



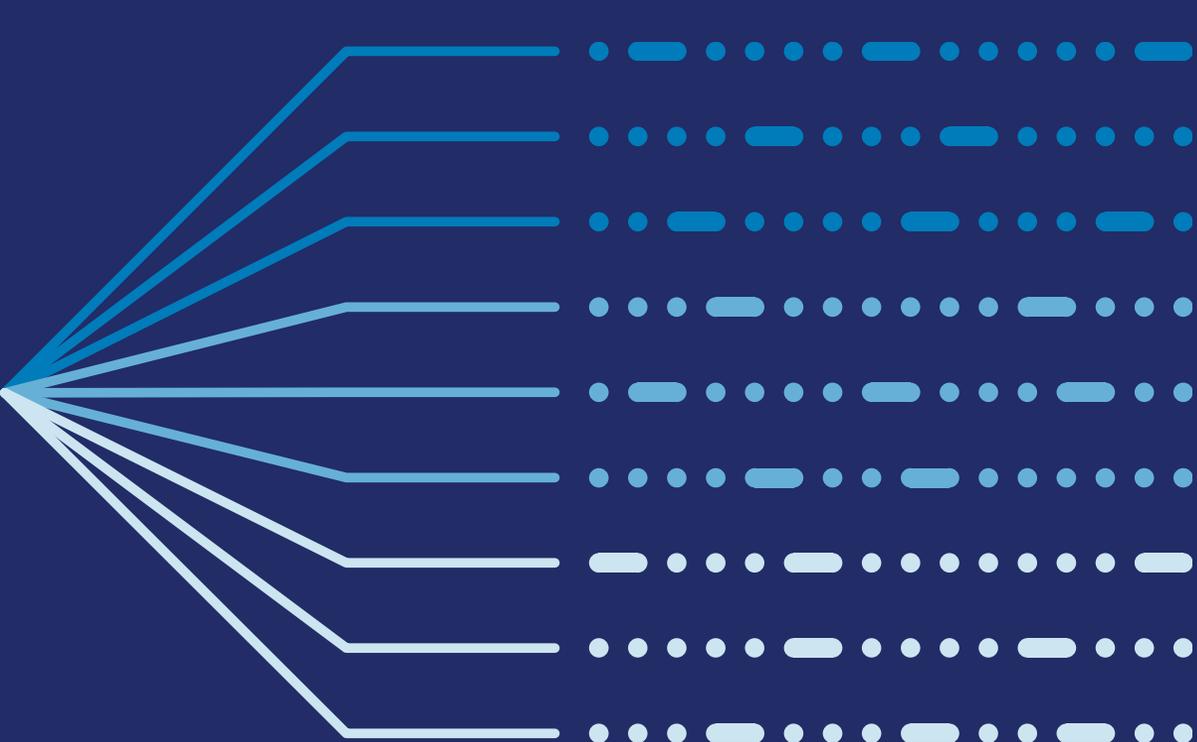
**U.S. FOOD & DRUG
ADMINISTRATION**

DIGITAL TRANSFORMATION SYMPOSIUM

2023

Hosted by FDA's Office of Digital Transformation





Warp Intelligent Learning Engine (WILEE)

Unleashing the Power of Big Data for Food Safety

Ernest K. Kwegyir-Afful- Office of Food Additive Safety (OFAS)

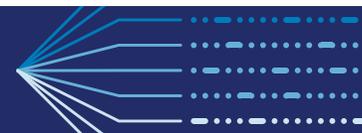
Thomas Farrell – Office of Management (OM), Scientific Innovation and Infrastructure Branch (SIB)

Office of Food Additive Safety (OFAS)

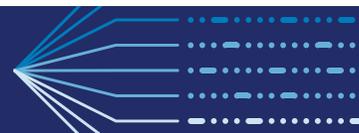
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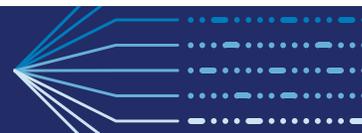
- As regulatory scientists our ability to identify associations between different ideas in a variety of contexts enables us to derive insights that advance our work. From identifying public health risks to predicting trends and addressing stakeholder concerns, this work requires us to constantly generate a corpus of relevant data. Dealing with the volume of these data can be onerous and synthesizing information from such sources can be daunting and time consuming. The WILEE project leverages some of our previous work using machine learning techniques to address some of these challenges and promises to deliver more efficiencies in our work.



