U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

WILEE Evolved: Expanding AI's Role in Food Safety Regulation



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Warp Intelligent Learning Engine (WILEE)

- WILEE is an intelligent knowledge discovery and analytic agent designed to identify and assist in the investigation of emerging chemical signals as they relate to food safety by synthesizing insights from a large corpus of text data.

Original Motivation for WILEE

Survey and integrate text data sources to predict emerging chemical signals relevant to food safety.

Signal Definitions

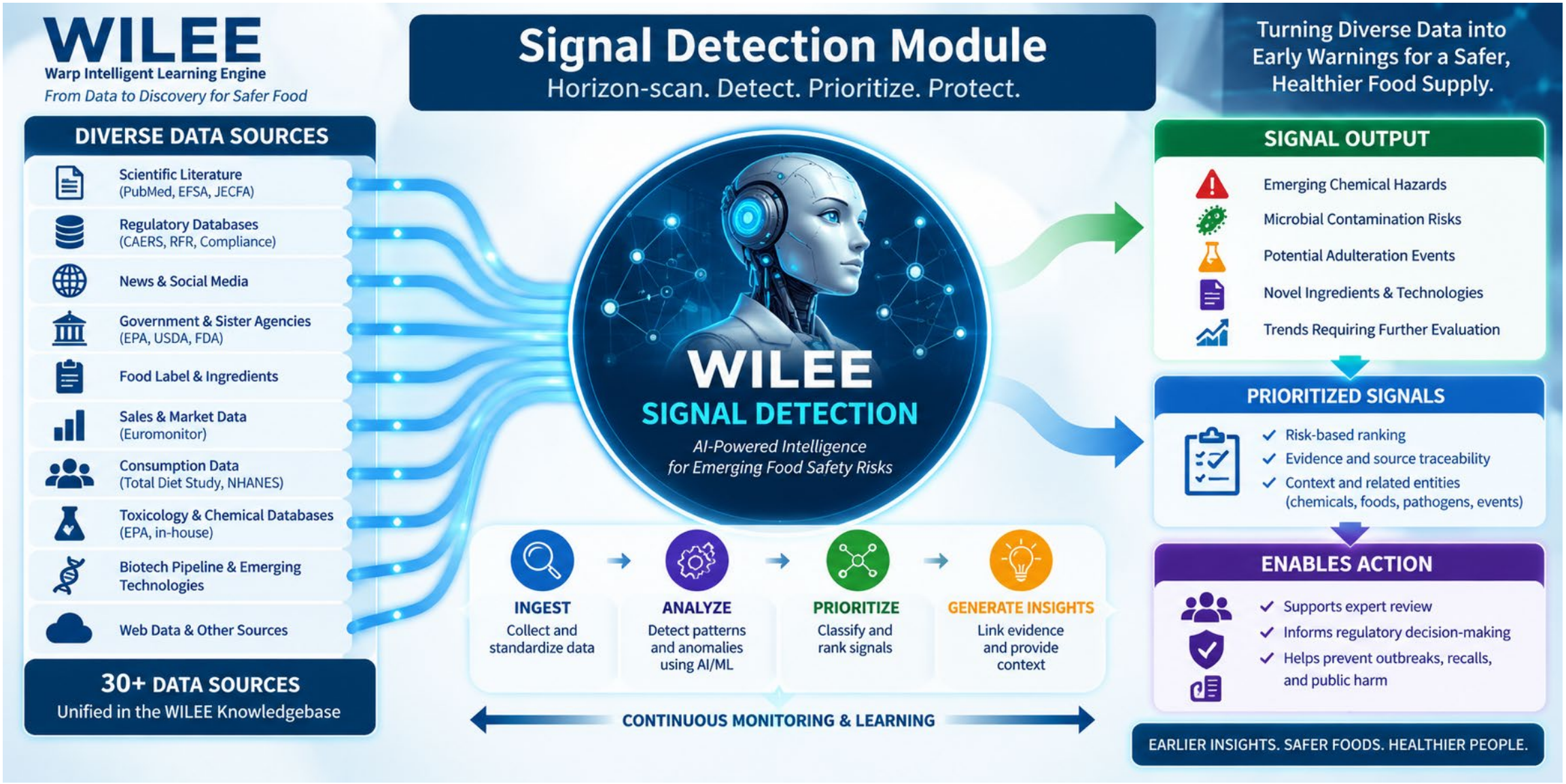
- Any information regarding a potential chemical contaminant hazard or reported adverse reaction to food, dietary supplements, or cosmetics that might be considered a risk or a perceived risk to public health; or
- Any use of a chemical or combination of chemicals that may be used in a new way in foods, dietary supplements, cosmetics, food packaging, or processing that could significantly increase exposure; or
- Any food, food packaging, dietary supplement, or cosmetic product or ingredients for which economic or supply conditions change substantially, leading to an increased probability of adulteration with chemicals (e.g., economically-motivated adulteration).
- Significant new sources of data and information indicating changes in exposure or safety information that suggest re-assessment may be warranted

(Adapted from Hauben and Aronson (Drug Safety 2009; 32(2):99-110) – CFSAN 2015 FAC document)

