

Navigating Regulations by Multiple Agencies:

How to Manage Interagency Cooperation

December 9, 2009



U.S. Customs and Border Protection
2009 Trade Symposium

Interaction Among the Government Agencies

- U.S. Customs and Border Protection's (CBP) Operations and Interaction with Other Government Agencies (OGA)
- New Legislation
- Joint Initiatives with OGAs
 - CPSC Overview
 - FDA Overview



U.S. Customs and Border Protection

- Office of International Trade - Import Safety and Interagency Requirements Division

Mission:

- Facilitate Communications and Strengthen CBP's Partnerships Between Other Government Agencies and the Trade Community.
- Assist in the Prevention of the Importation of Unsafe Products into the United States.



Interagency Cooperation

- Understand common goals.
- Share effective trade enforcement policies.
- Utilize CBP's specialized skill sets to enhance OGA trade security priorities.
- Provide regulation development and audit assistance.
- Monitor OGA trade operations.



CBP Enforces Laws for Multiple Agencies

- **Enforcement agencies** implement antiterrorism efforts and/or U.S. foreign policy.
- **Regulatory agencies** ensure imported merchandise is compliant with federal laws.
- **Statistical agencies** help determine monthly balance of trade.



Recent Legislation

- CPSC
 - Consumer Product Safety Improvement Act
- FDA
 - Family Smoking Prevention and Tobacco Control Act
- APHIS
 - Lacey Act



CBP & OGA Joint Initiatives

- Interagency Meetings
- Priority Trade Issue Meetings
- Special Operations
- Communications
- Co-location
- Enhanced Laboratory Capacity
- Partnerships



Coordination of Resources

- Authorities
- CBP & OGA Staffing
- Testing Capabilities
- Logistical Planning
- Alternate Plans
- Supply Chain Impact
- Facilitation



Facilitation & Partnerships

- Importer Self Assessment – Product Safety Pilot
 - Expansion of the Importer Self Assessment (ISA) Program
 - Voluntary Partnership Between the Trade, CPSC and CBP
 - Effective Control Environment
 - Adequate Risk Assessment Process
 - Effective Information and Communication
 - Sufficient Monitoring/Quality Assurance

- OGA Initiatives

- Strengthening Interagency Collaboration
 - CPSC Legislation and Initiatives
 - FDA Legislation and Initiatives



U.S. Consumer Product Safety Commission (CPSC)

- Jeremy Baskin, Office of the General Counsel, CPSC
- This presentation was prepared by CPSC staff, has not been reviewed or approved by, and may not reflect the views of, the Commission. Some information may not be accurate after the presentation date and should not be relied upon . Refer to www.cpsc.gov for up-to-date information.

U.S. Consumer Product Safety Commission (CPSC)

- Independent Federal Agency
- Headed by 5 Commissioners (1 Chair)
 - Chairman Inez Tenenbaum
 - Commissioners Nancy Nord, Anne Northup, Robert Adler and Thomas Moore
- Office of Compliance and Field Operations
 - Division of Import Surveillance (Feb 2008)
 - 14 Compliance investigators in the Division
 - Will be adding more

U.S. Consumer Product Safety Commission (CPSC)

- **Consumer Product Safety Improvement Act (CPSIA)**
- Consumer Product Safety Act (CPSA)
 - Lighters
- Federal Hazardous Substances Act (FHSA)
 - Fireworks
- Flammable Fabrics Act (FFA)
 - Sleepwear/mattresses
- Poison Prevention Packaging Act (PPPA)
- Refrigerator Safety Act (RSA)
- Virginia Graham Baker Pool and Spa Act

CPSC - GAO Report

- Recognized that CPSC has limited staff at the ports of entry
- Three recommendations
 1. Implement key provisions of CPSIA
 2. Update agreements with CBP
 3. Update strategic plan

CPSC – Consumer Product Safety Improvement Act (CPSIA)