WILEE as a Data Product



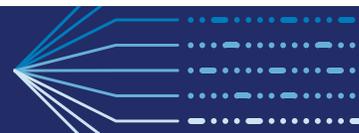
- WILEE (pronounced Wiley) is an advanced, data driven, risked based decision-making tool, that leverages AI technologies to integrate, process and analyze a large variety of data sources to provide horizon-scanning capabilities that will enable OFAS to maintain a proactive posture and the capacity to “forecast” industry trends so that the Office can stay ahead of the development cycle and prepare for how to handle a large influx of submissions (operational risk - e.g., change in USDA rules regarding antimicrobial residue levels in poultry processing), prioritize actions based on risk or stakeholder perceived risk regarding substances under the CFSANs’ purview. WILEE has multiple modules that enable postmarket surveillance, signal detection, and knowledge discovery.



WILEE Goals



- **Phase I:** Create a centralized data resource for CFSAN/OFAS with an architecture that enables advanced analytics and on-demand data analysis.
- **Phase II:** Build an intelligent knowledge discovery and analytic agent that enables advanced knowledge discovery, on-demand data analysis and signal detection.

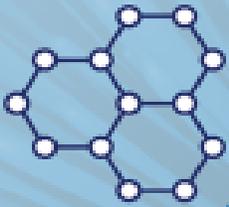


DATA INTEGRATION

- ADI
- Biotech monitoring
- CERES
- Cheminformatics
- Exposures
- FARM
- FSTA
- NIH funding
- **Products**
- Pubmed
- Total Diet Study
- TRAM
- Unit Cancer Risk
- Web Articles

- Chemical risks
- Microbial risks
- Packaging
- Sales

Substances

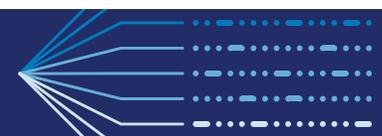


ANALYTICS

- Association Analysis --> Network Analysis
- Risk Prediction & Ranking
- Text Analytics
- Knowledge Discovery
- Signal Detection
- Trend Analysis

APPLICATIONS

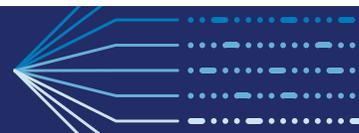
- Search & AI training
- Knowledge tree
- Data mining
- Data entry
- On-Demand analytics
- Signal detection