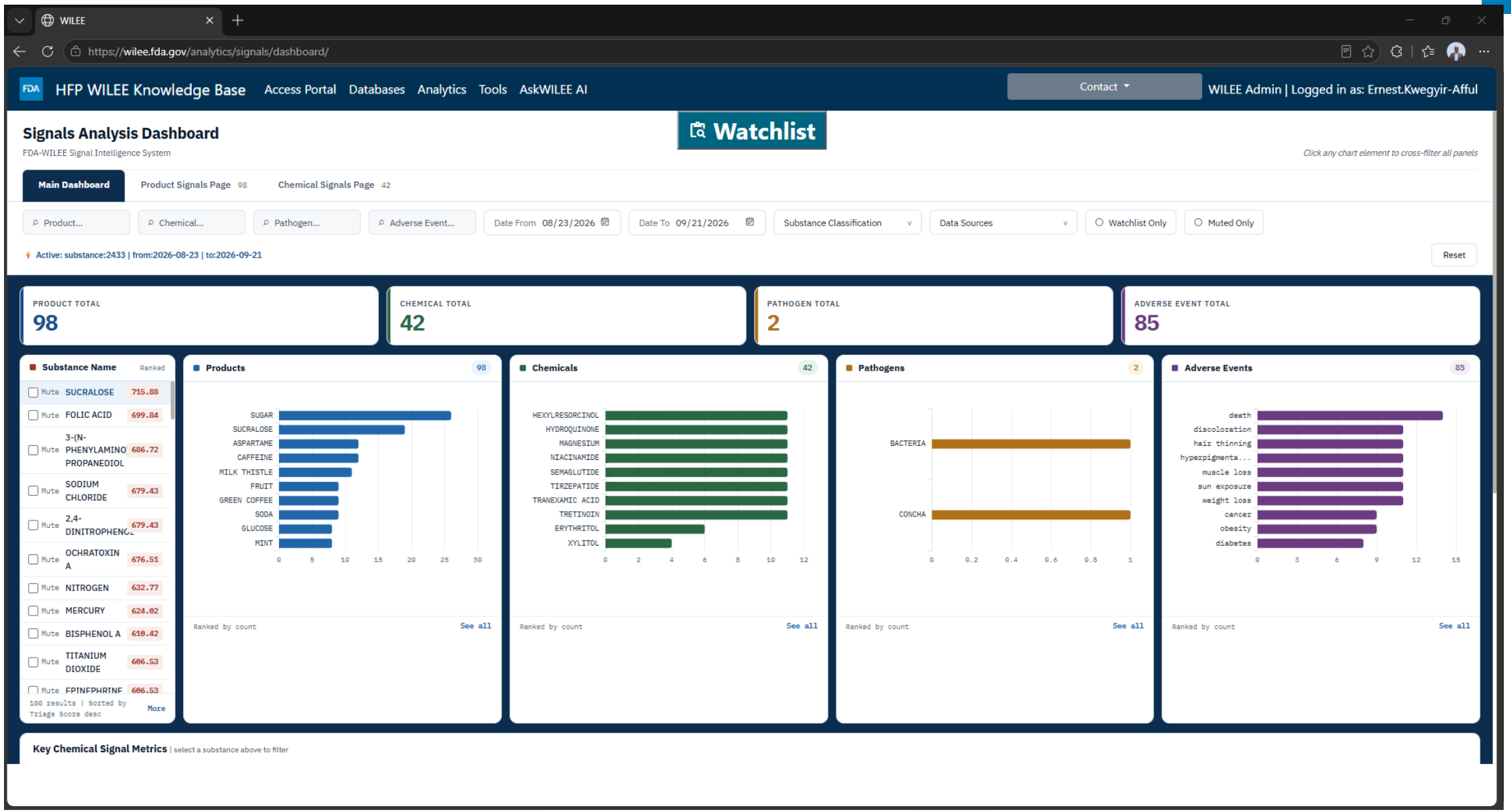
WILEE Data Integration



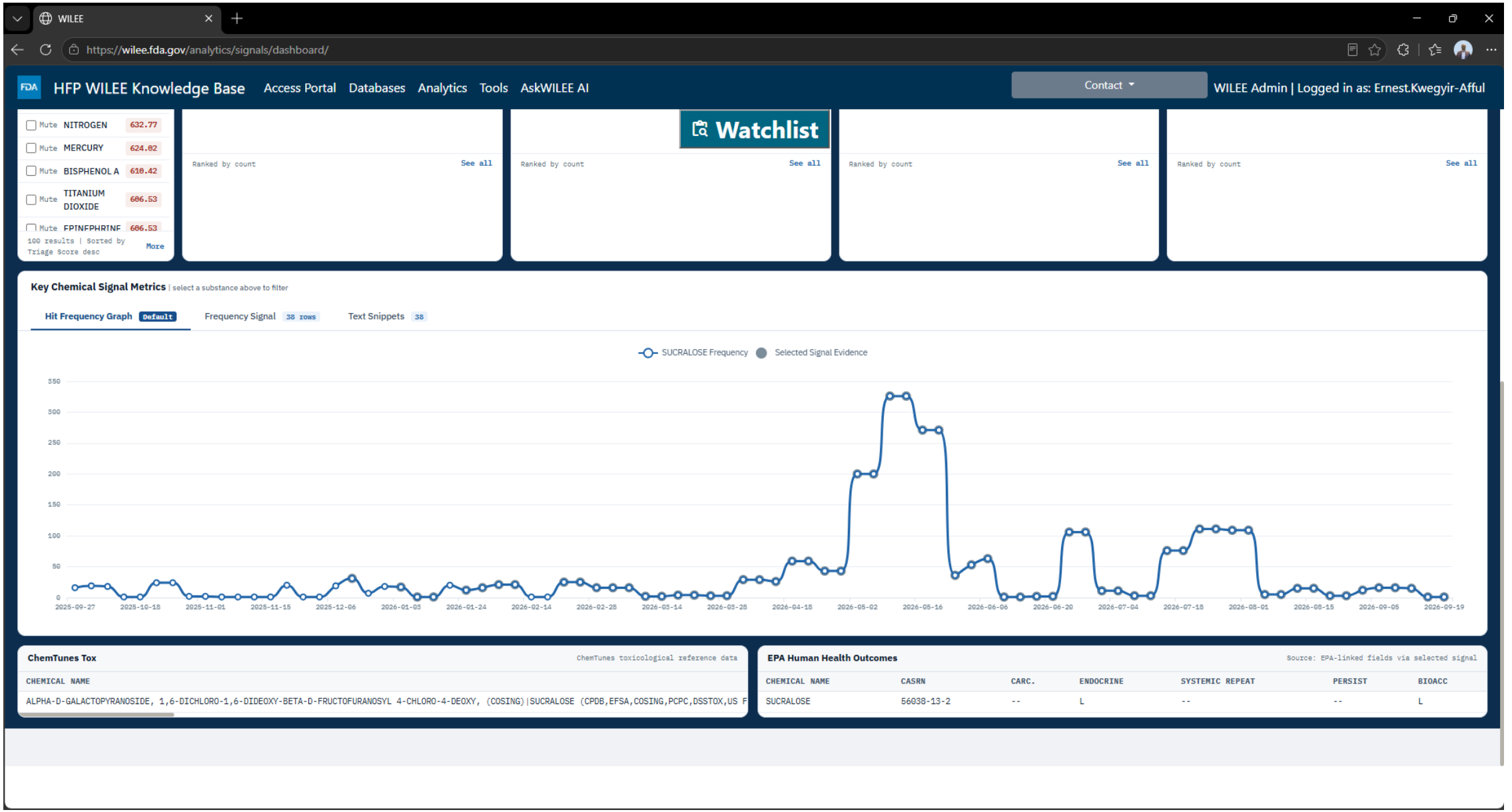
WILEE Signal Detection



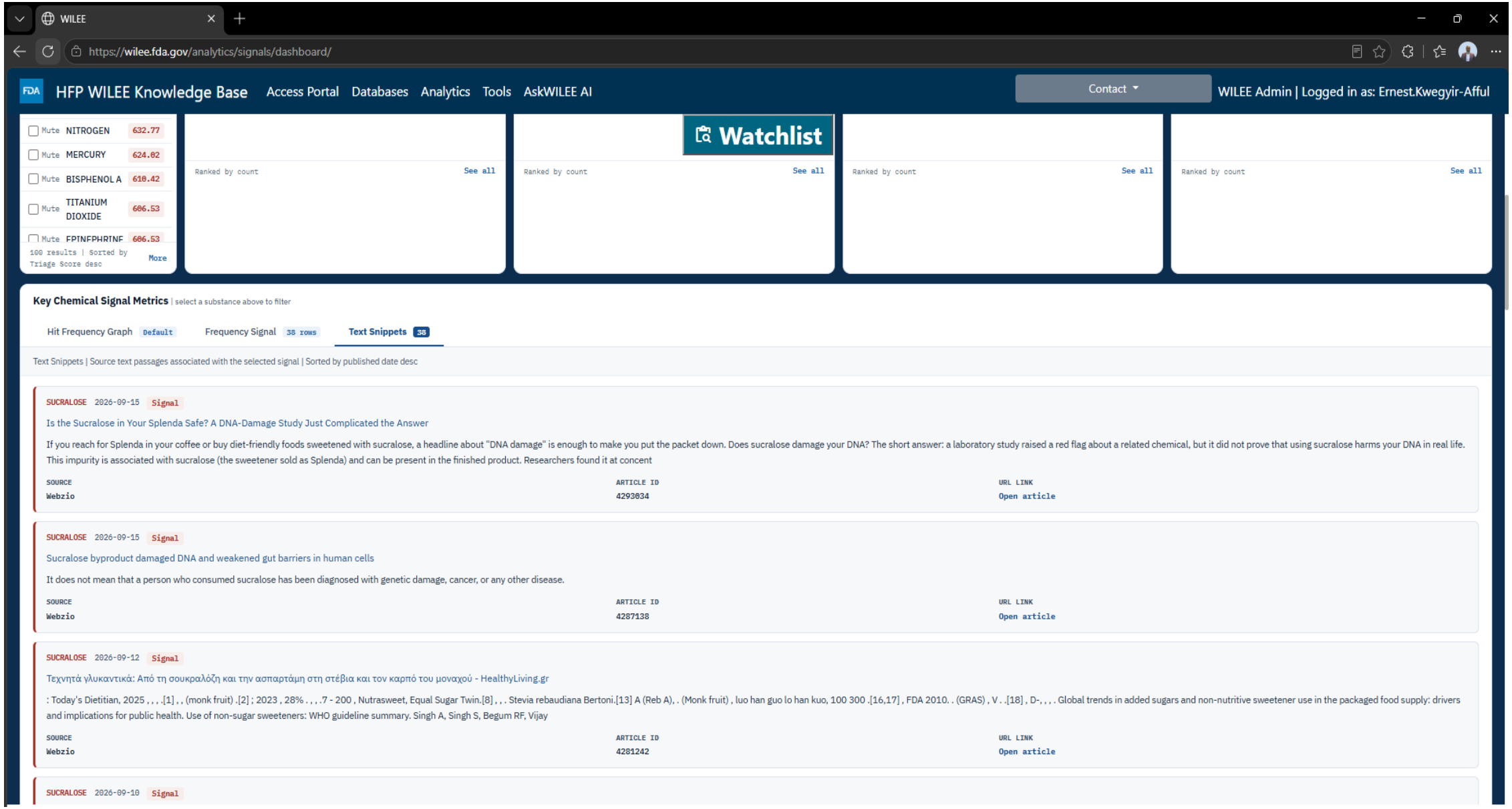
