Needle in a Haystack:

Using Machine Learning for Improved Compliance Targeting in the Human Food Program

FDA's Center for Food Safety and Applied Nutrition
Office of Compliance

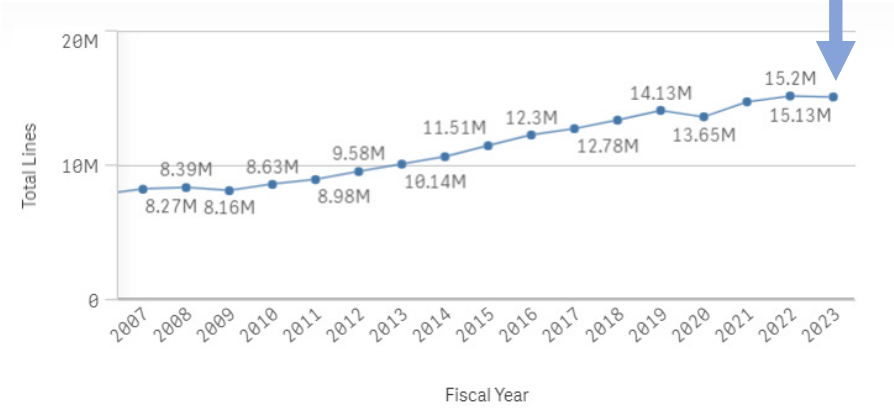
Background

“FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.”

Which container would you pick?

74% increase last decade

to 15M shipment lines in 2023



94%
Seafood

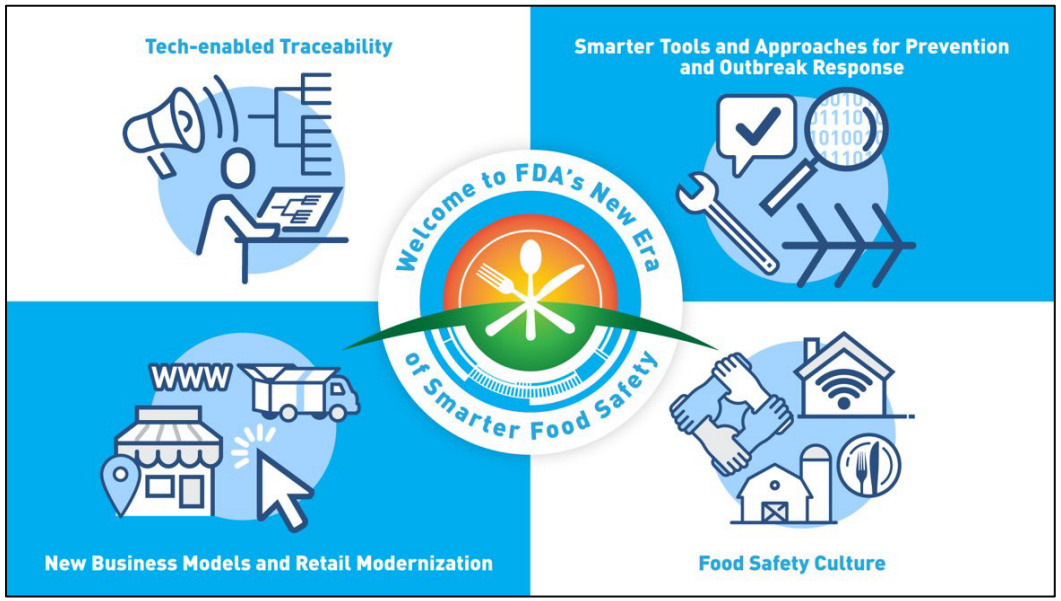
55%
Fresh Fruit

32%
Fresh Vegetables

***Source:** FDA Data Dashboard (https://datadashboard.fda.gov/ora/cd/impsummary.htm)

How Could Machine Learning Support FDA's Mission?

- Increasing amounts of food imported and produced domestically.
- Limited regulatory resources to sample foods, inspect facilities, etc.
- Ever changing inventory and supply chains
- FDA's New Era of Smarter Food Safety Initiative
  - Goal: Expand predictive analytic capabilities via AI and ML, etc.
  - Progressive Exploration and Implementation, to include most recently the Phase III of Imported Seafood AI Pilot



https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint

What is Machine Learning?