Phase II - Modules



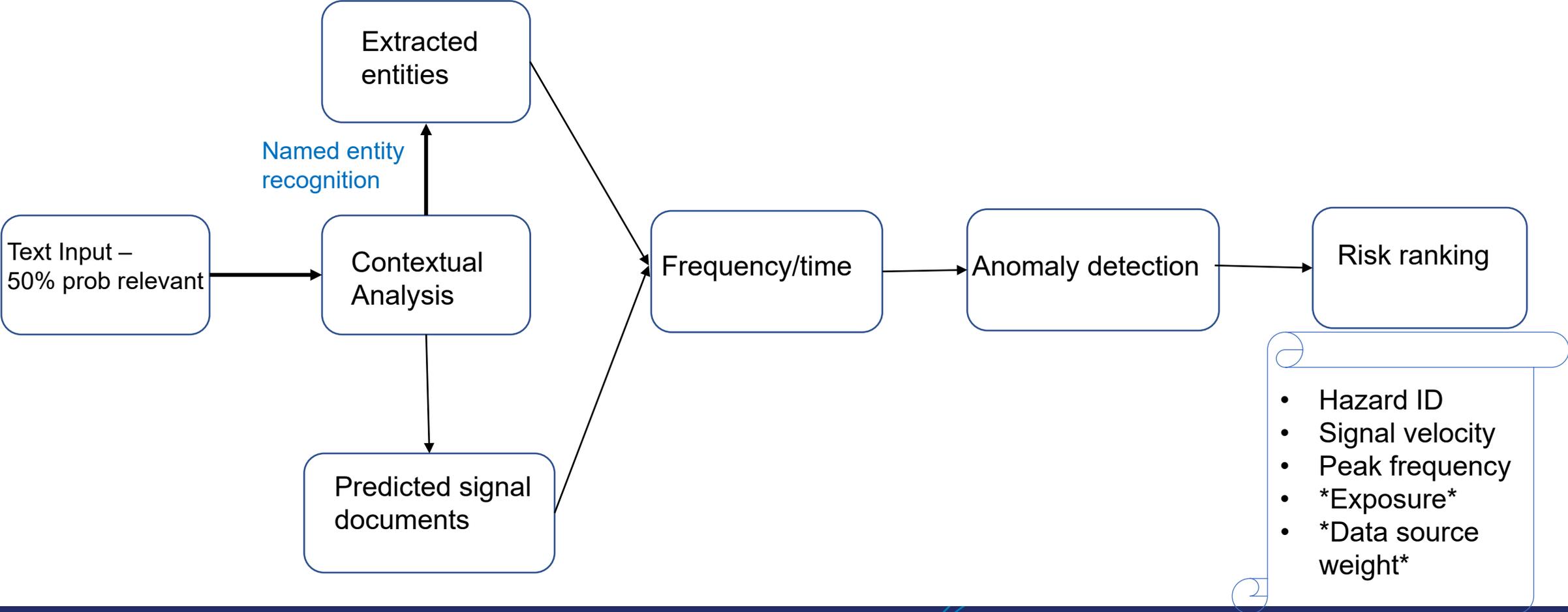
- Signal detection module and visualization
- Food label ingredient monitoring
- Knowledge discovery
- Knowledge graph - conversations



Signal Detection Module



■ Solutions Schematic



Signal Detection



Chemical Signals

Chemical Search

2022-07-23

Select Source(s)

Top N Chemical Signals

Clear all selections

Go to Product Signals Page

Chemicals by Risk Score

| Chemical Name | Risk Score |
|------------------|------------|
| TITANIUM DIOXIDE | 252.00 |