Signals Dashboard



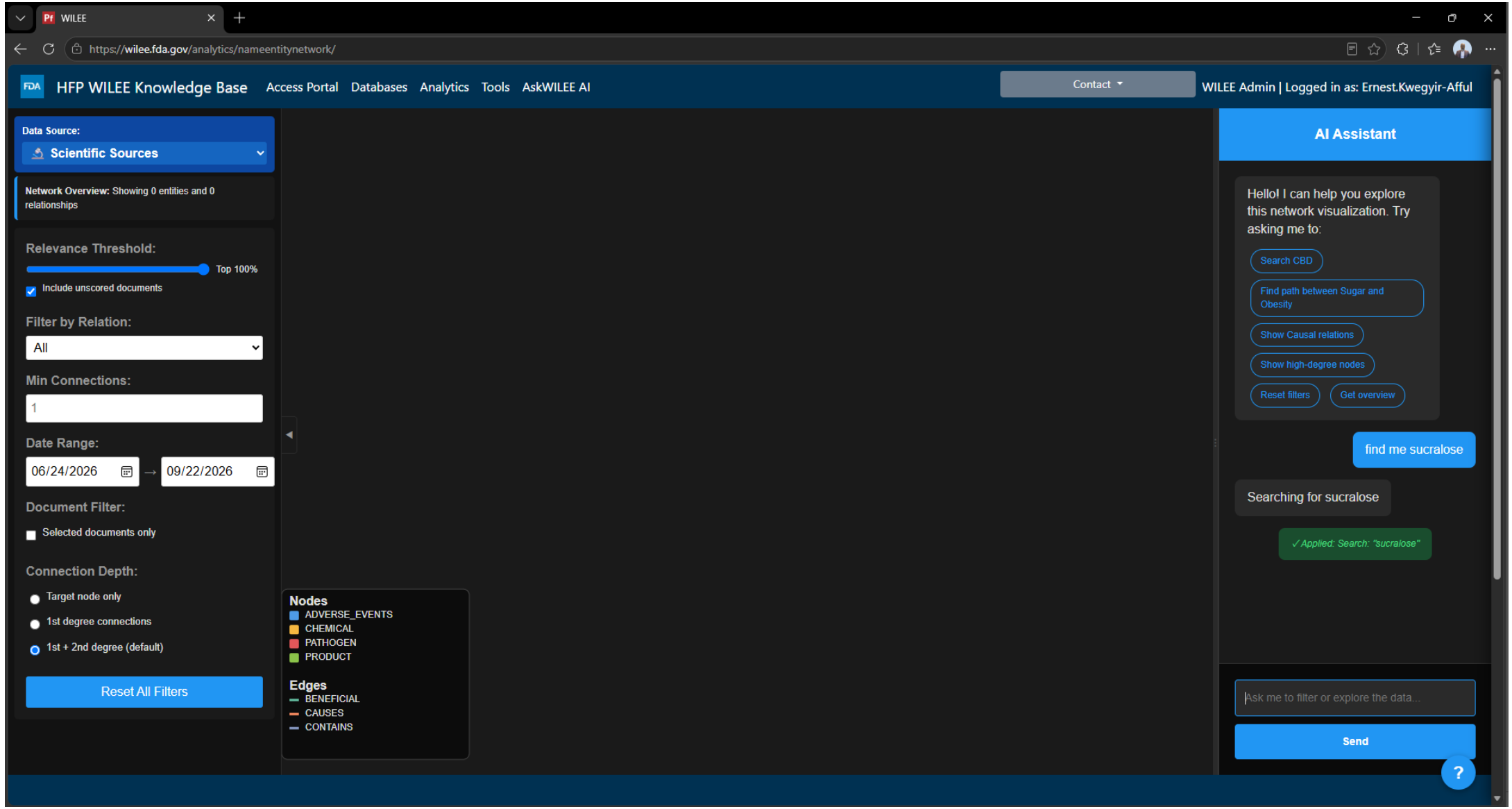
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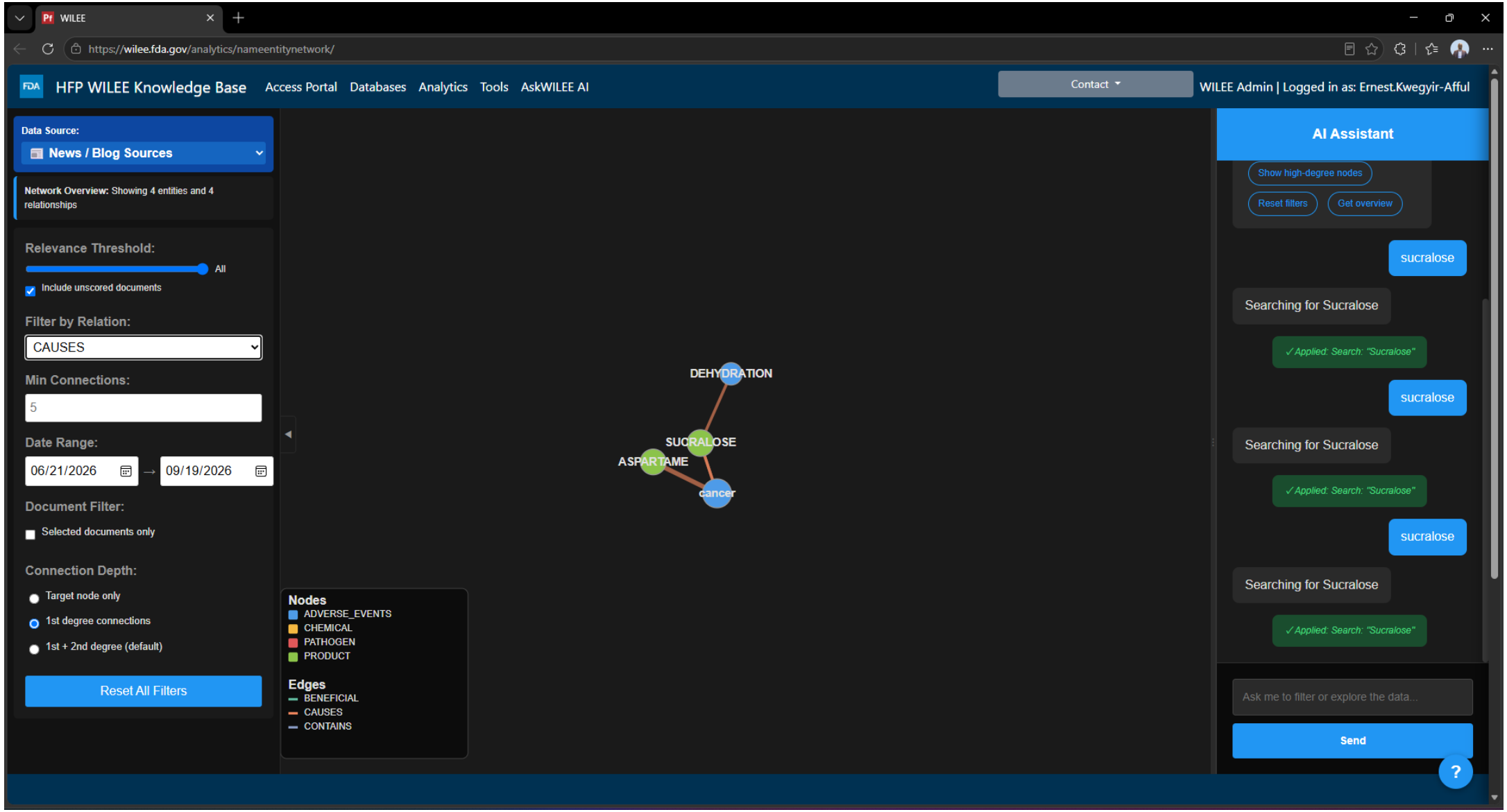
Signals Dashboard