- Prohibited Acts (15 USC 2068)
 - Import any product not in conformity with rule
 - Import any product subject to a voluntary corrective action taken by manufacturer, Commission has notified the public and manufacturer knew or should have known
- Imported Products (15 USC 2066)
 - Product refused admission shall be destroyed
 - Upon application by importer, Secretary of the Treasury permits the export in lieu of destruction

CPSC - CPSIA, continued

- All Terrain Vehicles (ATV) – 15 USC 2089
 - Unlawful to import any ATV without ATV action plan
 - ATV must comply with all provisions of standard
- Substantial Product Hazard List (15 USC 2064(j))
 - Commission may specify by rule any consumer product as a substantial product hazard
 - Characteristics whose presence or absence are readily observable and have been addressed by voluntary standards
 - Standards have been effective in reducing risk of injury and there is substantial compliance
 - Hair dryers and children's clothing with drawstrings

CPSC – CPSIA, continued

- General Conformity Certification (15 USC 2063(a)(1))
 - Every product imported for consumption or warehousing
 - Certify based on a test of each product or reasonable testing program that the product complies with all rules enforced by the Commission
- Requirements for Certificates (15 USC 2063(g))
 - Certificates shall accompany the applicable product
 - Certificates shall be furnished to each distributor or retailer of the product
 - Final Rule 73 FR 68328, November 18, 2008

CPSC –CPSIA, continued

- Third Party Testing Certification (15 USC 2063(a)(2))
 - Before importing for consumption or warehousing
 - Any children's product that is subject to a children's product safety rule
 - Lead Paint
 - Cribs and Pacifiers
 - Small parts
 - Children's metal jewelry
 - Lead content

CPSC –CPSIA, continued

- Tracking labels (15 USC 2063(a)(5))
 - Required on children's products
 - Requires permanent mark on product and packaging
- Civil penalties (15 USC 2069)
 - Not to exceed \$100,000 per violation with a maximum of \$15,000,000 for any related series of violations

CPSC –CPSIA, continued

- Stays of enforcement until February 10, 2010
- Doesn't apply to requirements for third-party testing and certification of certain children's products subject to:
 - The ban on lead in paint and other surface coatings effective for products made after December 21, 2008;
 - The standards for full-size and non full-size cribs and pacifiers effective for products made after January 20, 2009;
 - The ban on small parts effective for products made after February 15, 2009; and
 - The limits on lead content of metal components of children's jewelry effective for products made after March 23, 2009.

CPSC –CPSIA, continued

- Doesn't apply to:
 - Certification requirements applicable to ATV's manufactured after April 13, 2009.
 - Pre-CPSIA testing and certification requirements, including for: automatic residential garage door openers, bike helmets, candles with metal core wicks, lawnmowers, lighters, mattresses, and swimming pool slides; and
 - Pool drain cover requirements of the Virginia Graeme Baker Pool & Spa Safety Act.

CPSC – Miscellaneous

- Commercial Targeting Analysis Center (CTAC)
 - Operated by CBP
 - Staffed by CBP, CPSC, and other agencies responsible for import safety
- Notice of Workshop on Product Testing (74 FR 58611, dated November 13, 2009)
- More information www.cpsc.gov

TRADE SYMPOSIUM 2009

Navigating Regulation by Multiple Agencies:

FDA Update

December 9, 2009



Homeland
Security



Presentation Overview

- New Legislation

- ✓ The Food Safety Enhancement Act HR. 2749
- ✓ The Food Safety Modernization Act S. 510

- President's Food Safety Working Group

- MARCS V1.1

- ✓ PREDICT
- ✓ ITACS



New Legislation

➤ House HR 2749

Title I – FOOD SAFETY

- ✓ Subtitle A – Prevention
- ✓ Subtitle B – Intervention
- ✓ Subtitle C – Response

Title II – MISCELLANEOUS

➤ Senate S. 510

TITLE I - IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

TITLE II - IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

TITLE III - IMPROVING THE SAFETY OF IMPORTED FOOD

TITLE IV - MISCELLANEOUS PROVISIONS

What have we been doing?