Top 10 Affiliated Products

Top 10 Affiliated Adverse Events

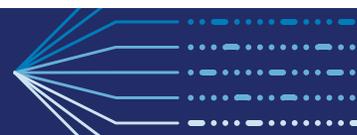
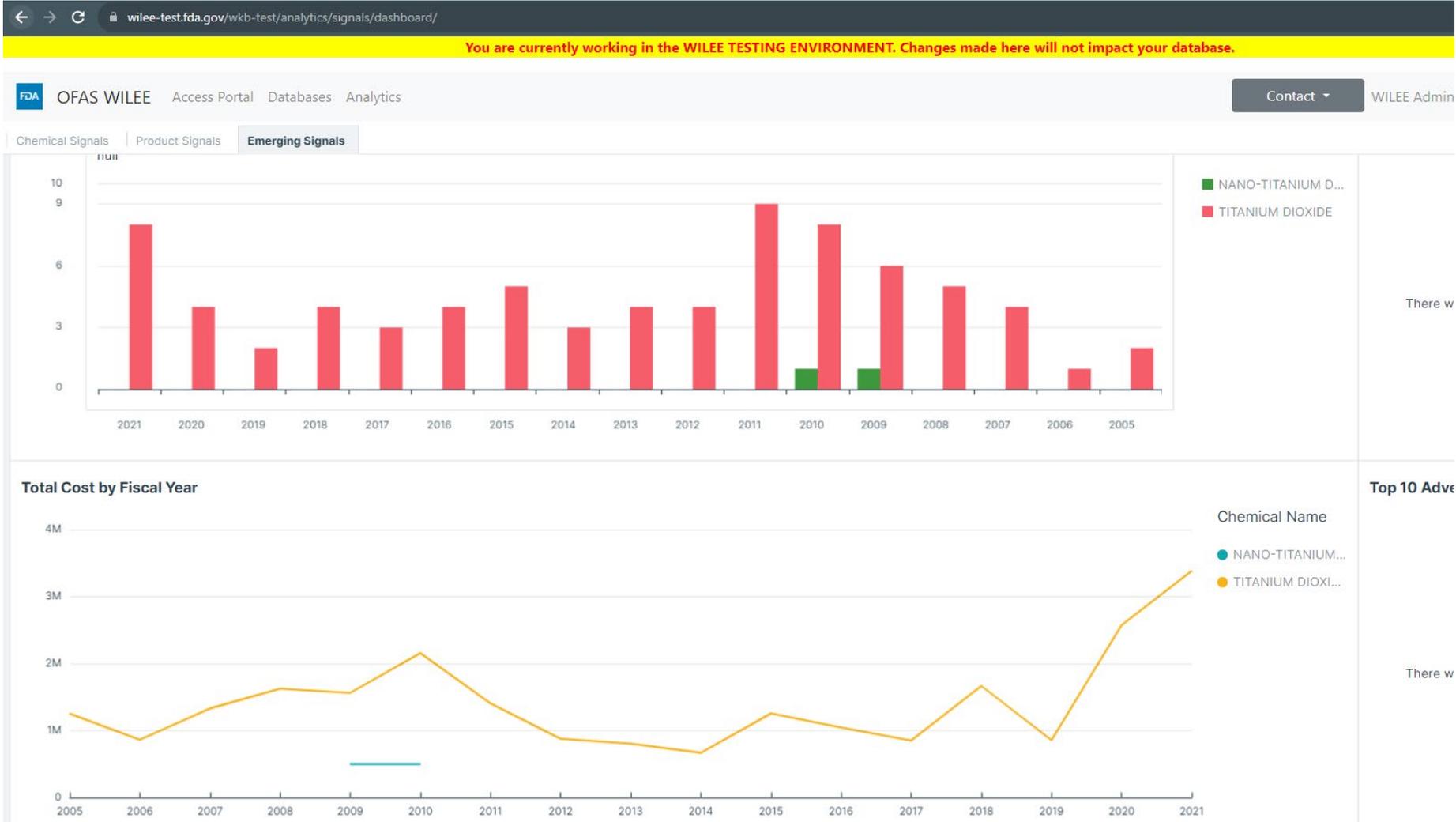
Top 10 Signal Frequencies by Chemical Name

| Chemical Name | Frequency |
|------------------|-----------|
| TITANIUM DIOXIDE | 60 |

Top 10 Signal Frequencies by Chemical Name

| Articles Titles | Web Source Links | Matched String |
|--|------------------|----------------|
| Class Action Lawsuit Claims Skittles Are 'Unfit For Human Consumption', But Why? | | 1 |
| Class Action Lawsuit Claims Skittles Are 'Unfit For Human Consumption', But Why? | | 1 |
| Lawsuit Alleges Eating Skittles Poses a Safety Risk | | 1 |
| Lawsuit Claims 'Toxic' Chemical Used in Skittles | | 1 |
| Lawsuit claims that Skittles are 'unfit for human consumption' | | 1 |
| SFDA follows up on what affects food products via Rapid Alert Center - Saudi Gazette | | 1 |
| Skittles 'unfit for human consumption,' California lawsuit claims - Times News Express | | 1 |
| Skittles 'unfit for human consumption,' California lawsuit claims | | 2 |
| Skittles 'unfit for human consumption,' lawsuit claims | | 1 |