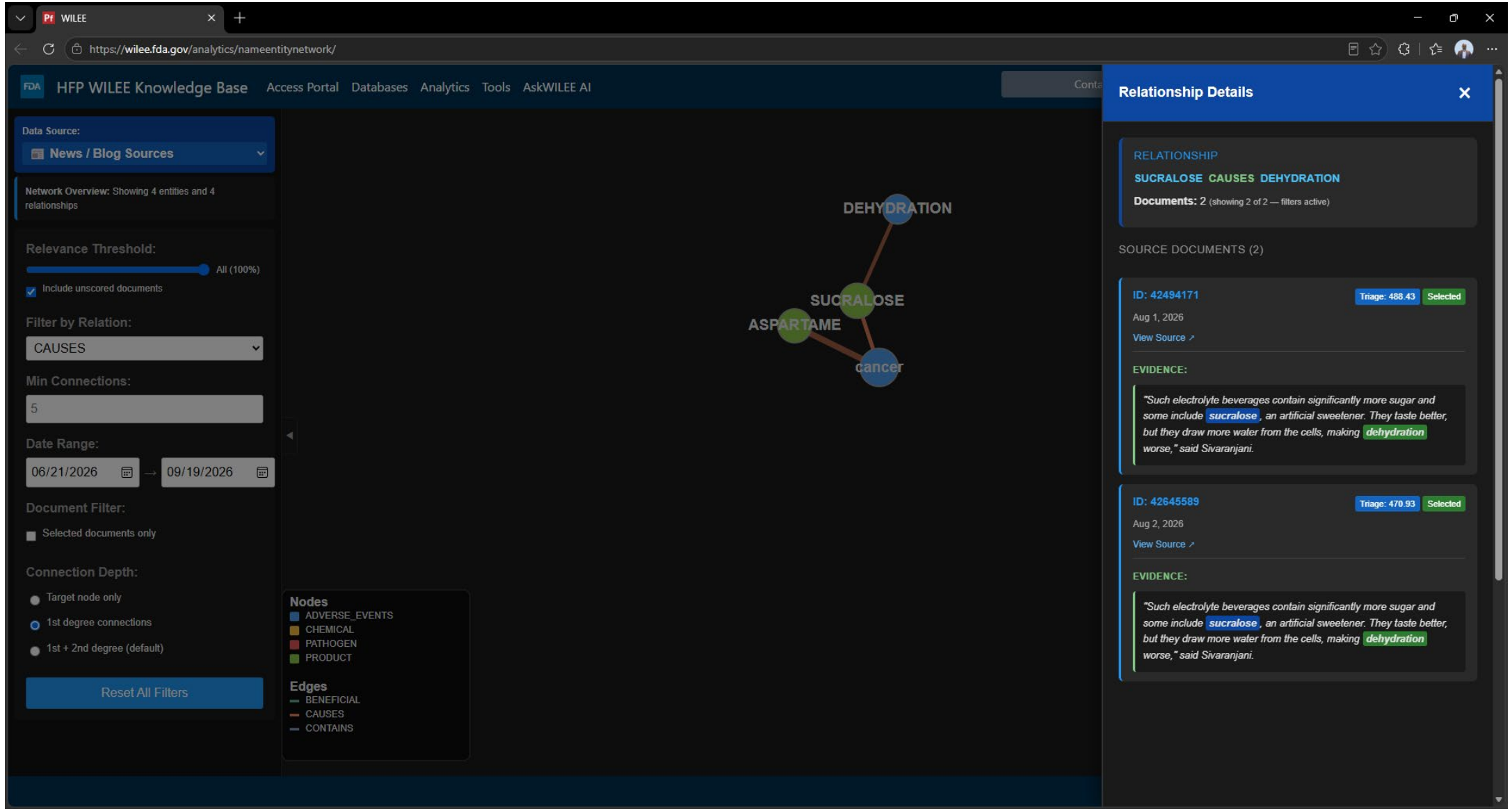
WILEE Knowledge Graph



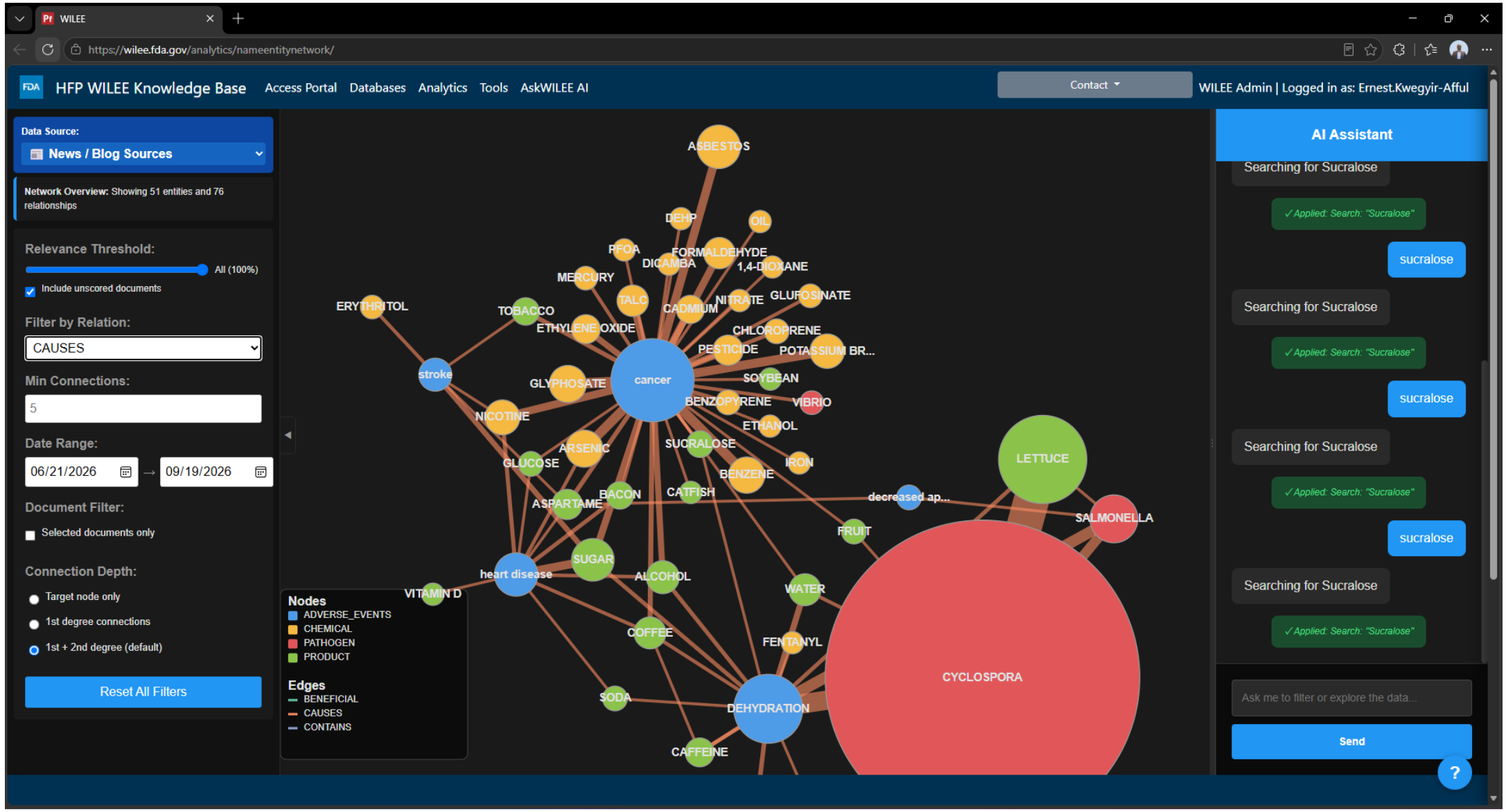
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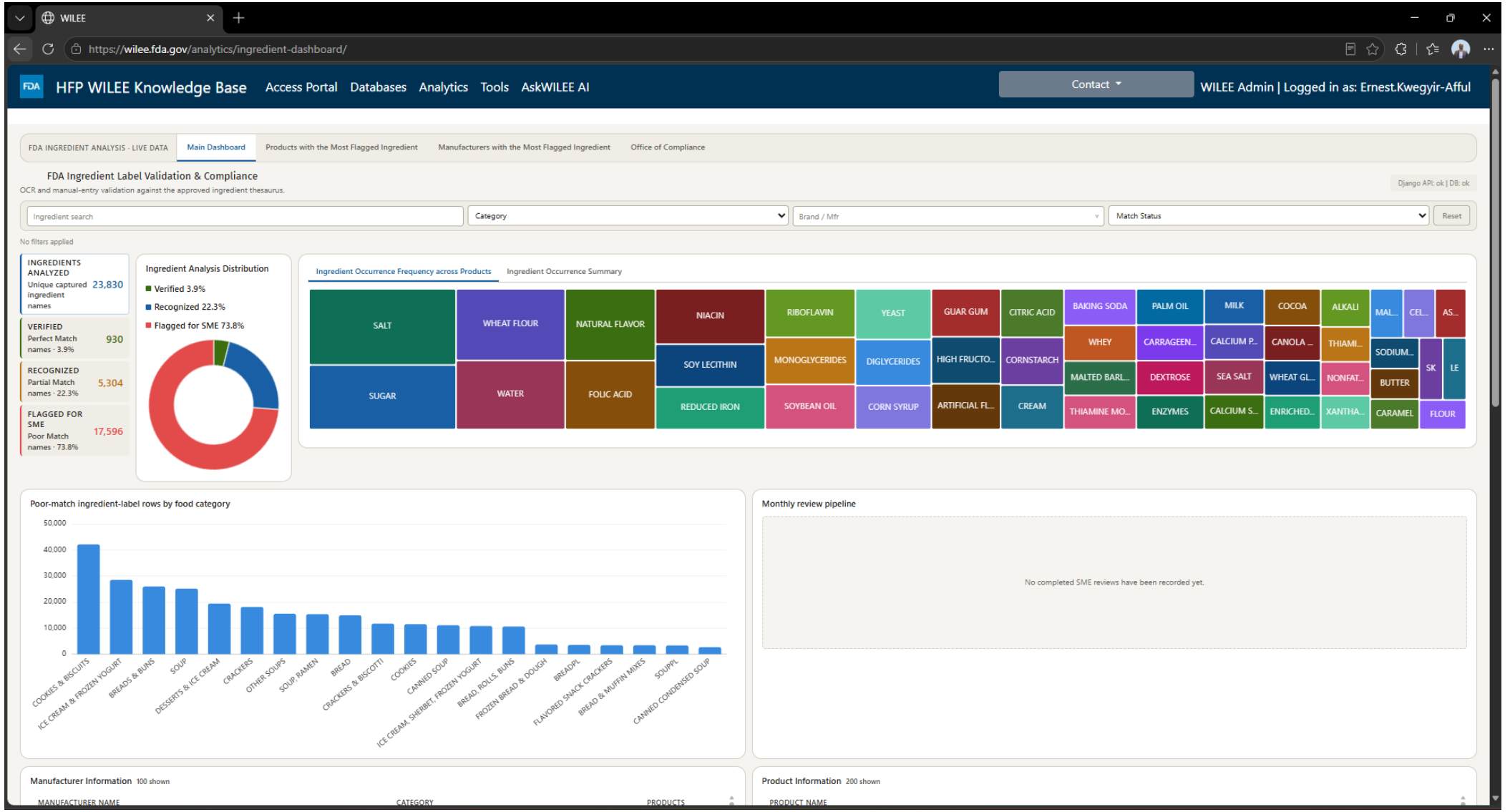
WILEE Knowledge Graph



