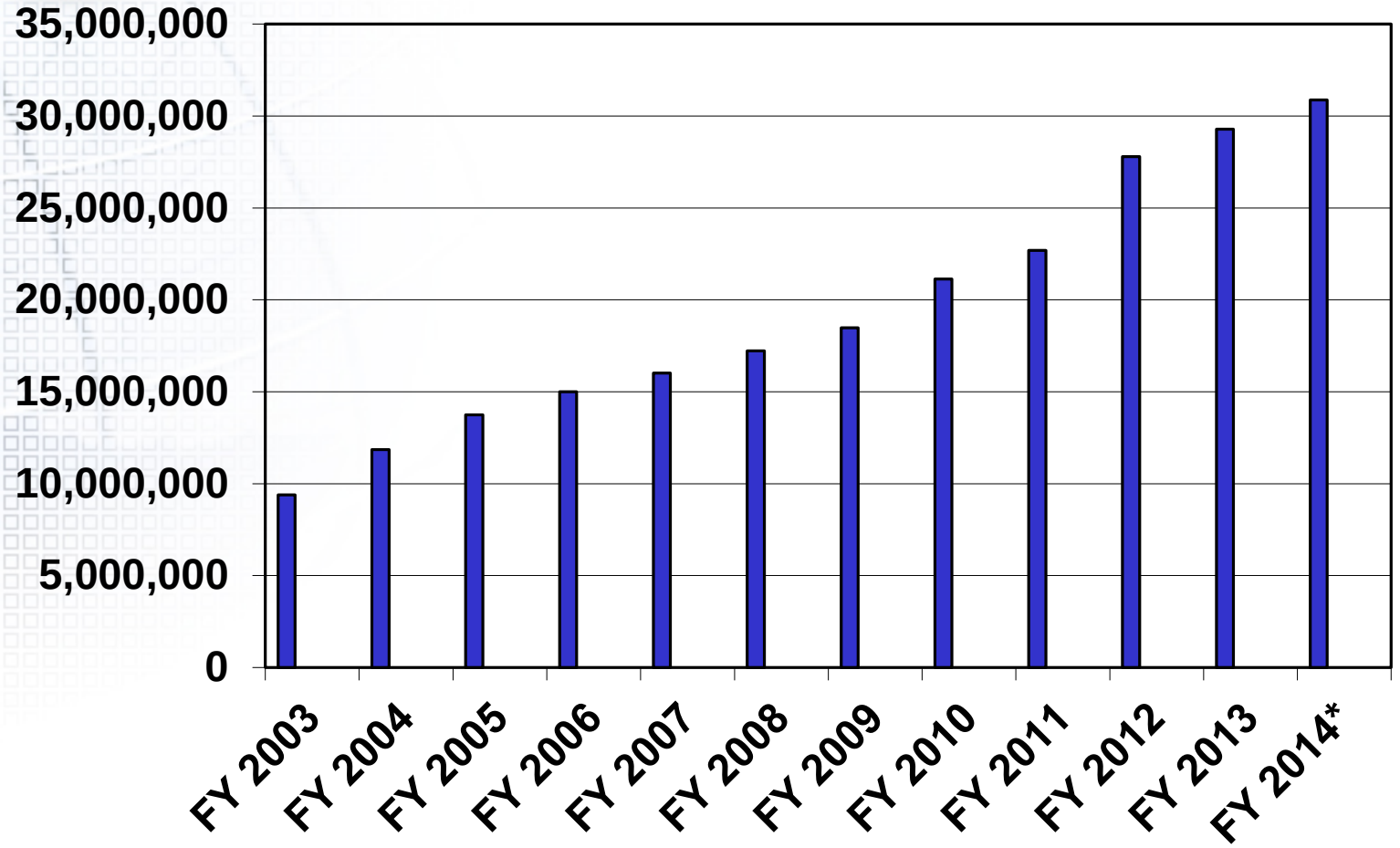
Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

Updated February 2014

U.S. Department of Health and Human Services
Food and Drug Administration

Number of Import Entry Lines Electronically Screened per Fiscal Year Since 2002



* Projected

Electronic Transactions
Import Entry Lines

Entry Filer

Firms, product code

OASIS
PN screening – food

foods

others

foods

Division of Food Defense Targeting

PREDICT
801(a) screening

Yes

OK?

No

"FDA review" message

"May proceed" message

FDA District Entry Reviewer

No

Review?

Yes

FDA Field and Compliance Workflow

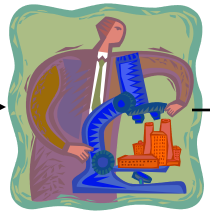
FDA District Entry Reviewer

Documents requested by FDA

Initial Action?

Field Exam

Sample, Analyze



Results?

Good

Bad

"May Proceed" message

Detain w/o Physical Exam

Detain

Release with comment

Release

IB release

Compliance action

Compliance Officer

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.

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

Risk types to be included in targeting scores

- Compliance risk of firms associated with the imported line
- Product-related
  - ✓ Inherent health risk
  - ✓ Incremental health risk in view of previous FDA physical examination results for products of the same manufacturer
  - ✓ Risk factors identified by the FDA or other sources that create the need to implement expert rules indicating further action by field staff

Note: Product-related risk factors are continually under development.

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 relevant affirmations of compliance
- With those data elements, PREDICT will be able to issue a system ‘May Proceed' quickly for low-risk shipments not held due to any other screening criteria
- Data anomalies and poor data quality are used to adjust the risk scores

Affirmations of Compliance

- Affirmations of compliance are data elements submitted voluntarily to the FDA to expedite the entry review process. For example:
  - ✓ Establishment registration number
  - ✓ Product listing number
  - ✓ Product approval number
  - ✓ Radiological health product report accession number
  - ✓ Low Acid Canned Food/Acidified Foods establishment and process identifiers

With PREDICT:
Affirmations of compliance

- With accurate and complete affirmations of compliance, PREDICT will validate information against internal databases.

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

Importers and Filers

- The quality of the data submitted to the 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 physical examination by the FDA.

Thank you for your time!