Statistical technique that feeds the computer large amounts of data and asks it to “learn” from it to:

1. **Supervised** learning: Predict an outcome (risk classification, violative (OAI) inspection, violative (LC3) sample, etc.)
2. **Unsupervised** learning: Find hidden patterns in a dataset by analysis and clustering (e.g. are those that fail to register more likely to not implement corrective actions?)
3. **Reinforcement** learning: Reward desired behaviors and/or punishing undesired ones (e.g. gaming)

CFSAN OC is mostly focused on supervised learning, but aspires to explore other uses of ML as regulatory needs dictate

Modeling Approach

Portfolio of ML Models Developed So Far

Sampling Models:

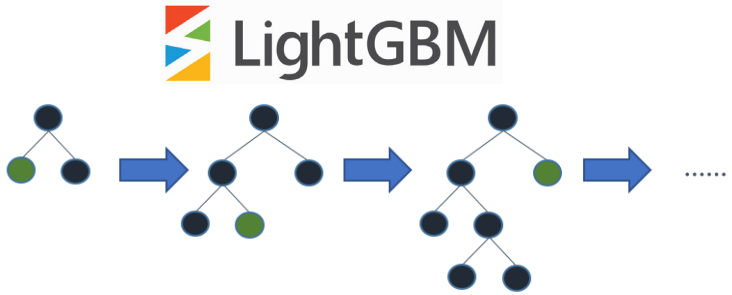
Hazard Code	Hazard Description	Hazard Examples	Target Feature	Commodities of Interest	Domestic / Import?
MIC	Microbiological (pathogenic bacteria)	*E. coli, Salmonella, Listeria*, etc.	Presence of pathogen	Most commodities	Imports and domestic
DEC	Decomposition (toxic compounds from spoilage)	Histamines, scrombotoxins, etc.	Detection of decomposition in sensory test	Seafood only	Imports only
ANT	Unapproved Antibiotics	Tetracyclines, florfenicol sulfonamides, etc.	Antibiotic concentration above safe threshold	Seafood only	Imports only
ELE	Toxic elements	Lead, arsenic, mercury, etc.	Element concentration above safe threshold	Most commodities	Imports and domestic

Inspections Models: Various models to predict violative inspections for domestic and foreign food facility inspections, farms, and importers.