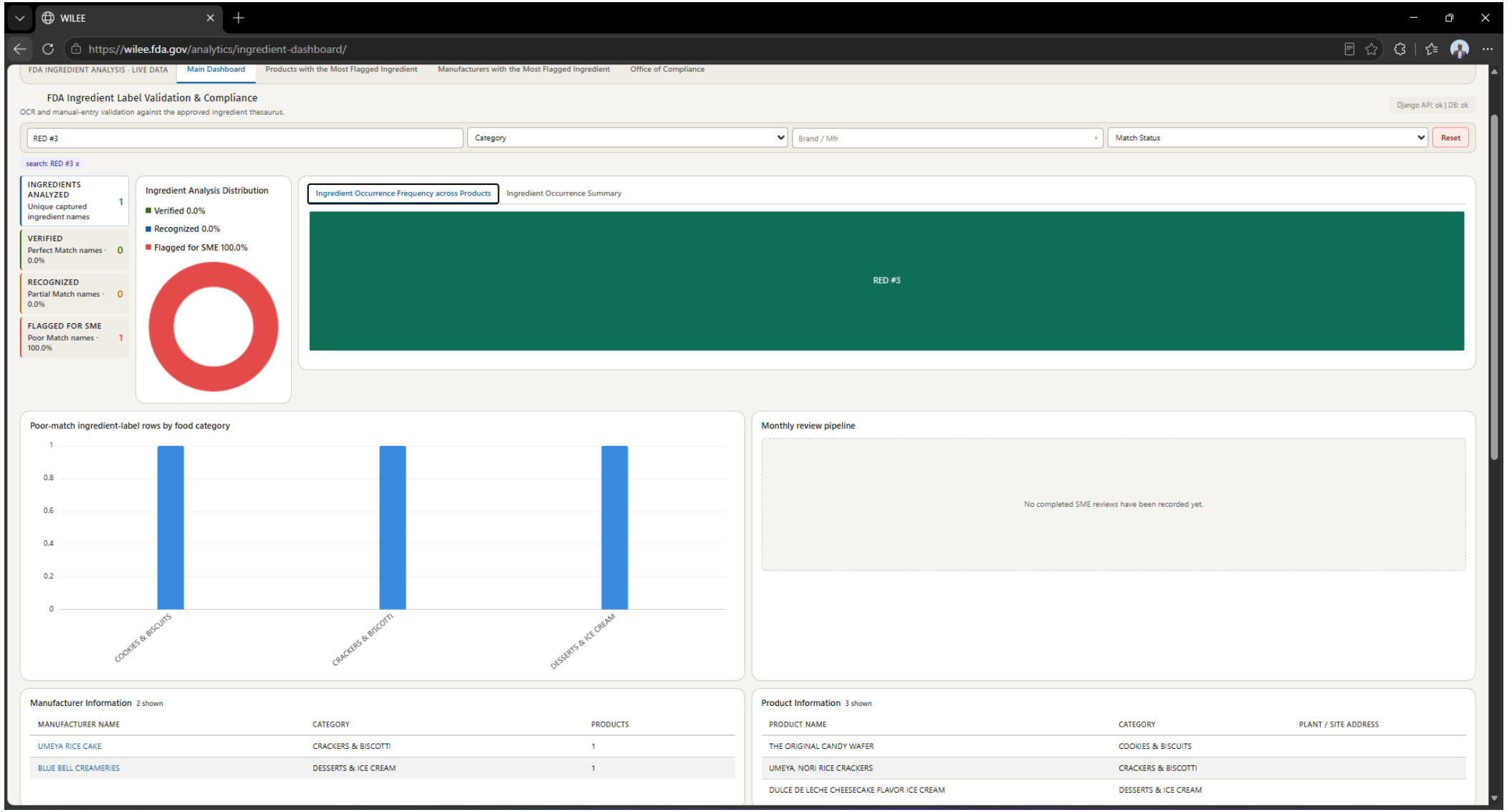
WILEE Knowledge Graph



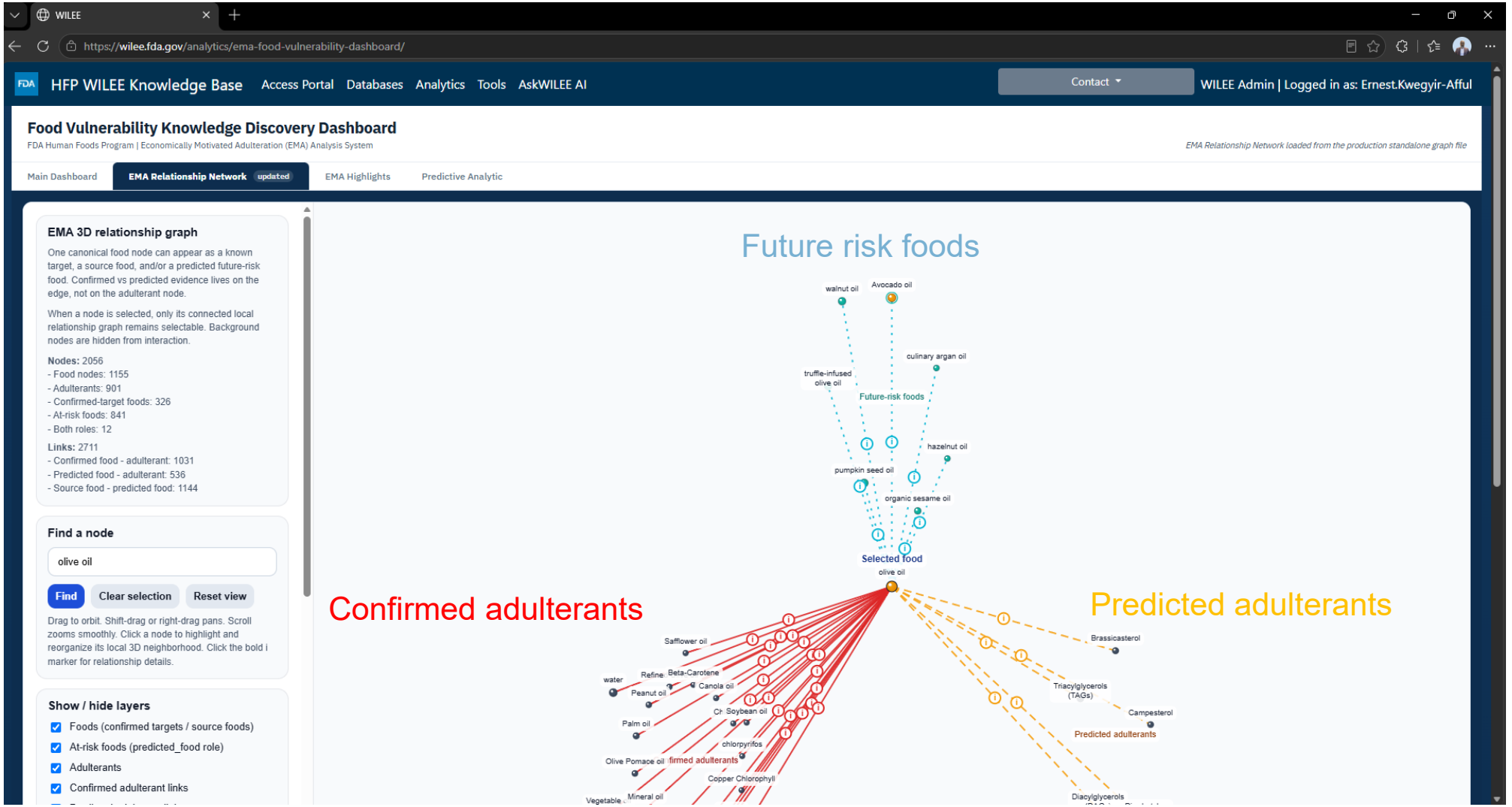
Post market food ingredient monitoring



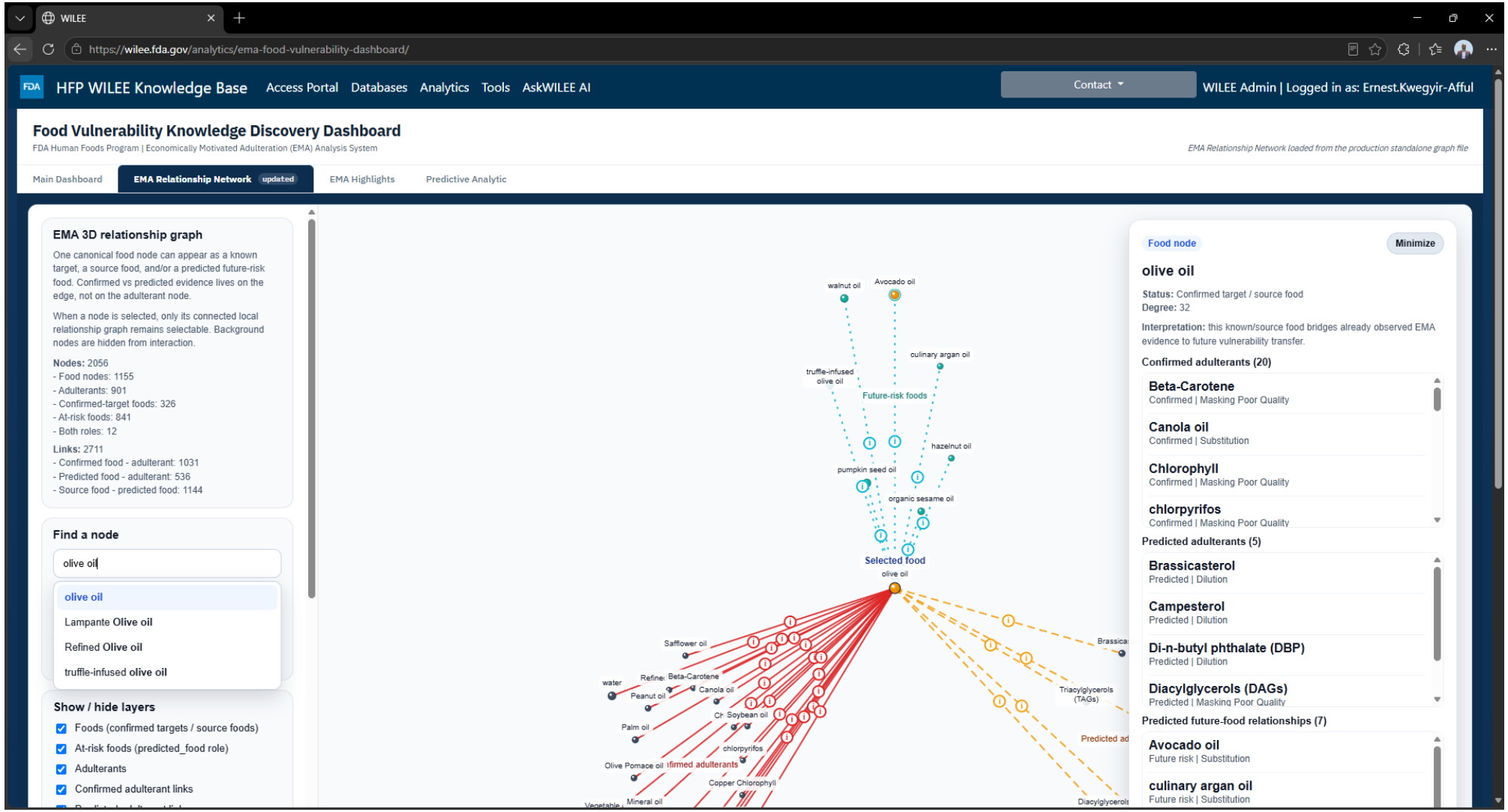
Post market food ingredient monitoring



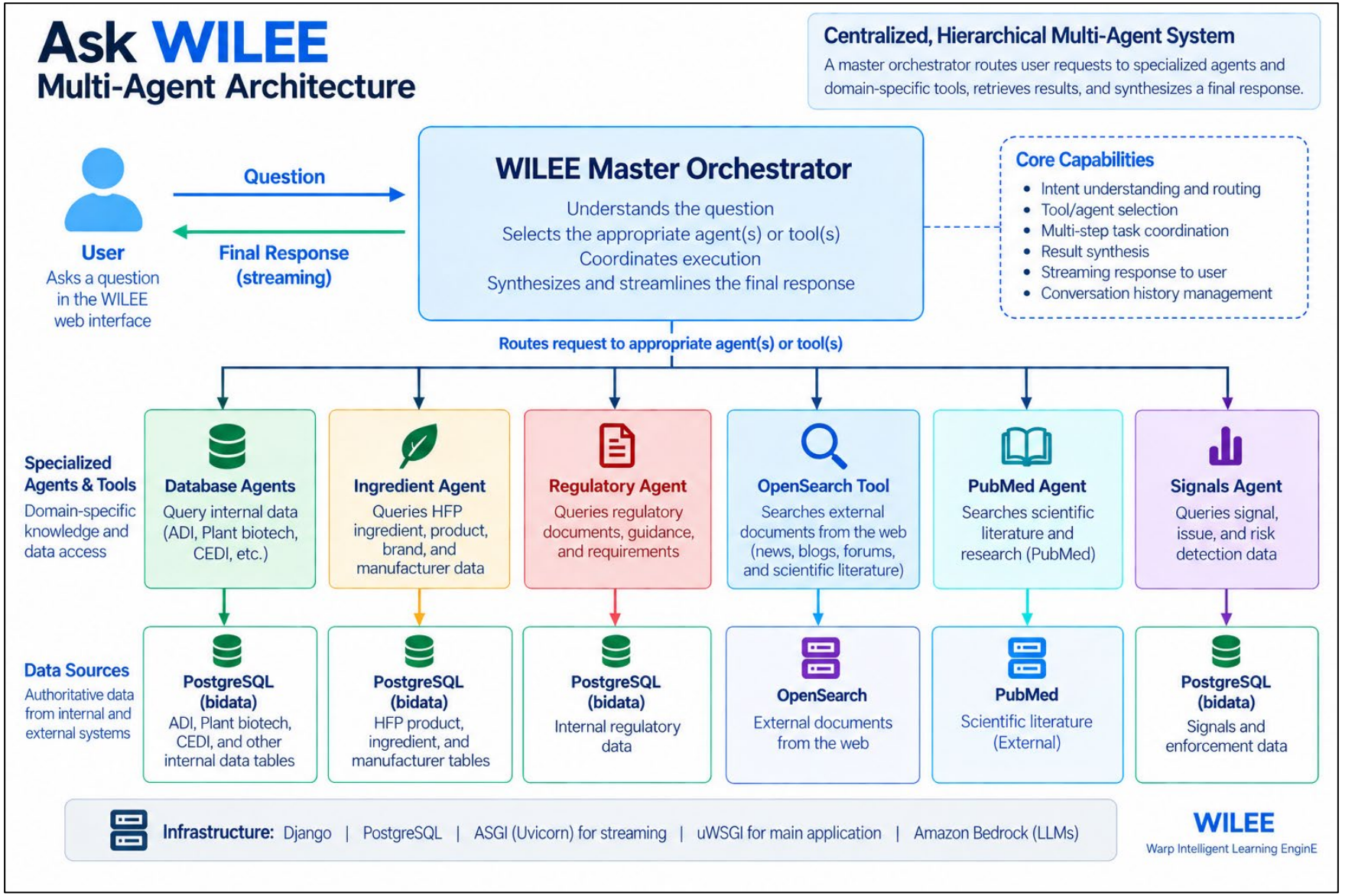
Economic Adulteration Prediction



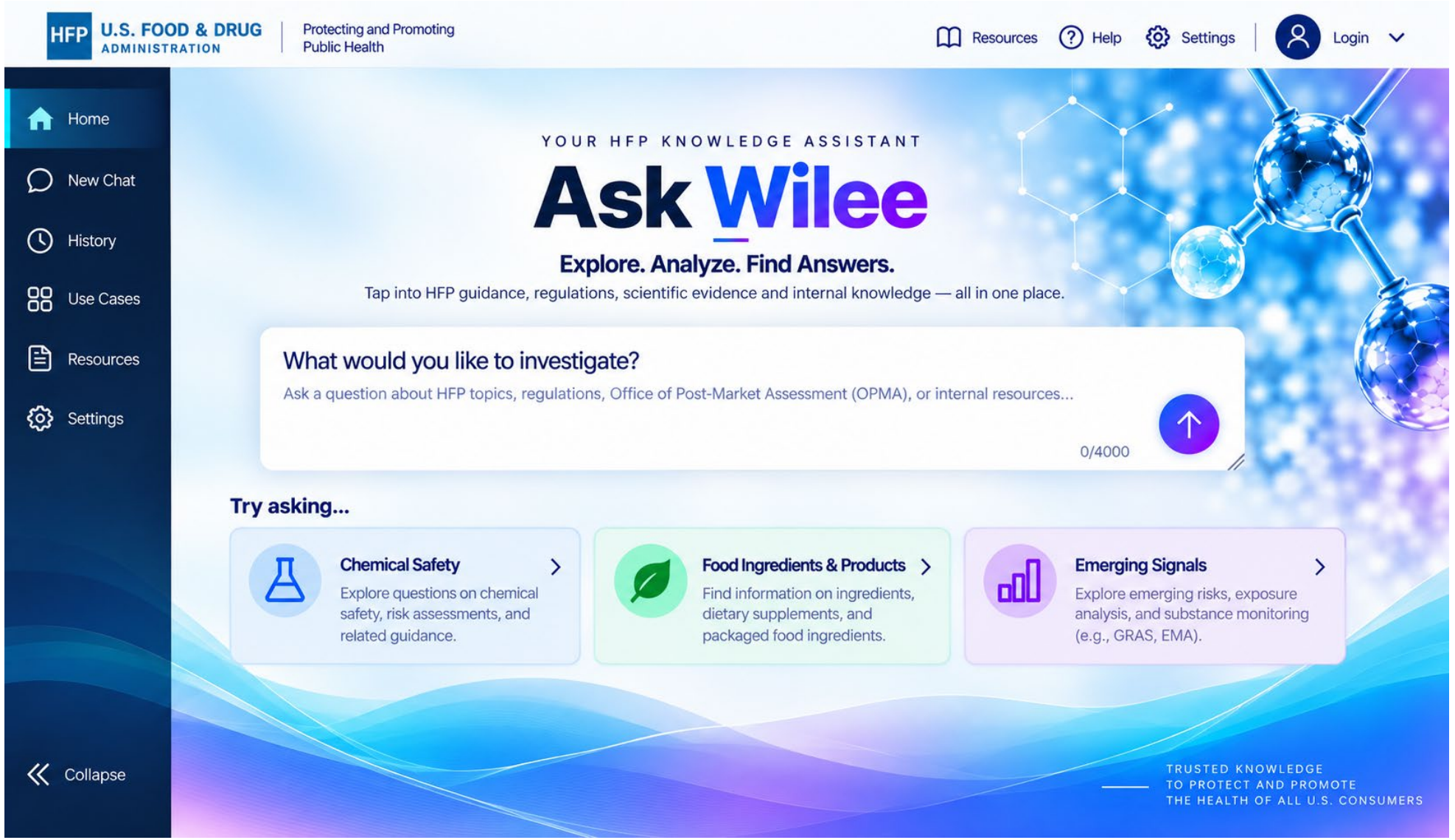
Economic Adulteration Prediction



Ask WILEE


Ask WILEE
Multi-Agent Architecture
Centralized, Hierarchical Multi-Agent System
A master orchestrator routes user requests to specialized agents and domain-specific tools, retrieves results, and synthesizes a final response.
User
Asks a question in the WILEE web interface
Question
Final Response (streaming)
WILEE Master Orchestrator
Understands the question
Selects the appropriate agent(s) or tool(s)
Coordinates execution
Synthesizes and streamlines the final response
Core Capabilities
Intent understanding and routing
Tool/agent selection
Multi-step task coordination
Result synthesis
Streaming response to user
Conversation history management
Routes request to appropriate agent(s) or tool(s)
Specialized Agents & Tools
Domain-specific knowledge and data access
Database Agents
Query internal data (ADI, Plant biotech, CEDI, etc.)
Ingredient Agent
Queries HFP ingredient, product, brand, and manufacturer data
Regulatory Agent
Queries regulatory documents, guidance, and requirements
OpenSearch Tool
Searches external documents from the web (news, blogs, forums, and scientific literature)
PubMed Agent
Searches scientific literature and research (PubMed)
Signals Agent
Queries signal, issue, and risk detection data
Data Sources
Authoritative data from internal and external systems
PostgreSQL (bidata)
ADI, Plant biotech, CEDI, and other internal data tables
PostgreSQL (bidata)
HFP product, ingredient, and manufacturer tables
PostgreSQL (bidata)
Internal regulatory data
OpenSearch
External documents from the web
