

# Collaborative Food Safety Forum

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## PREDICT

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# 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

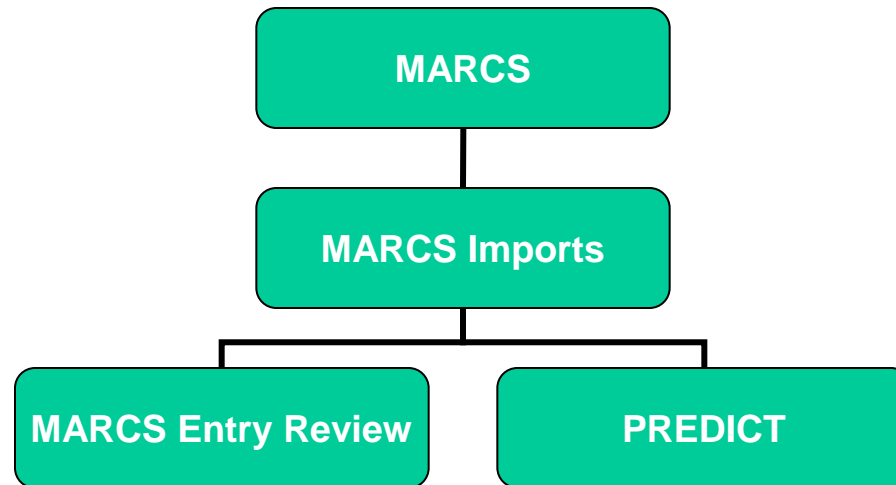
Method: Replace the admissibility screening portion of FDA's legacy electronic system for processing import entries.



# PREDICT is not MARCS Entry Review

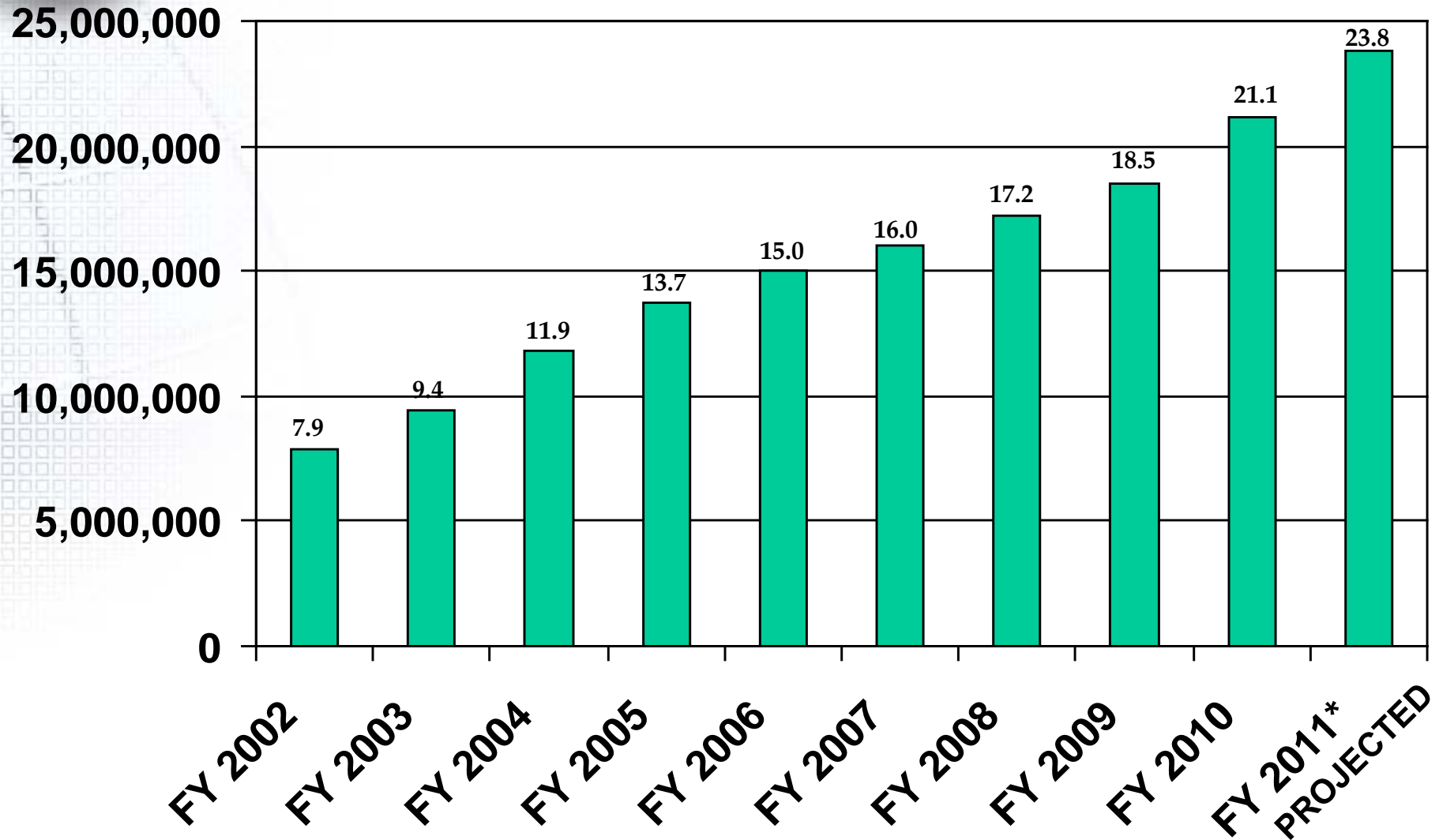


- PREDICT functions mostly behind the scenes.
- MARCS Entry Review replaces the legacy entry review screens from OASIS.
- Entry reviewers have access to PREDICT screening results through a “mash-up” within MARCS Entry Review.





# FY 2002 – 2011\* LINES





# PREDICT purpose and 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 purpose and method



- Use automated data mining and pattern discovery for rules development
- 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.)

# 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)

# PREDICT and FSMA





# QUESTIONS?