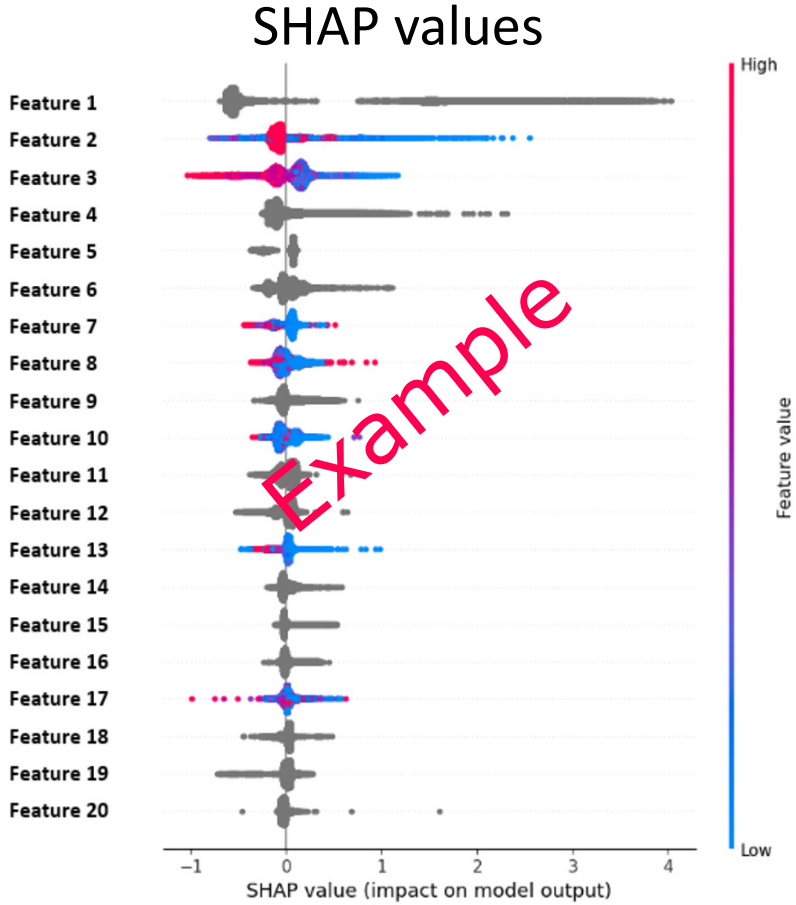
Data and Modeling Process Overview

Data → Model Training → Feature Evaluation

- Identify relevant features (variables) from FDA and external databases
- Clean and merge data with input from team of SME's and data scientists

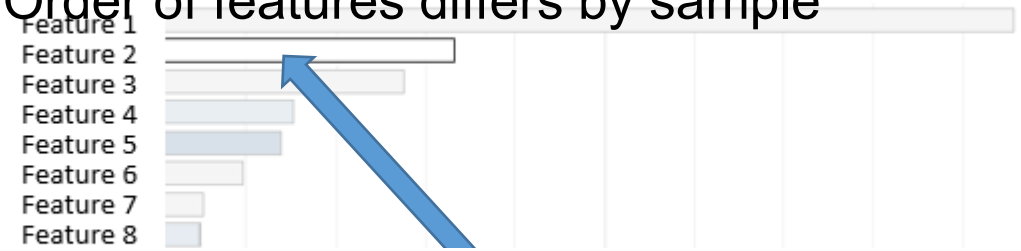


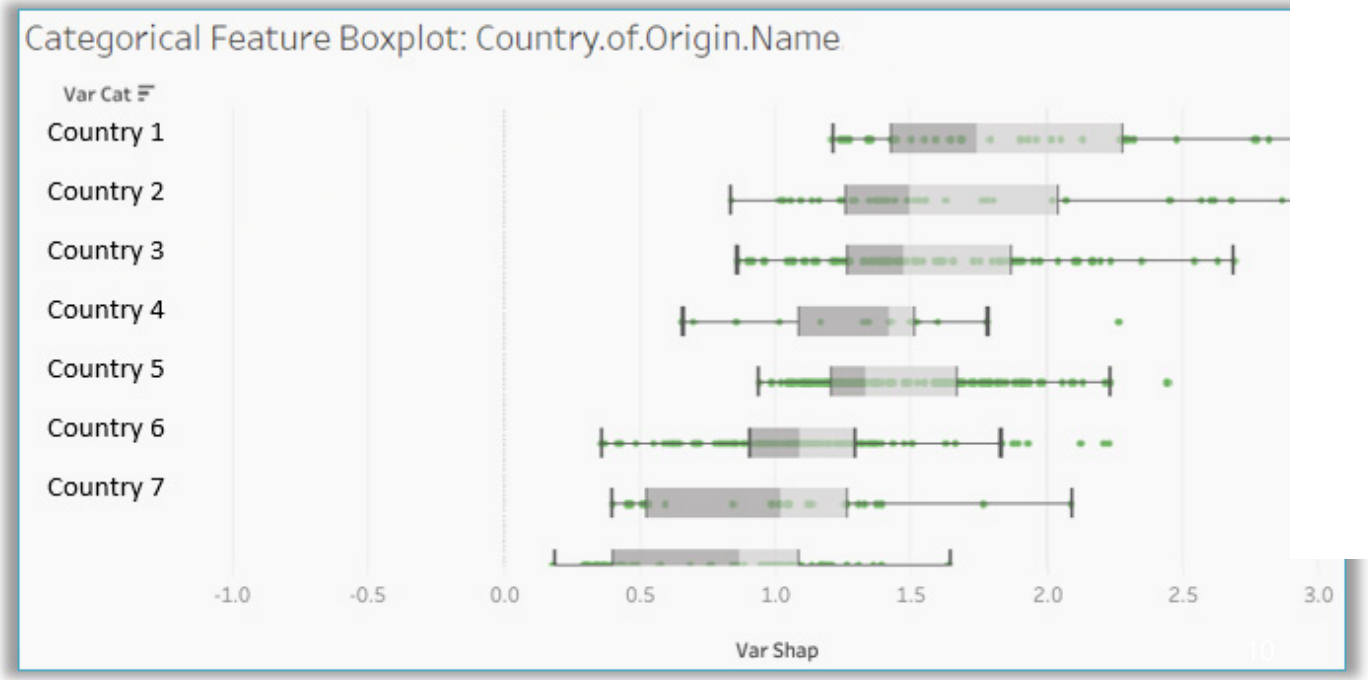
- Boosted Tree algorithm
- Target: predict violative supply chain hazards