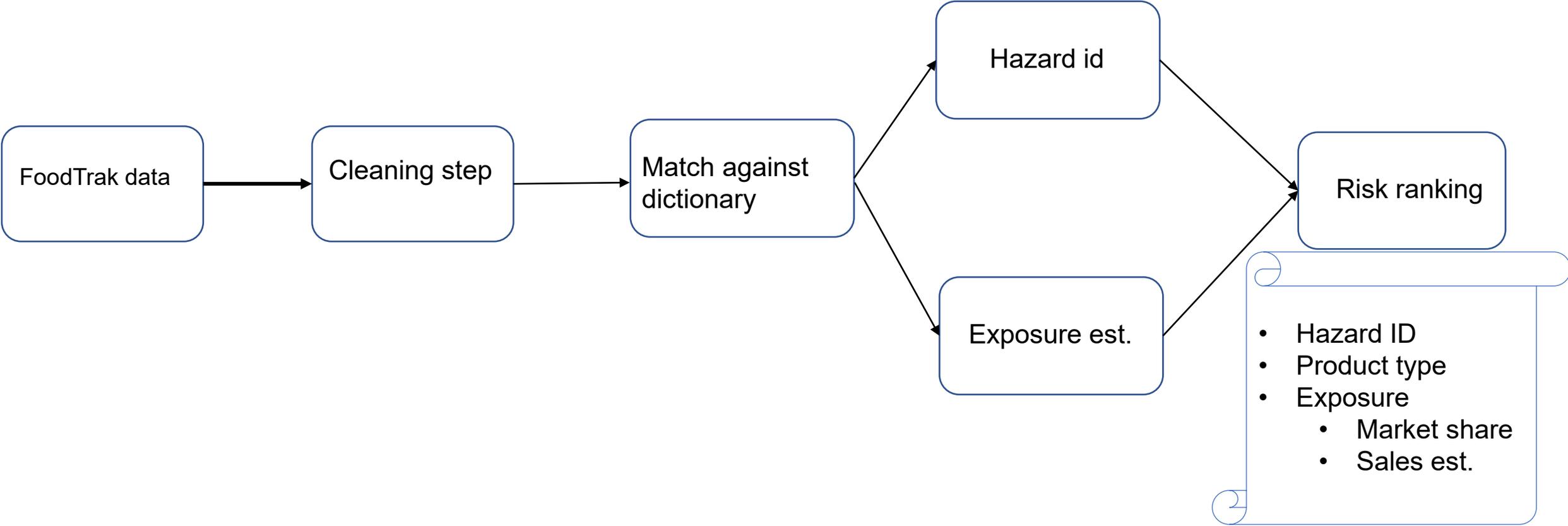
Signal Detection – Emerging Signals



Food Ingredient Monitoring Module



- Solutions Schematic



Label Ingredient Monitoring Analysis



You are currently working in the WILEE TESTING ENVIRONMENT. Changes made here will not impact your database.

FDA OFAS WILEE Access Portal Databases Analytics

Contact

WILEE Admin | Logged in as: Ernest.Kwegyir-Afful

Overview - Ingredient Analysis | For Review - Unverified Ingredients | **Risk Assessment ToolKit** | Action Tracks

Controls TOPN_Risk 5

Risk Assessments of Food Label Ingredients

SELECTOR: Ingredient Search

- Dropdown Search
- Exact Search

INGREDIENT DROPDOWN SEARCH

All

REVIEW RANKINGS

All

RISK INDICATORS

- Moderate Risk
- Zero Risk
- Medium Risk
- High Risk**

TOP INGREDIENTS WITH HIGH-RISK SCORE

| | | |
|--------------------|---|------|
| RED 1 | ↑ | 10 |
| RED 4 | ↑ | 10 |
| RED 2 | ↑ | 10 |
| SODIUM BICARBONATE | | 1.4 |
| CITRIC ACID | | 1.09 |