PubMed
Scientific literature (External)
PostgreSQL (bidata)
Signals and enforcement data
Infrastructure: Django | PostgreSQL | ASGI (Uvicorn) for streaming | uWSGI for main application | Amazon Bedrock (LLMs)
WILEE
Warp Intelligent Learning EnginE

Ask WILEE


HFP U.S. FOOD & DRUG ADMINISTRATION
Protecting and Promoting Public Health
Resources
Help
Settings
Login
Home
New Chat
History
Use Cases
Resources
Settings
Collapse
YOUR HFP KNOWLEDGE ASSISTANT
Ask Wilee
Explore. Analyze. Find Answers.
Tap into HFP guidance, regulations, scientific evidence and internal knowledge — all in one place.
What would you like to investigate?
Ask a question about HFP topics, regulations, Office of Post-Market Assessment (OPMA), or internal resources...
0/4000
Try asking...
Chemical Safety
Explore questions on chemical safety, risk assessments, and related guidance.
Food Ingredients & Products
Find information on ingredients, dietary supplements, and packaged food ingredients.
Emerging Signals
Explore emerging risks, exposure analysis, and substance monitoring (e.g., GRAS, EMA).
TRUSTED KNOWLEDGE
TO PROTECT AND PROMOTE
THE HEALTH OF ALL U.S. CONSUMERS

Ask WILEE – Tracking

WILEE Tracking Infant formula supply chain monitoring 2026-09-11 to 2026-09-18

WILEE Mail

Weekly Tracking Summary

Abbott Settles $385 Million Infant Formula Contamination Case as Supply Chain Monitoring Concerns Continue

On **September 15, 2026** , Abbott Laboratories agreed to pay $385 million to settle allegations related to contaminated infant formula manufactured at its Sturgis, Michigan facility, marking a significant development in infant formula supply chain monitoring [1,2,3] . The settlement resolves claims brought by the U.S. Department of Justice, several whistleblowers, and state Attorneys General concerning the company's manufacturing practices and the 2022 recall of powdered infant formula [1] .