➤ FDA's Initiatives

- ✓ ORA Tactical Plan
 - ✓ Science Strategic Plan
 - ✓ Import Operations Strategic Plan
 - ✓ Dedicated foreign Cadre
 - ✓ MARCS / PREDICT / ITACS
- ✓ Beyond our Borders
- ✓ Third Party Certification Pilot
- ✓ Good Importer Practices
- ✓ Rapid Response Teams
- ✓ High throughput labs
- ✓ Inspectional Tools
- ✓ Private Lab Guidance

➤ FDA's Initiatives

- ✓ Registration Verification Program
- ✓ Use of State Data
- ✓ Joint Operations with CBP
- ✓ Secure Supply Chain Pilot
- ✓ Unique Identifier
- ✓ Harmonizing procedures w/CBP
- ✓ BPI - Import Alert – CMS
- ✓ ACE/ITDS
- ✓ CTAC
- ✓ Integrated Food Safety System
- ✓ Hiring
- ✓ Reportable Food Registry

PREDICT Definition

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

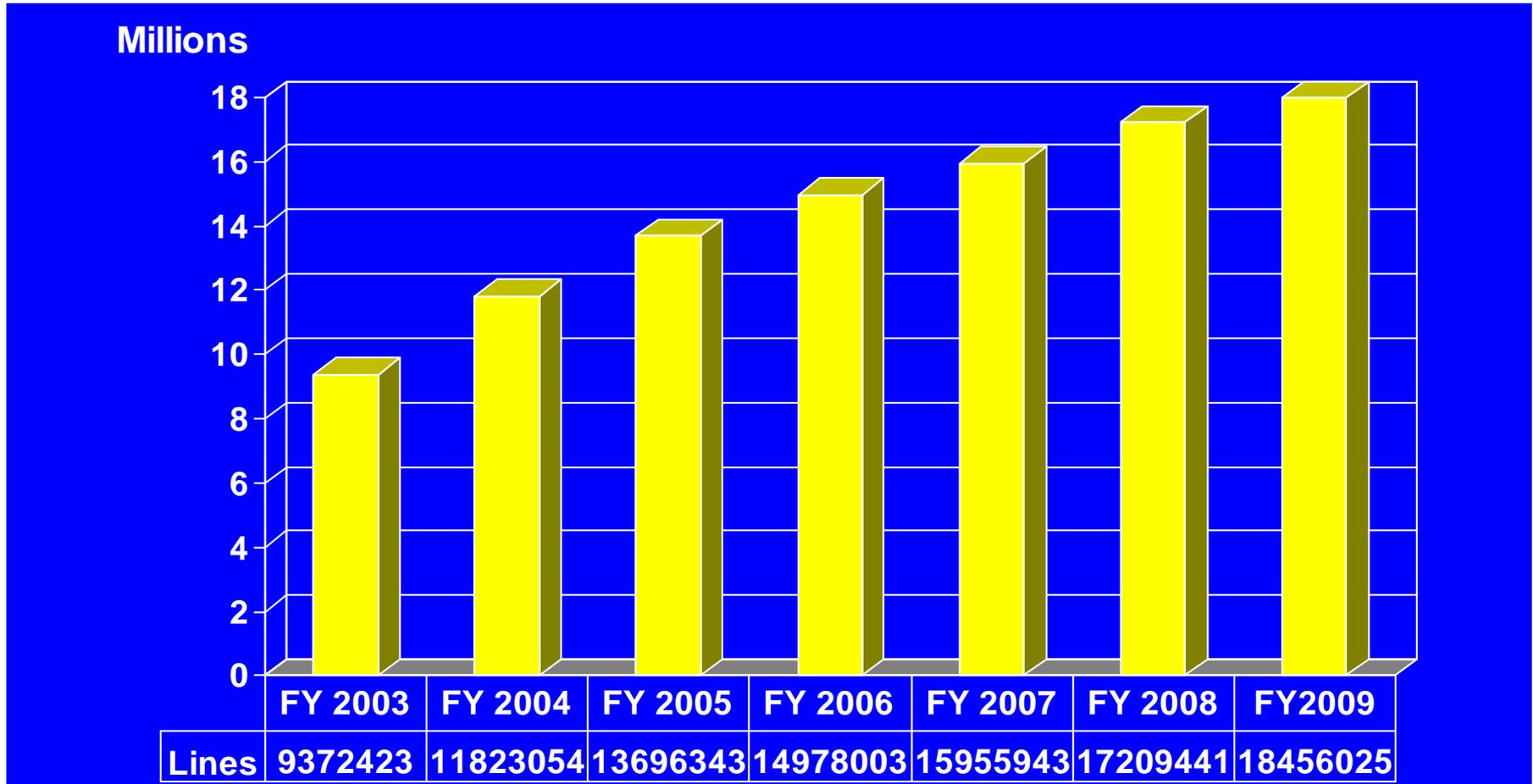
- Legacy system operating 24/7 FDA-wide since 1998

