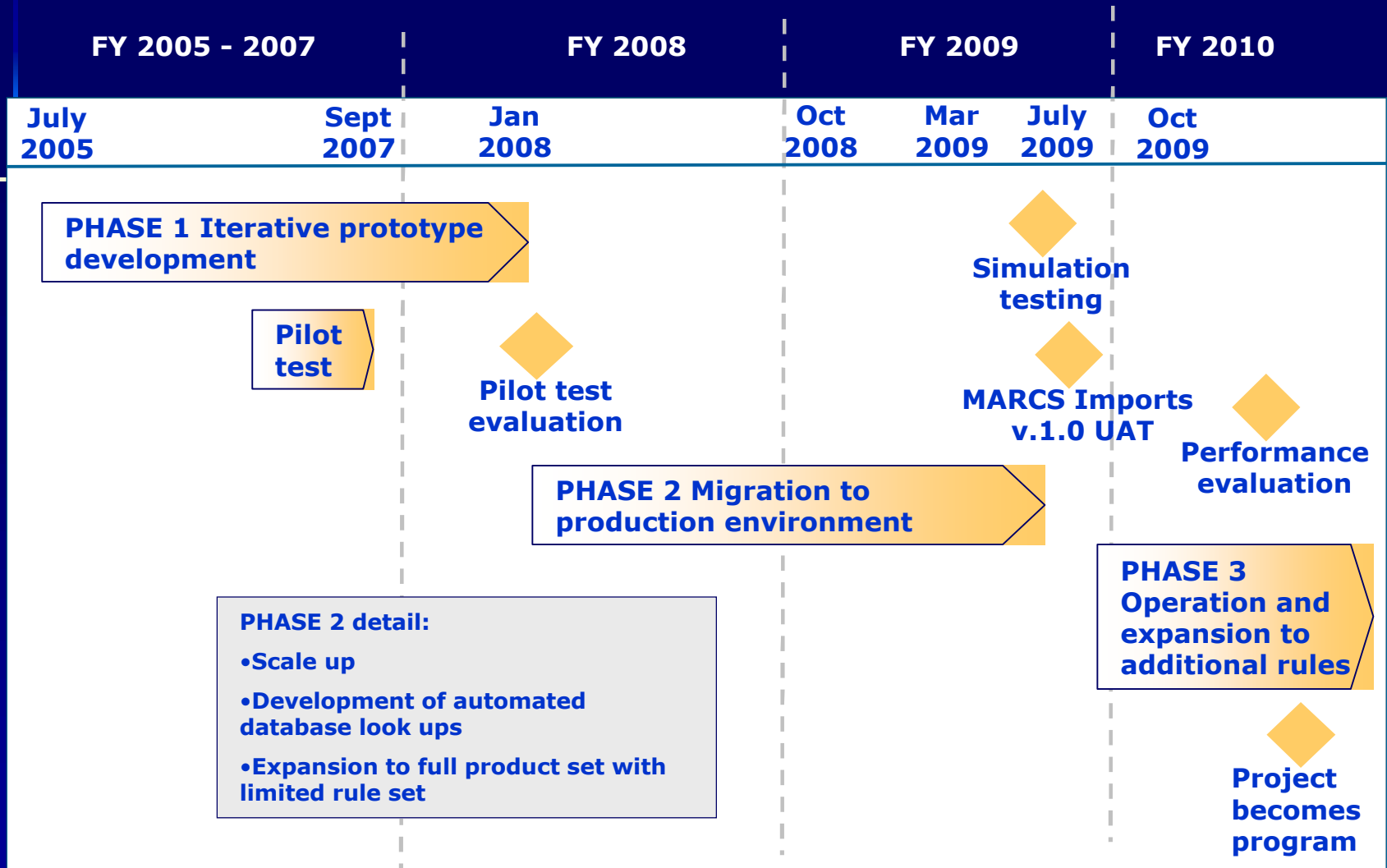
PREDICT



■ "May proceed" ■ Held for review

The effective rate is lower than the individual line rate because of a business rule which requires that if any one line of an entry does not receive a “may proceed,” all lines will be held.

Timeline



NOTE: Timeline is not to scale.