The Sturgis Facility Investigation

The case stems from reports of infant illnesses involving *Cronobacter sakazakii* bacteria at Abbott's Sturgis facility, which became the focus of regulatory scrutiny after four infant illnesses were reported to the FDA in 2022 [1] . The Justice Department alleged that Abbott "knowingly manufactured infant formula purchased with taxpayer dollars in an environment that put the products at unacceptable risk of microorganism contamination" [2] .

FDA inspections revealed unsanitary conditions including roof leaks that required umbrellas to divert water from production areas, creating environments conducive to bacterial growth [2] . The complaint also alleged that Abbott "intentionally did not test for bacterial growth to avoid obtaining positive test results showing contamination" and failed to disclose certain test results during FDA inspections [2] .

Ask WILEE – Tracking

WILEE Tracking Plant biotech 2026-09-11 to 2026-09-18

WILEE Mail

Weekly Tracking Summary

Plant Biotechnology Research Advances: September 2026 Summary

Recent developments in plant biotechnology highlight significant progress across multiple fronts, from gene editing regulations to novel crop protection strategies and innovative breeding techniques.

European Gene Editing Policy Breakthrough

A major development occurred on **September 15, 2026** , when new European Union regulations eased restrictions on gene-edited crops[1]. The revised framework divides gene-edited crops into two categories: New Genome Technologies 1 (NGT-1) for limited modifications considered equivalent to conventional breeding, and NGT-2 for more complex edits that remain under strict GMO regulations. While this represents progress, critics note that arbitrary limits on the number of edits and DNA base pairs could hinder innovation in developing climate-resilient crops[1].

Breakthrough in Disease Detection

Cornell researchers made significant strides in plant health monitoring with the development of "Red Alert" tomato plants that visually signal nitrogen stress[2]. Published on **September 15, 2026** , this

WILEE Expanding Components

WILEE TOOLS

Powering Smarter Food Safety Decisions

WILEE includes a comprehensive suite of AI-powered tools designed to make regulatory work more efficient, accurate, and consistent.

- Detect emerging signals
- Connect data to build knowledge
- Analyze to generate insights
- Protect public health



WILEE TOOLS

DOCKET COMMENT REVIEW WORKBENCH
Extract, triage, and review public comments.

STARI REPORTS
Preview STARI data and download Excel-ready reports.

SUBSTANCE NAME QC
Standardize and review substance names.

WILEE CAS VERIFY
Verify CAS numbers or HFP temporary IDs.

REVIEW TOOL
Review and map ingredient names.

TDER REPORTS
Automate generation of TDERs for Ames test studies.

SIGNAL TRAINING DASHBOARD
Review and score signal training records.

WILEE FORGE
Plan projects, track delivery risk, and keep every Branch's status visible.

ASK WILEE
Multi-agent AI chat interface to answer questions, search the knowledgebase, track emerging issues, and generate actionable insights.

AND MORE...
Additional specialized tools to support evolving regulatory needs.