- 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)



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

PREDICT method

- Change the model from “entry review” to “line review”
 - ✓ Work in “line view” mode, not “entry view” mode
 - ✓ Review line targeting scores across all pending entries
 - ✓ Use targeting scores to heavily influence the selection of lines for field exam and/or sampling

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.

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

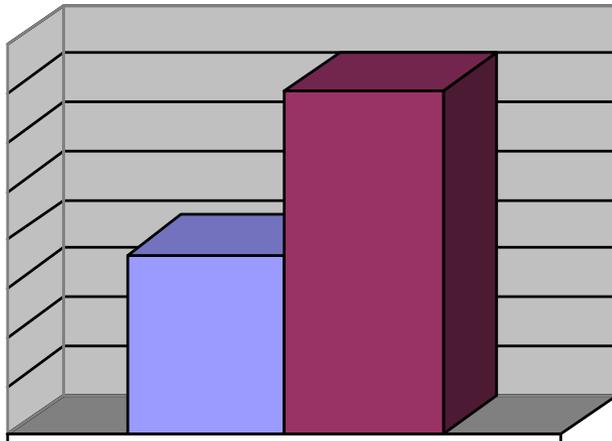
- To expedite entry screening by PREDICT, importers and entry filers must provide:
 - ✓ Consistent, accurate identifiers for firms
 - ✓ Accurate product codes
 - ✓ All of the relevant affirmations of compliance
- With those data PREDICT will be able to issue system 'may proceeds' quickly for low-risk, 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

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

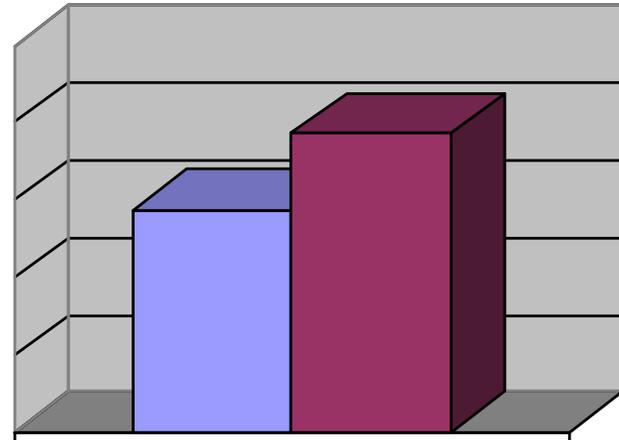
“Hit rates”