Timeline

(As revised 7/28/09)

July 21 – 24, 2009	User acceptance testing
Late September through early October	Beta testing at Los Angeles
Early November through mid-December	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 lines with lower targeting scores
- OASIS tracks FDA corrections of data submission errors, and PREDICT uses these data to adjust the targeting 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



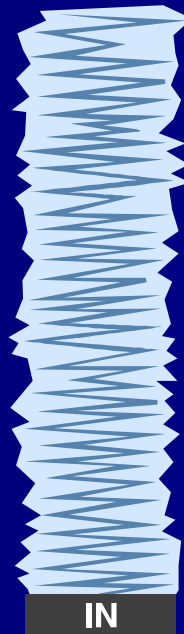
- With accurate and complete affirmations of compliance (NDA, ANDA, PMA, 510(k), NDC numbers, etc.), PREDICT can do the automated lookups for marketing status.
- If an automated lookup fails, the entry line will be forwarded to a reviewer for manual processing.



Entry reviewer workload

Entry lines not given a "may proceed" by PREDICT go to an entry reviewer for manual processing.

"In" box





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.

Medical devices and electronic products

- New affirmation of compliance codes have been created, and the descriptions of some existing codes have been revised. Four codes are being retired.
- For details, see the ACS admin message to filers scheduled to issue September 18, 2009. A current list of codes and descriptions will also be posted on the FDA website at <http://www.fda.gov/ForIndustry/ImportProgram/default.htm>.
- Note that affirmations for some electronic products require the filing of a second, related affirmation of compliance.
- **PREDICT's automated lookups for medical devices and electronic products will fail if the data submitted do not conform to the current codes and definitions.**

Medical device registration numbers

Code	Title	Description
DEV	Device Foreign <u>Manufacturer</u> Registration Number	The qualifier for this code should be the device registration number issued by CDRH for the firm manufacturing the product identified in the FDA line.
DFE	Device Foreign <u>Exporter</u> Registration Number	The qualifier for this code should be the device registration number issued by CDRH for the exporter who exports, or offers for export, to the U.S. a device manufactured or processed by another individual, partnership, corporation or association in a foreign country, as well as devices originally manufactured in the United States.

Medical device registration numbers

Code	Title	Description
DII	Device Initial <u>Importer</u> Registration Number	The qualifier for this code should be the device registration number issued by CDRH for the importer who takes first title to devices imported into the U.S.

Acidified and low acid canned foods (ALACFs and LACFs)

- **FCE: Food canning establishment number**

This is typically a 5 digit number assigned by FDA

- **SID: Scheduled process identifier number**

YYYYMMDDSSS (11 digits) where:

YYYY represents the calendar year

MM represents the month (e.g., 02 for February, 10 for October)

DD represents the day of the month (e.g., 02, 19, 30, etc.)

SSS represents a unique sequence number to identify each process submitted to FDA by the manufacturer on the same date

Acidified and low acid canned foods (ALACFs and LACFs)

- LACF container dimensions are to be declared in specific data fields (defined as part of the ABI to ACS interface), not as affirmations of compliance. Those data fields are:
 - Container dimension #1 (width or diameter)
 - Container dimension #2 (height)
 - Container dimension #3 (length for rectangular containers)

Acidified and low acid canned foods (ALACFs and LACFs)

- Use the appropriate PIC (Process Indicator Code):
 - Use “E” (Commercially Sterile) for most LACF products, including water activity controlled/formulated products.
 - Use “F” (Aseptic) for LACF commercially sterile aseptically packaged products, which may include various low-acid beverages, puddings, baby foods, etc.

Acidified and low acid canned foods (ALACFs and LACFs)

- Use “I” (Acidified) for all acidified products (i.e., products covered under 21 CFR 114).
- Do not use other PICs such as “T” for LACF or for ALACF products.
- The product description for the entry line should match the description of the food as it was given to FDA when the scheduled process was filed.

Acidified and low acid canned foods (ALACFs and LACFs)

- Use the importer's text description field to supplement the product code description when necessary, for example, to indicate packing media (oil, brine, tomato sauce, etc.) and/or product style (sliced, chopped, etc.), and/or when there is no product code product name that matches the SID food name.
- See the following web pages for further information:
<http://www.fda.gov/Food/FoodSafety>



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 targeting 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:

Questions?

