A Machine Learning Approach for Balancing Risk and Time For Evaluation of Import Entry Filers

Revati Rajane¹, Eckart Bindewald¹, Lija Fellows², Indu Konduri², Tyler Poppenwimer², John Jackson², Serajus Salaheen², Robert Timmons¹, Isaac Garcia¹, Brandon Tao¹, Ben Duan¹, Faiad Rahaman² 1: Precise Software Solutions, Rockville, MD; 2: Office of Regulatory Affairs, FDA, Silver Spring, MD

Abstract

Entry filers (also called customs brokers) play an important role in the process of US food imports. They undergo evaluations by the FDA Import Filer Program. Here we present a data-driven approach that uses machine learning for risk estimation and an innovative operations research approach for balancing the risk of evaluation outcome with the time since the last evaluation. A data dashboard is augmenting this approach and provides FDA inspectors with the needed information via a user-friendly interactive display.

Filer Evaluation Program

- Entry Filer submits required product information
- Determines the quality & accuracy of the import's entry data • Classification of the filer evaluation outcome is based on the significance of the discrepancies between submitted data and entry documents
- Routine filer evaluations are scheduled based on risk and resources
- 4-year rotational schedule in the past
- Outcomes are available to the public

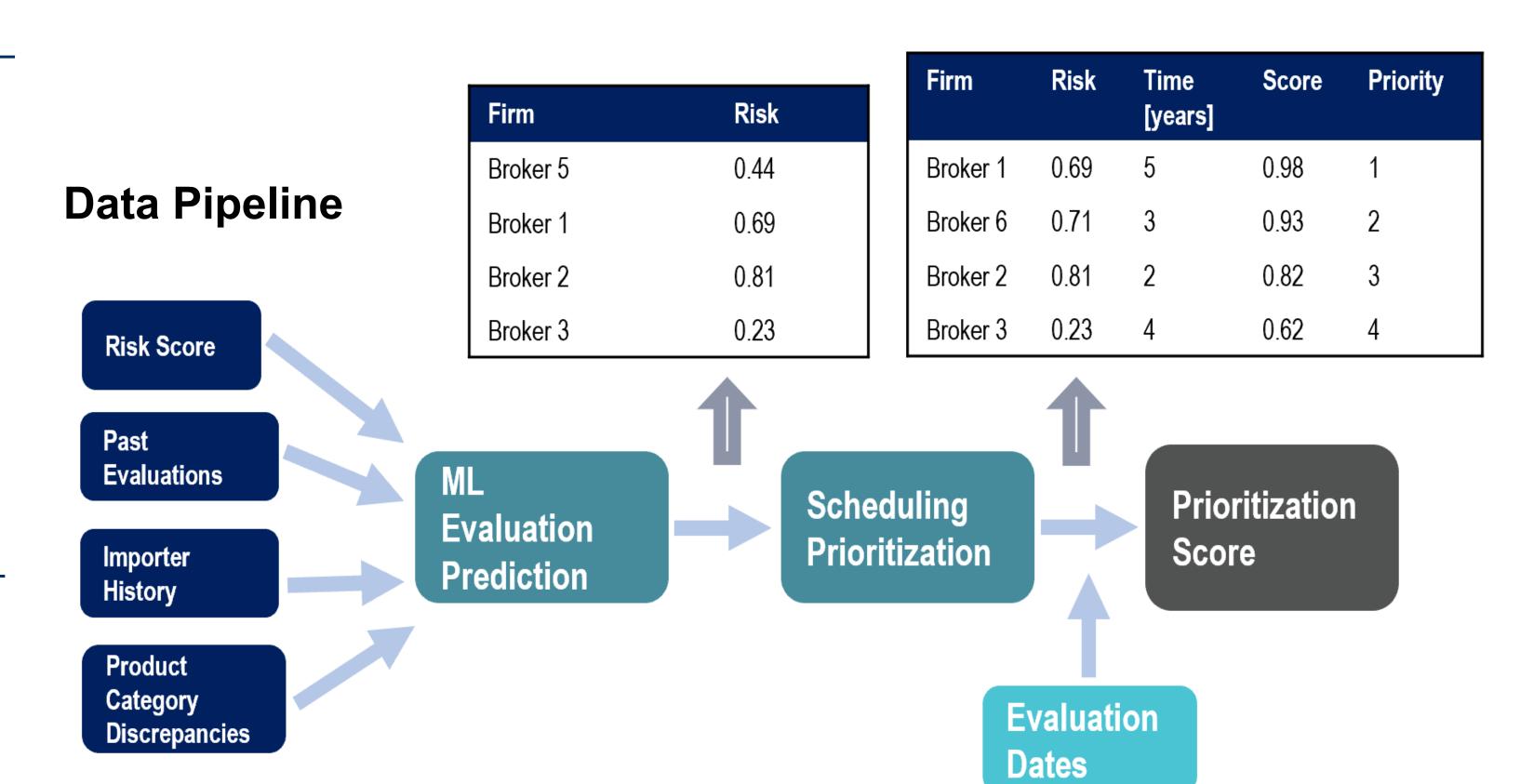
Machine Learning Methodology

•Evaluation prediction: 2-class classification of acceptable versus unacceptable evaluation outcome

"Acceptable": NAI, VAI, VWR, P1, P2, RP

- "Unacceptable": OAI, CA, SC, OC1, RU, UN
- •Risk scores, past evaluations, importer history & updates and corrections to product information are considered
- •Non-numeric categorical data has been encoded using mean encoding
