CONECT
Northeast Trade & Transportation Conference

March 15, 2012

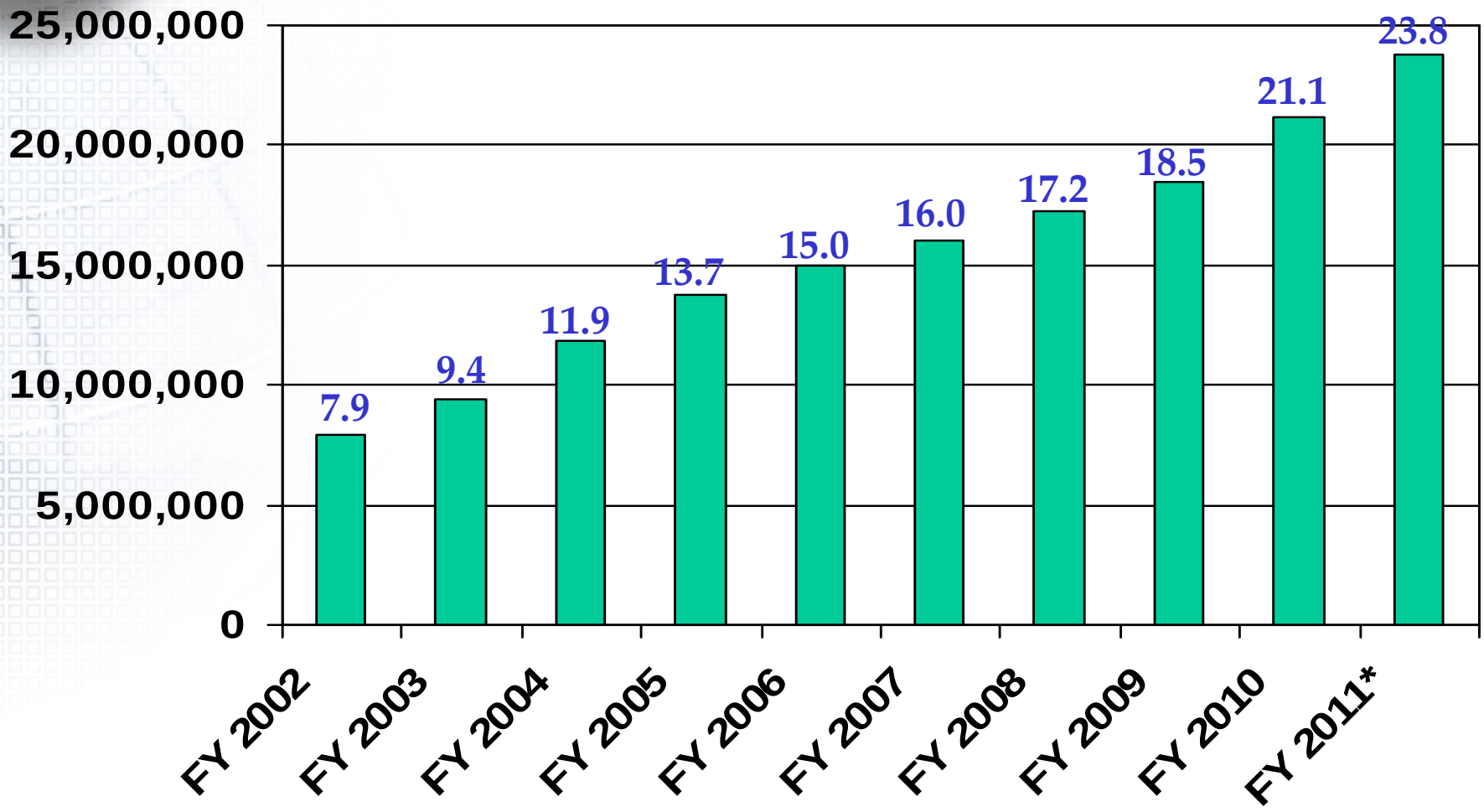
Facilitating Trade in the 21st Century

Presentation by:
Ted Poplawski, Special Assistant
Division of Import Operations & Policy