HIGHEST PROPORTION SCORE BY INGREDIENTS

| | |
|------------|------|
| SALT | 1.39 |
| SUGAR | 1.1 |
| WATER | 0.92 |
| FOLIC ACID | 0.76 |
| NIACIN | 0.75 |

TOP 5 INGREDIENTS WITH HIGHEST HARZARD SCORE

| | |
|------------------|----|
| RED 1 | 10 |
| RED 4 | 10 |
| RED 2 | 10 |
| AMMONIUM SULFATE | 9 |
| ZINC | 9 |

TOTAL INGREDIENTS ANALYZED

30,402

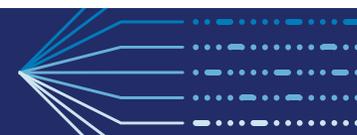
PREVALENCE OF HIGH-RISK INGREDIENTS

| Label Ingredient | FDA Dictionary Name | Review Ranking | Risk Score | Proportion Score | Hazard Score |
|--------------------|----------------------|-------------------|------------|------------------|--------------|
| RED 1 | C.I. ACID RED 1 | For Expert Review | ↑ 10 | 0 | 10 |
| RED 4 | NATURAL RED 4 | For Expert Review | ↑ 10 | 0 | 10 |
| RED 2 | RED 29 | For Expert Review | ↑ 10 | 0 | 10 |
| SODIUM BICARBONATE | SODIUM BICARBONATE | Verified | 1.4 | 0.16 | 9 |
| CITRIC ACID | citric acid | Verified | 1.09 | 0.36 | 3 |
| IRON | IRON | Verified | 1.09 | 0.12 | 9 |
| MONOSODIUM ... | MONOSODIUM GLUTAMATE | Verified | 1.06 | 0.12 | 9 |
| CALCIUM SULFATE | CALCIUM SULFATE | Verified | 0.78 | 0.26 | 7 |