- •Balancing predicted risk with time: Combined predicted evaluation risk with time span between current date and last evaluation
- •Training on data from 2,268 different import filers
- Binary classification of predicted evaluation outcomes
- •Choice of lightGBM as classification algorithm algorithm is optimizing large number of decision trees
- •Classification based on multiple weighted decision trees
- •Performance: Area Under the Curve (AUC) of 0.81

			One-hot Encoding					
Eval Result	Category	Outcome	NAI	VAI	OAI	Outcome		
NAI	1	1	1	0	0	1	Eval Result Mean	Outcome
VAI	2	0	0	1	0	0	0.037	1
OAI	3	1	0	0	1	1	0.163	0
		/					0.379	1



Sample ML Data

Description	Example		
Evaluation Result Code	0		
Result of most recent evaluation- Classification*	P2*		
Evaluation type - routine, follow-up, for-cause*	RT*	I Batama	
Time between 2 most recent evaluations	215	History	
Time between 2 evaluations prior to most recent	226		
Evaluation Result, Classification prior to most recent*	P2*		
Min percentile rank of rule-based score	66.67		
Max percentile rank of rule-based score	82.67	Risk	
75th percentile rank of rule-based score	78	Percentile &	
Lines that passed automated queries	17		
Lines that failed automated queries	4.33	Import Rule	
Total disclaimed lines transmitted by the filer	11	Stats	
Total Entries transmitted by the filer	8.33		
Country of shipment corrected by FDA staff	0		
Product code corrected by FDA staff	3		
Correction on production/source	0	No. of	
Corrections on Shipper data	4	Corrections	
Manufacturer data element corrected by FDA staff	0		
Quantity corrected by FDA staff	7	by FDA	
Intended Use Code (IUC) corrected by FDA staff	0		
Corrected Description corrected by FDA staff	2		
Filer Fault	1		
Importer Fault	0	Corrections	
No ones fault	0	Corrections	
Inconclusive - Fault Non-assigned	0		
Value data element corrected by FDA staff	0	ing moon oncoding	