Topics for discussion

- ✓ OASIS
- ✓ PREDICT
  - ✓ Risk-based Targeting
- ✓ ITACS
- ✓ FSMA
- ✓ ITDS

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



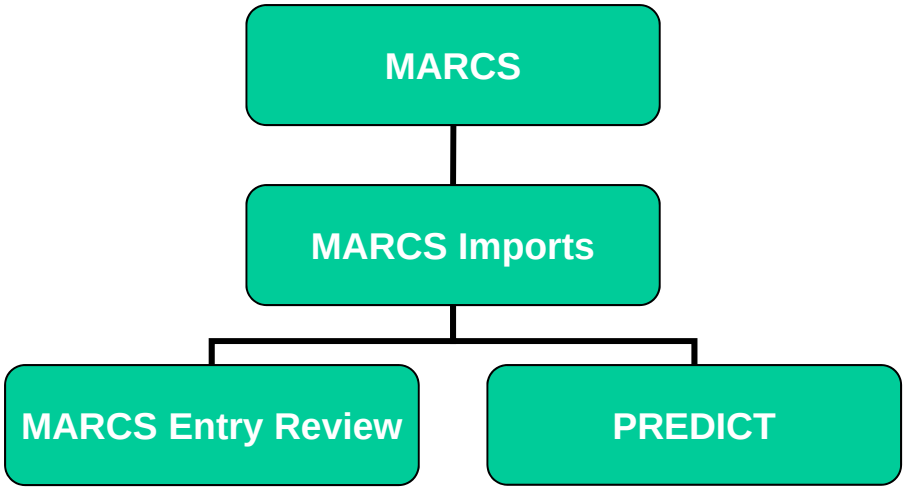
OASIS

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

MARCS

- Mission Accomplishment and Regulatory Compliance Services
- MARCS Entry Review replaces the legacy entry review screens from OASIS.
- PREDICT functions mostly behind the scenes. PREDICT is not MARCS Entry Review
- Entry reviewers have access to PREDICT screening results through a “mash-up” within MARCS Entry Review.



MARCS Imports

- **Three major components integrated with OASIS**
  - PREDICT
  - Import Trade Auxiliary Communications Service (ITACS)
  - Improved cross-district entry review capability
- **Redesigned, modern screens for entry reviewers**

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 screening and processing import entries.

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
- 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
  - ✓ Incremental health risk in view of previous FDA analytical results for products of the same manufacturer
  - ✓ 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.

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 this 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

ITACS

Import Trade Auxiliary Communications System

- **Internet portal for import trade**
  - Ability for the trade to check the status of individual entries/lines
  - Submission of entry documentation which will be linked to specific entries/lines
  - Provide availability information for targeted shipments

ITACS Benefits

- Allows a quick way to check entry status
  - CBP/FDA interface is down
  - No need to wait for returned phone calls
  - More specific information regarding a shipment
- Submit entry documents
  - No need to FAX or deliver documents to FDA
  - No problems with “lost” document submissions
- Provide availability information

Entry/Line Statuses

- Note: ITACS will only display statuses for “open” entries. If a final FDA admissibility decision has been made for all lines of an entry, the entry is “closed” in FDA’s import system and users will need to check their ABI Messaging or Notices of FDA Action for the status.

Future Functionality

- Transmission of Notices of FDA Action
- Query for FDA Firm Identifiers
- Query for FDA Product Codes
- Display of Laboratory Timeframes
- Submission of other document types
- Improved CAPTCHA legibility
- Virus scanning of submitted documents
- Printer friendly version of Status page
- Link to FDA Import Reference materials

ITACS Link

- **Internet link:** https://itacs.fda.gov

- To report technical problems or ask questions about ITACS, please send emails to itacssupport@fda.hhs.gov

- Users should contact the Districts directly for questions regarding activities performed on a line, timeframes for review of an entry, and compliance issues.

Division of Import Operations & Policy

FSMA

- Food Safety and Modernization Act

- All entities involved in food production, distribution, and oversight take responsibility for assuring safe foods. This includes:
  - Government regulators
  - Growers
  - Manufacturers/processors
  - Holders/Distributors and transporters
  - Importers and consignees

Import Safety Mandates

Sec. 301. Foreign supplier verification program

- Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements.

Sec. 302. Voluntary qualified importer program

- Allows for expedited review and entry; facility certification required

Import Safety Mandates

Sec. 307. Accreditation of third-party auditors

- FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements

Sec. 303. Certification for high-risk food imports

- FDA has discretionary authority to require assurances of compliance for high-risk foods

Sec. 306. Inspection of foreign food facilities

- Can deny entry if FDA access for inspection is denied

Import Safety Mandates

Sec. 309. Smuggled Food

- In coordination with DHS, better identify and prevent entry of smuggled food

Sec. 305. Capacity building

- FDA mandate to work with foreign governments to build food safety capacity

ITDS Integration into ACE

- ✓ The transition to ACE will complete FDA's upgrade to modernize its automated import system and its interface with Customs and Border Protection IT System for screening and processing of FDA -regulated cargo and mandatory Prior Notice submissions.
- ✓ The PGA Message Set will enable brokers to make a direct entry into MARCS through ACE as they always have done, however, it will remove the need for affirmation of compliance codes (AofC) and
- ✓ It will improve communication and the sharing of information electronically between agencies.

The Work Continues

1. Finalize the MOU with CBP and other Agencies
2. Provide additional data elements as a result of new legislation
3. Digital Imaging Systems of each agency need to be modified to the same format
4. Obstacles of sharing of information needs to be identified and solved.