INGREDIENT FREQUENCY DISTRIBUTION



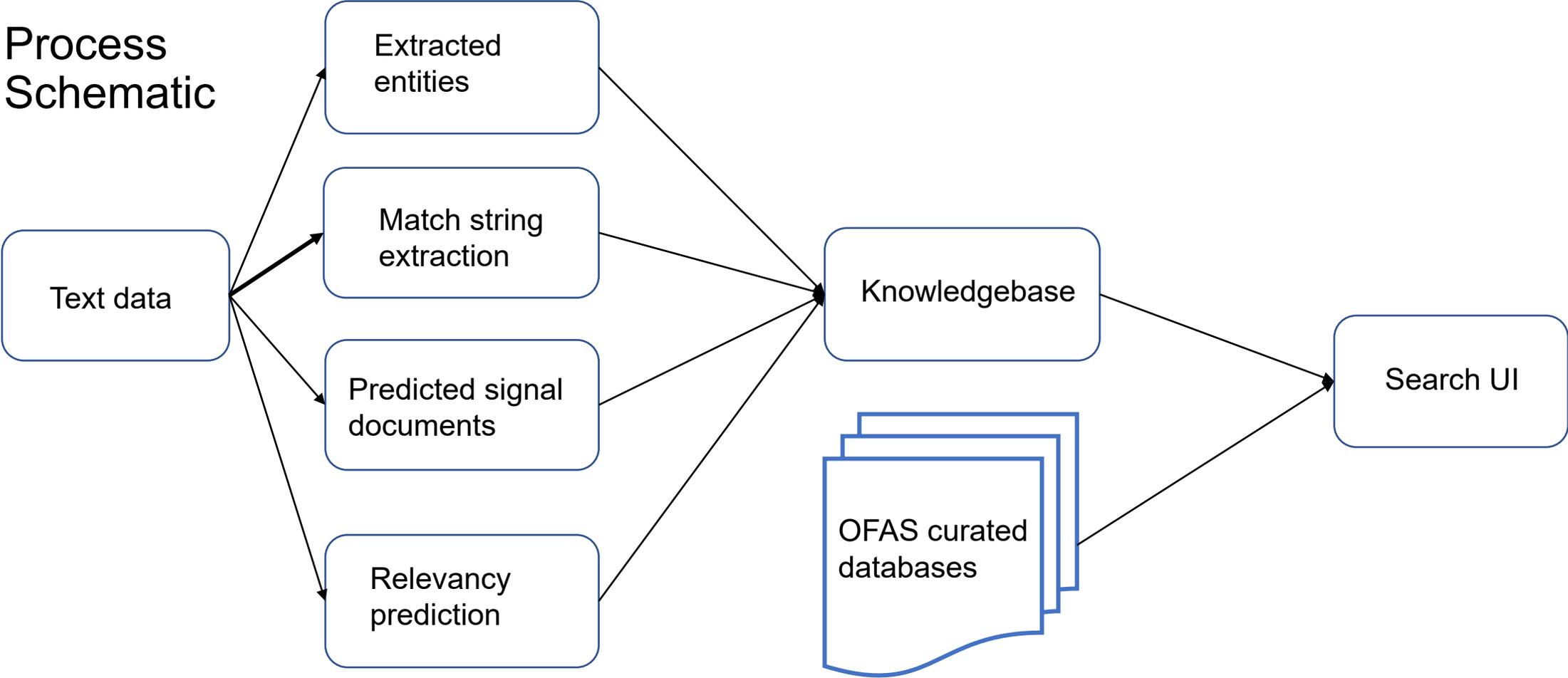
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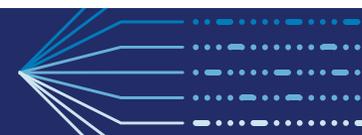