FDA | SYMPOSIUM | SCIENTIFIC COMPUTING + DIGITAL TRANSFORMATION | 2024

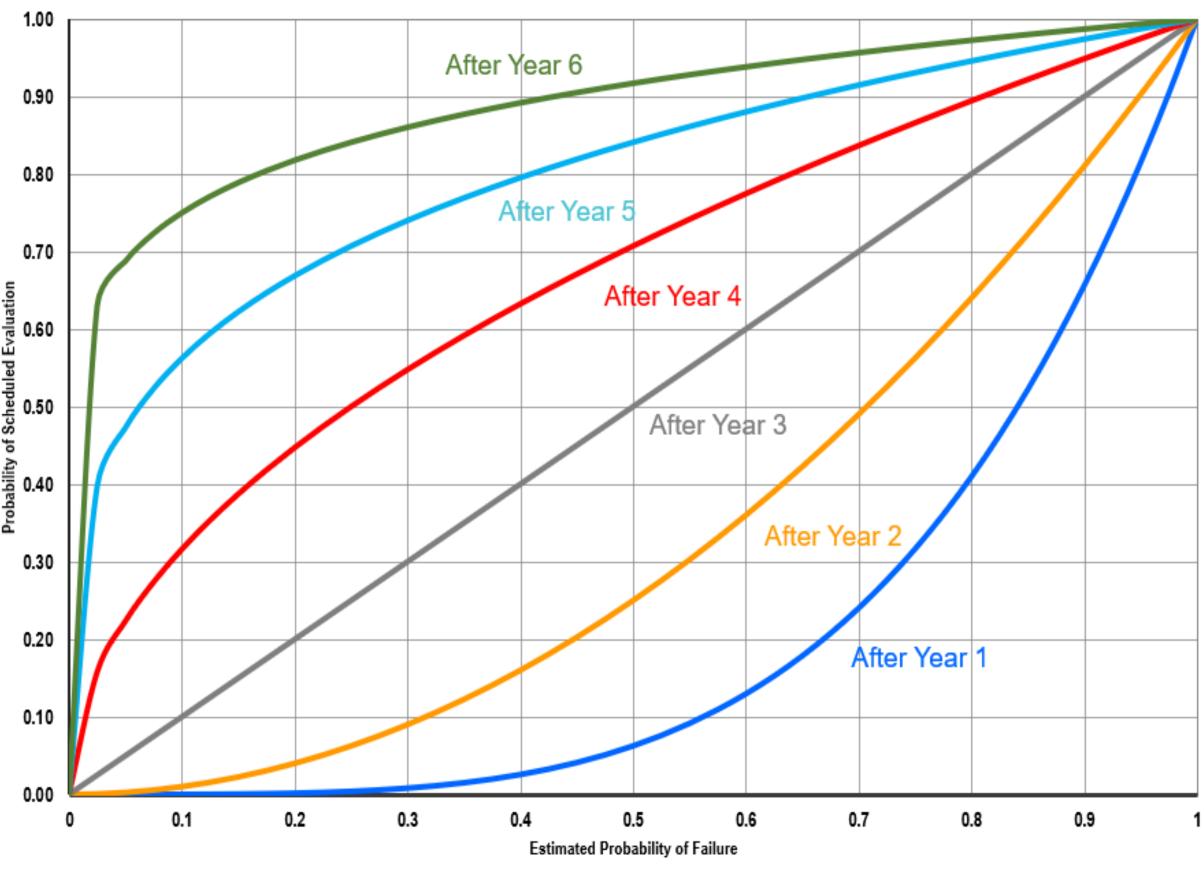




* converted using mean encoding

Balancing Risk vs. Time

- time has passed



Data Visualization

- Developed an interactive data-dashboard

Accomplishments

- unacceptable evaluation outcomes
- evaluations
- Potential applications for other similar programs

Next Steps

- Incorporation of extended filer histories
- vector machines, etc.

FDA U.S. FOOD & DRUG ADMINISTRATION





• Prioritization score is a function of time past the previous evaluation •High-risk entities have a non-negligible probability of being evaluated if short

• Prioritization score is high for both high and low-risk entities for larger time spans

Priority of Evaluations as a function of Predicted Probability of Failure

•Displays map view, data and accomplished evaluations in percentage •Graphic display of information about evaluations

Developed a novel machine learning approach for estimating risk of

• Developed a system for balancing risk vs time since last evaluation Provided a balanced multi-factor approach for scheduling evaluations &

Developed an intuitive user-friendly data dashboard

•Use of ensemble of additional classifier algorithms like neural networks, support