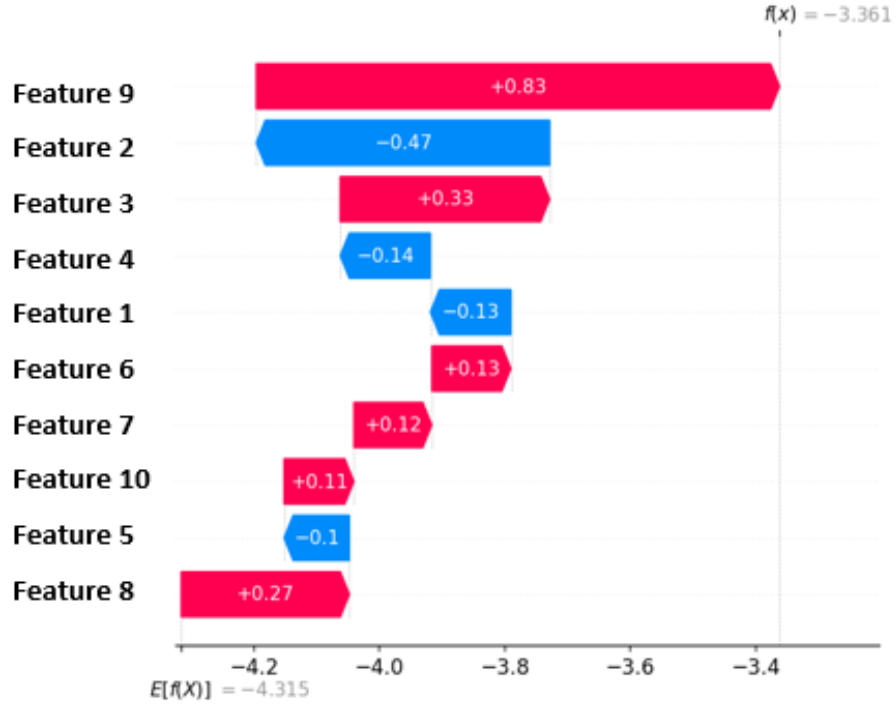
More about SHAP: Increasing Transparency and Stakeholder Trust in ML Modeling

- SHAP Dashboard for Categorical Features
- (MIC-Imports model)
  - Example: Tuna from Firm ABC
    - Order of features differs by sample