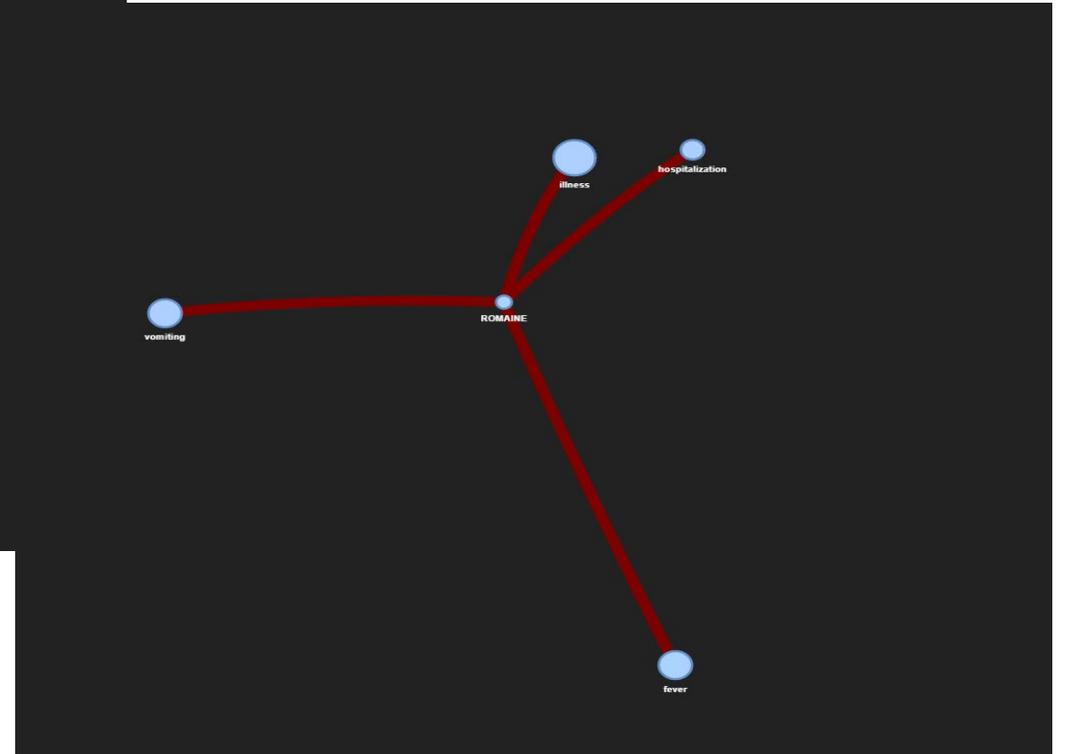
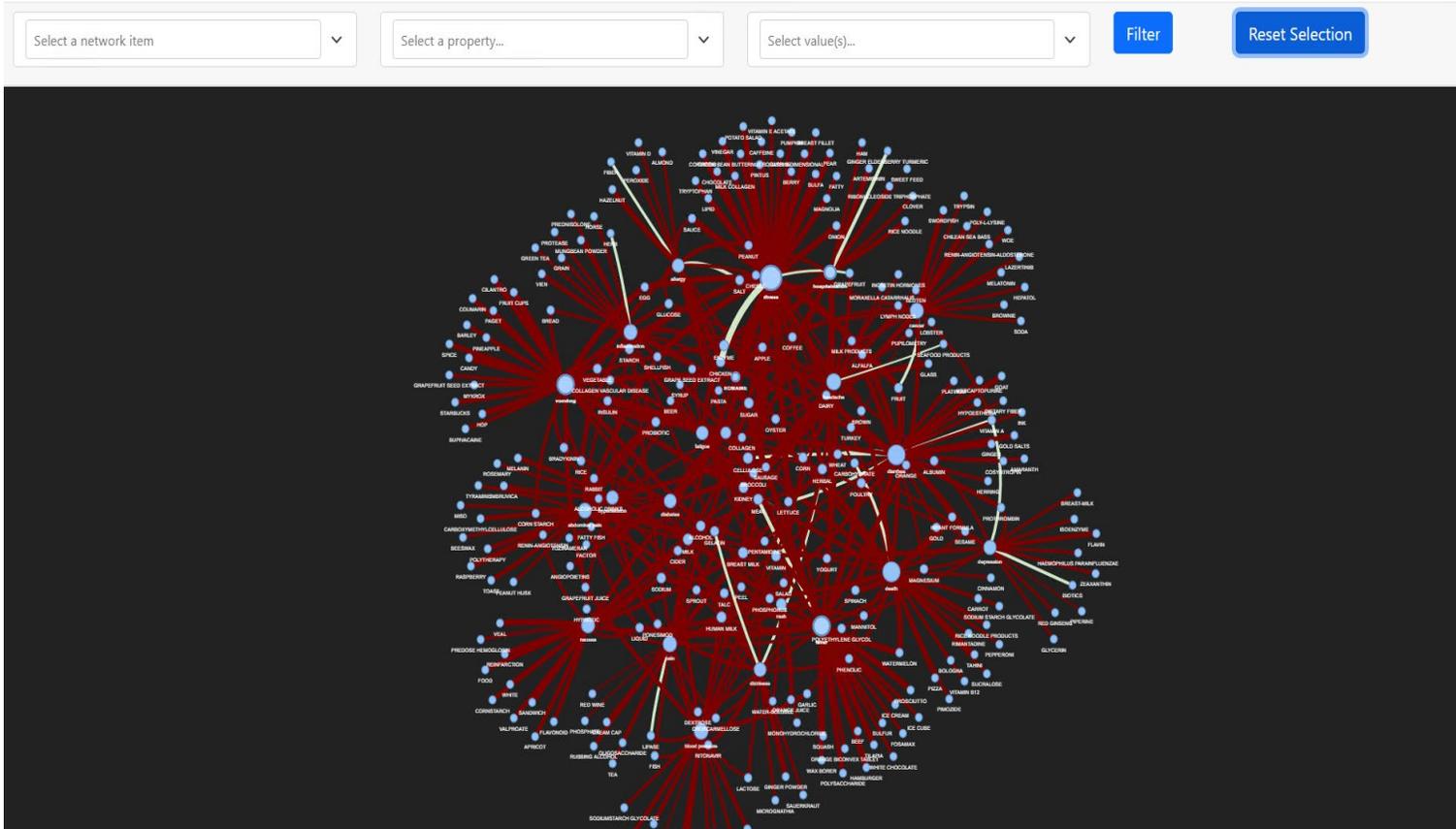
Knowledge Discovery Module



- Process Schematic



Conversations – Knowledge Tree





Questions