Field Exams



- FY 2006 (OASIS)
- PREDICT pilot test

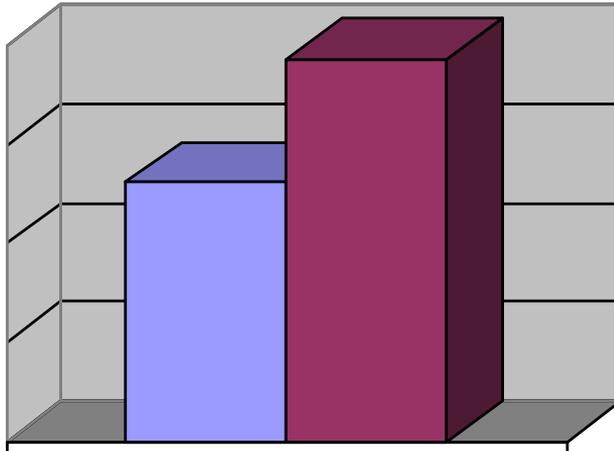
Sample Analyses



- FY 2006 (OASIS)
- PREDICT pilot test

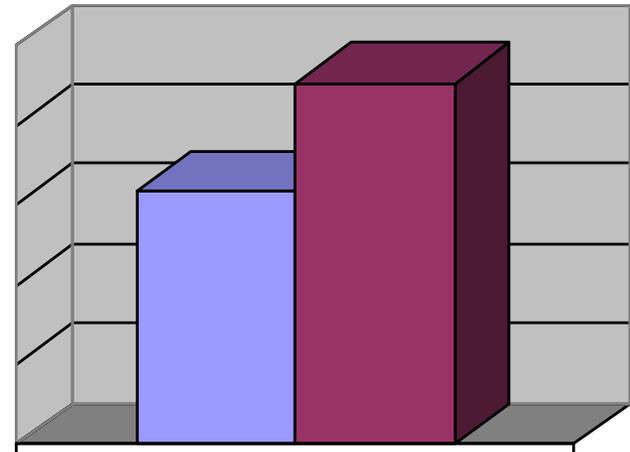
Violation Significance Index

Field Exams



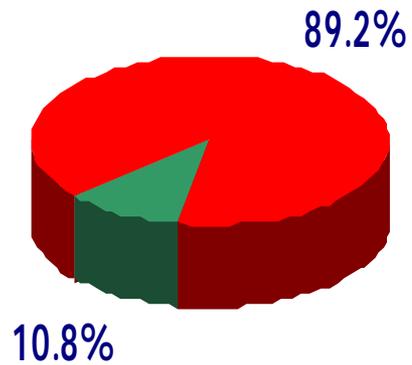
- **FY 2006 (OASIS)**
- **PREDICT pilot test**

Sample Analyses

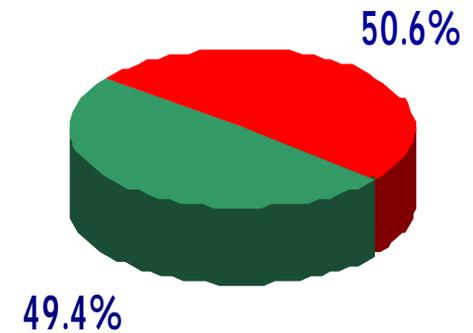


- **FY 2006 (OASIS)**
- **PREDICT pilot test**

Individual lines – Automated “may proceed” rates



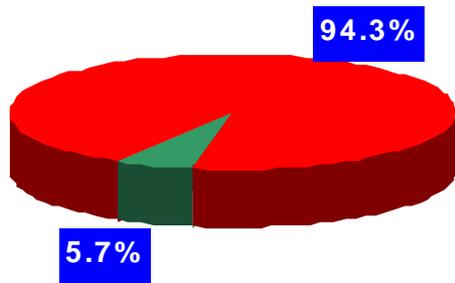
■ "May proceed" ■ Held for review



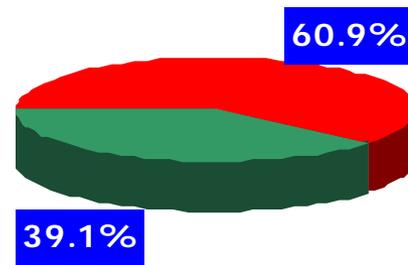
■ "May proceed" ■ Held for review

Effective rates

Automated "may proceed"



■ "May proceed" ■ Held for review



■ "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.

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