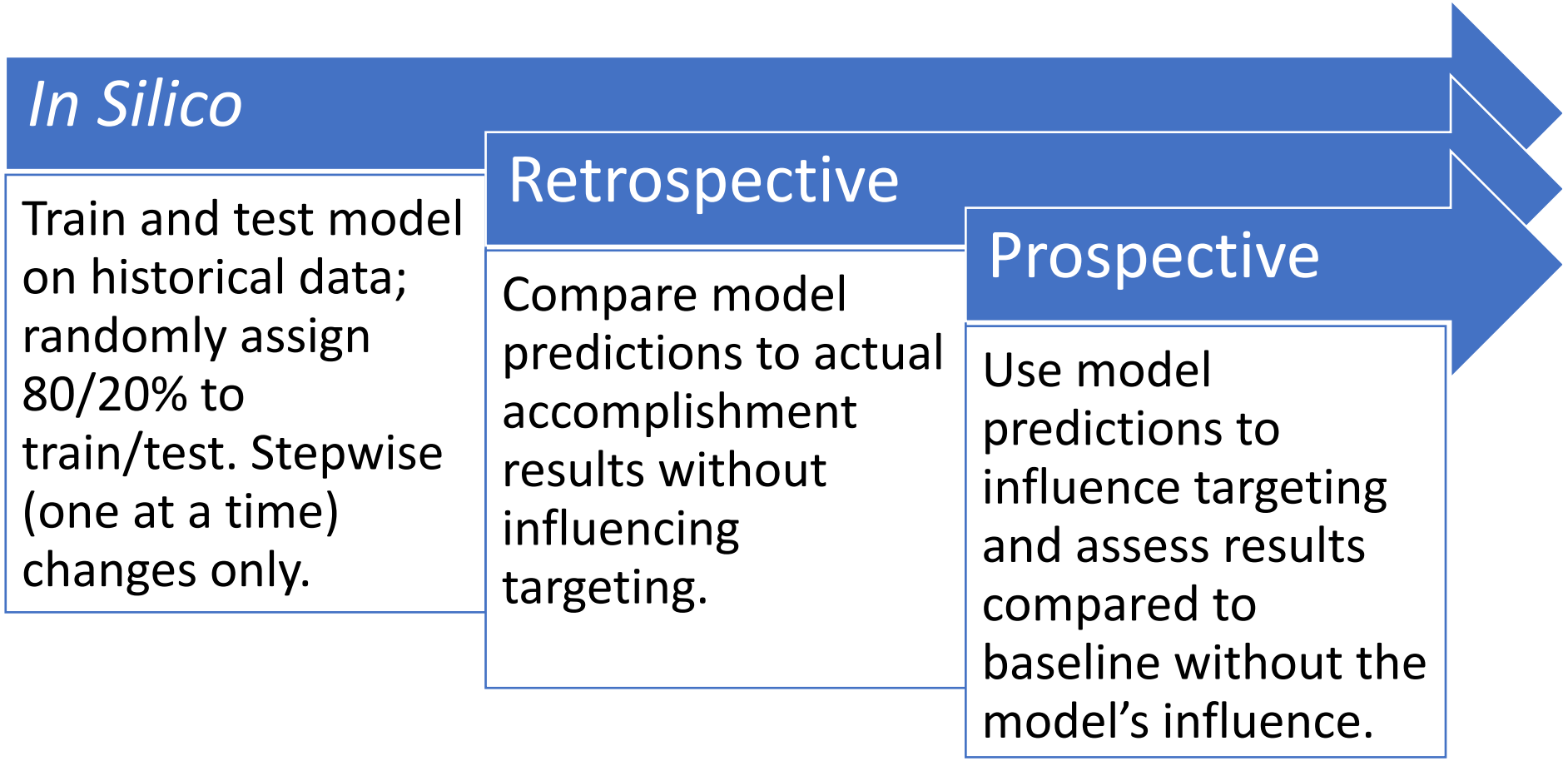


- SHAP for Individual Supply Chains: Waterfall Plots



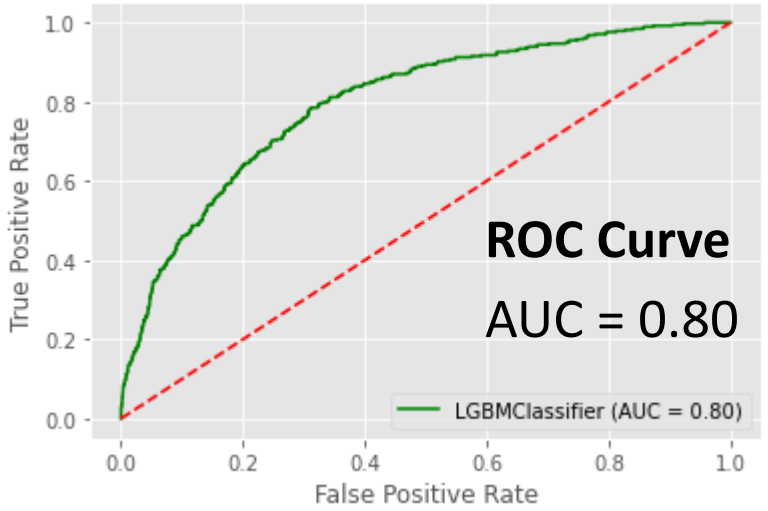
Modeling Performance

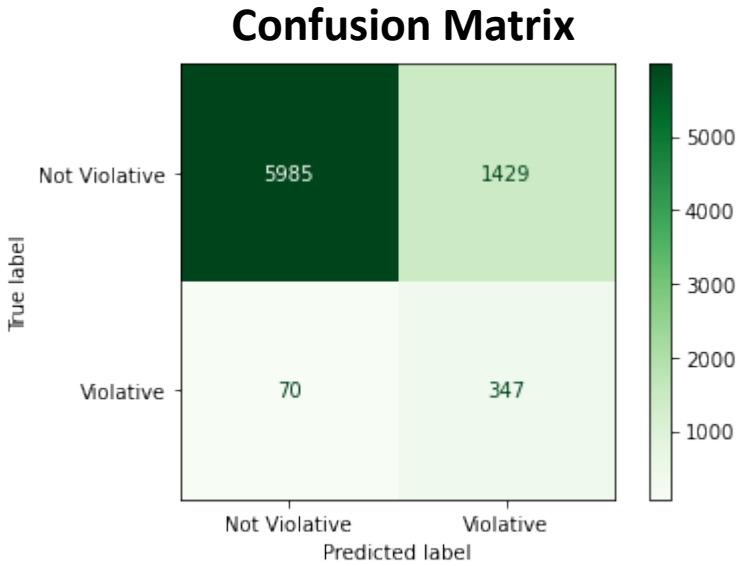
How we assess our models



In Silico Model Results (DEC–Imports example)

- Trained model on 80% of data, reserve 20% for testing
- Selected results
  - Accuracy: 72.4%
  - Sensitivity/Recall: 74.3%
  - Specificity: 72.2%
  - PPV (Positive Predictive Value)/Precision: 22.4%
  - Historical Violative Rate: 5.5%





ML Model Retrospective Results*

Model	Import vs Domestic	Date Started	Number of Observations	Accuracy	Positive Predictive Value (PPV)	Baseline Violative Rate (Model Period)	Statistically significant (Model vs. Baseline PPV) (p<0.05)
MIC	Import	7/14/22	3,726	73%	5.5%	3.4%	Yes
ELE	Import	1/2/22	1,355	78%	18.34%	11.44%	Yes
DEC	Import	7/14/22	2,133	73%	11.3%	4.6%	Yes
ANT	Import	8/19/21	977	91%	11.1%	4.4%	Yes
Inspections	Domestic	3/16/23	2,786	83%	7.9%	3.0%	Yes

- Model makes predictions for known supply chains. If FDA collects sample for it, results are compared to ML prediction.
- All models show significant increase ($p<0.05$) in samples predicted to be violative (PPV) vs. baseline violative rate.

*Data as of 10/23/23

Experimental Design for the Seafood AI Phase III Pilot

2x2 Factorial Design

		PREDICT	
		YES	NO
ML	YES	**Group A** n=250 MIC n=250 DEC	**Group B** n=250 MIC n=250 DEC
	NO	**Group C** n=250 MIC n=250 DEC	**Group D** n=250 MIC n=250 DEC

- Selected target hazards
  - MIC: microbiological (n=1000)
  - DEC: decomposition (n=1000)
- Control for main effects of:
  1. PREDICT (existing risk-targeting algorithm)
  2. ML model
  3. Expert knowledge (group D)
- FDA Consumer Safety Officers (CSO's) collecting samples are **blinded** from group identities.

Forging Ahead

Implications of ML Results

- Better protecting public health
- Better using limited resources
- Identifying emerging trends
- Facilitating trade
- Complimenting/codifying human intelligence

Moving towards “smart” regulation

Next Steps

Learn: Solicit feedback from public, academia, and industry on how to improve models or consider additional data or features

Grow: Continue to expand model deployment and carefully monitor results

Evolve: Move into a more dynamic deployment to support regulatory decision making in real-time

Acknowledgments

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