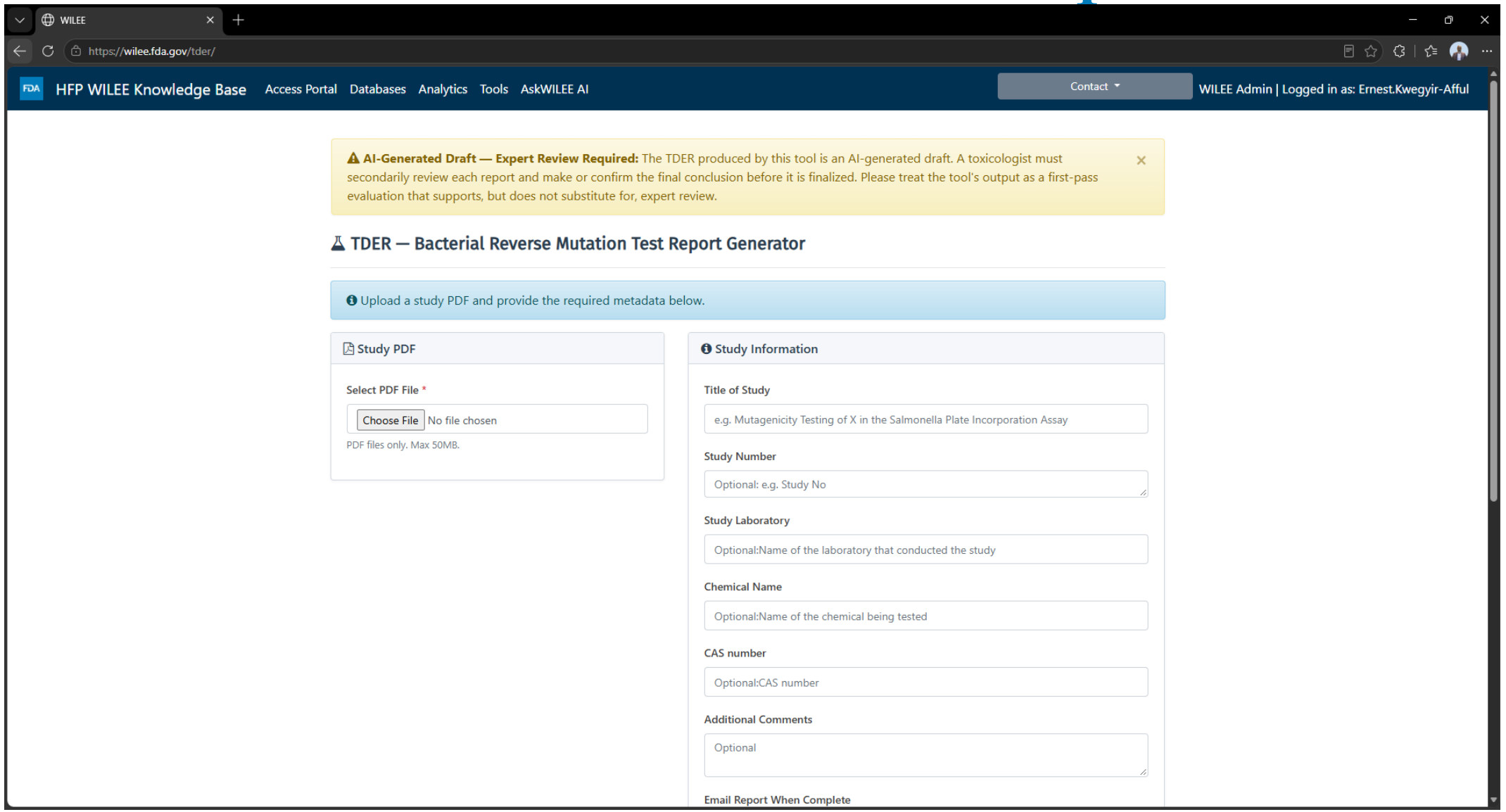
30+ Data Sources

5+ Core Modules

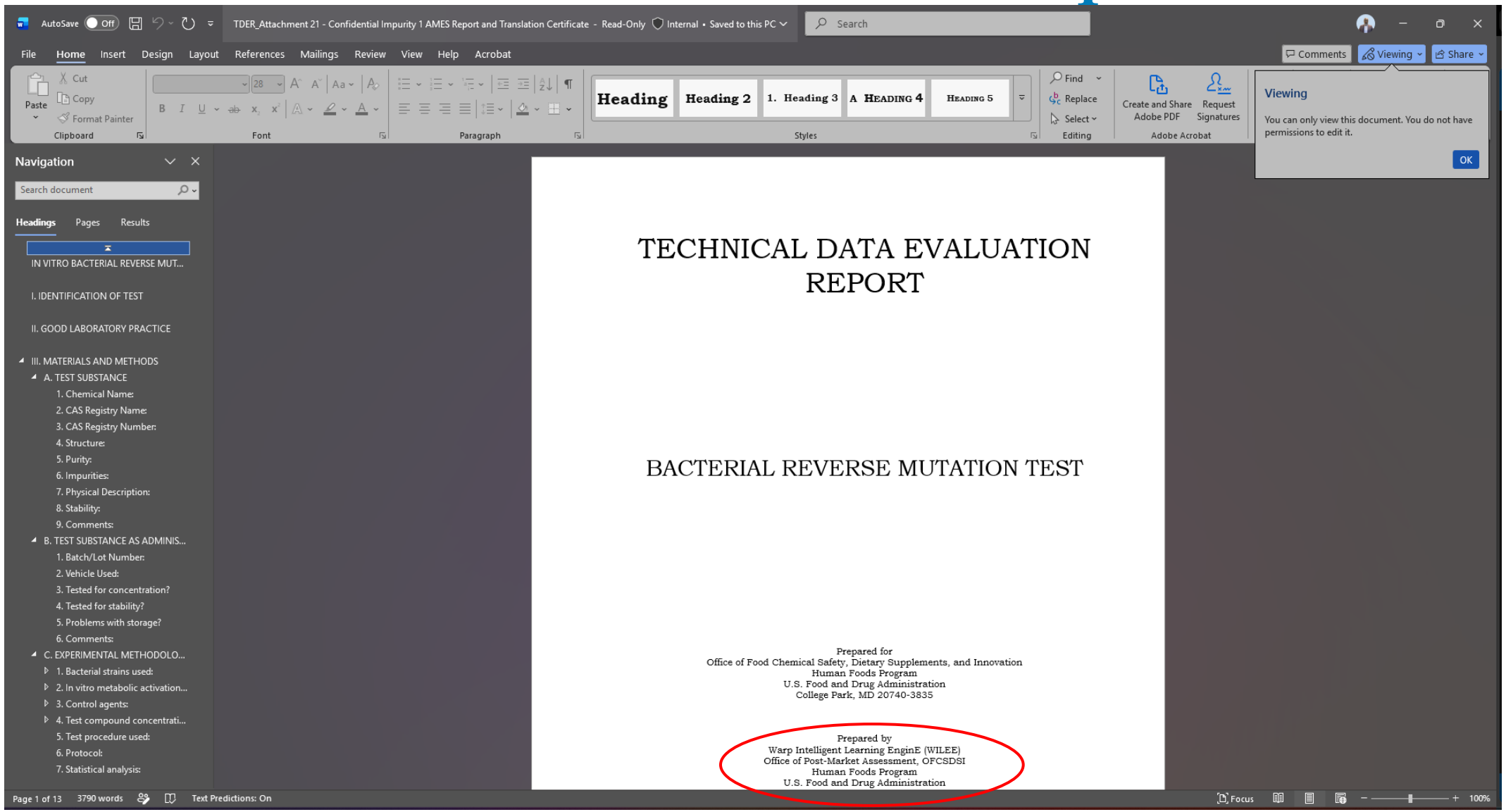
15+ Specialized Tools

Built for FDA. Driven by Intelligence.
One Mission: Public Health.

Technical Data Evaluation Report



Technical Data Evaluation Report



Technical Data Evaluation Report

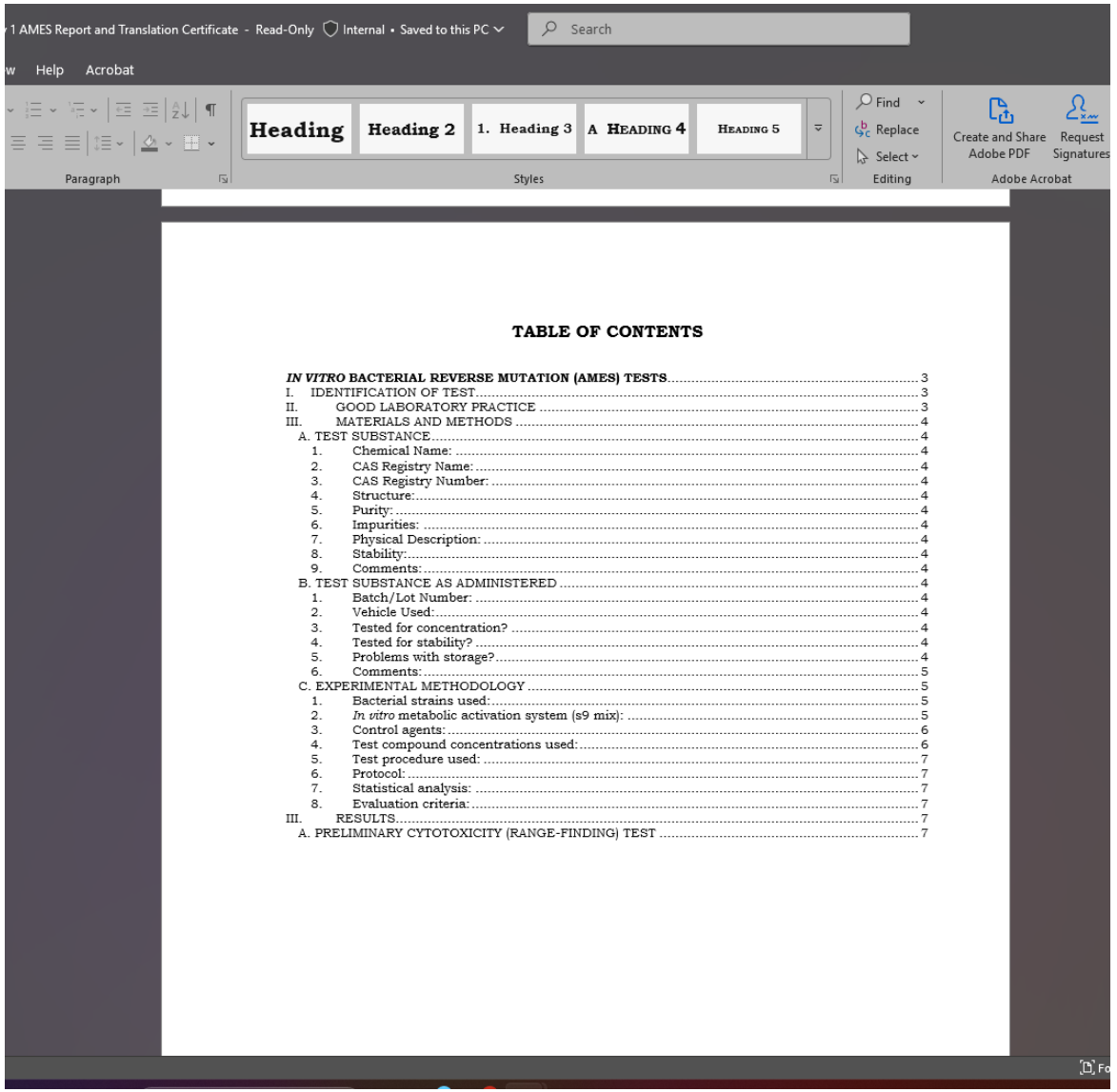
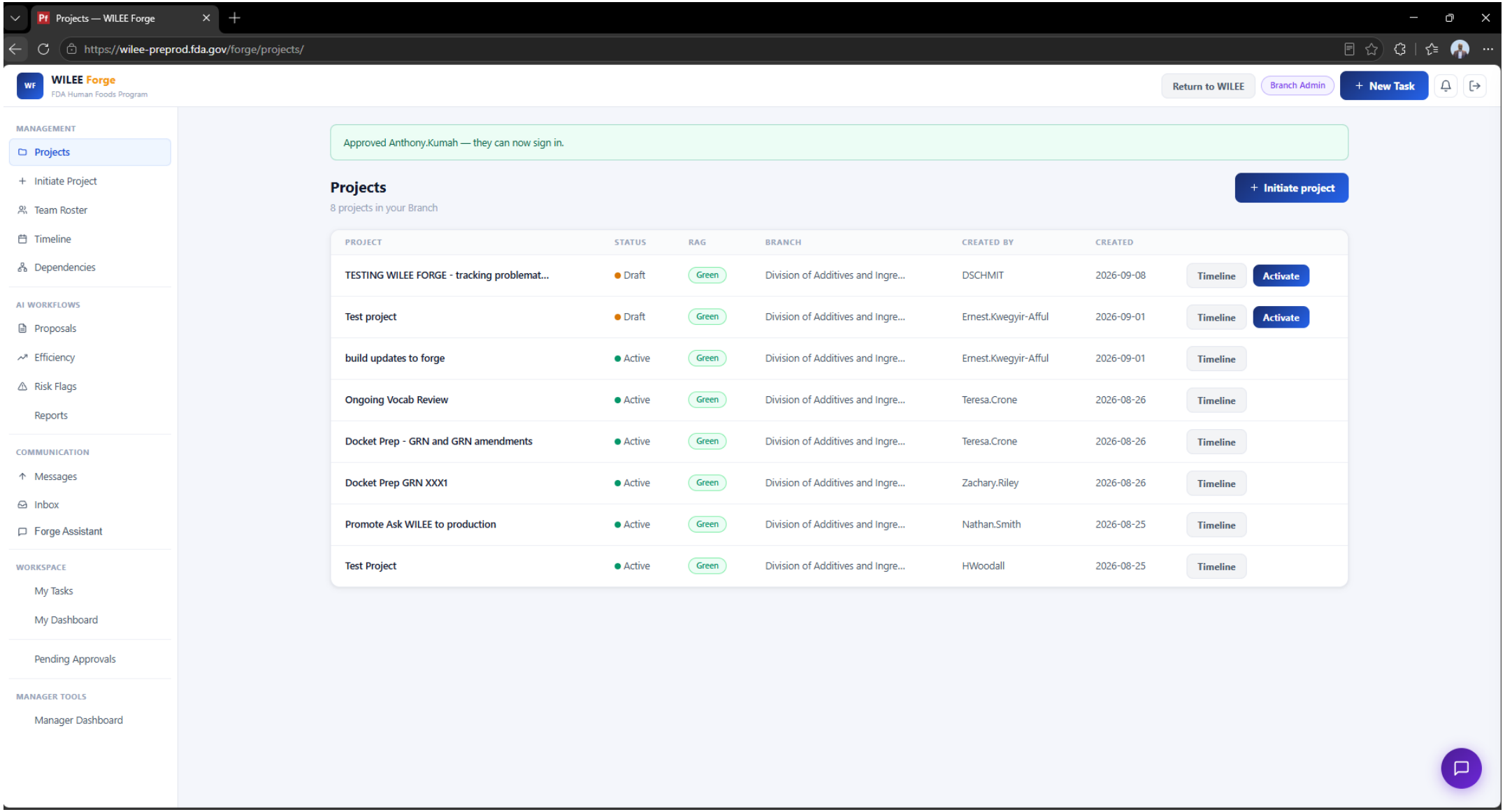


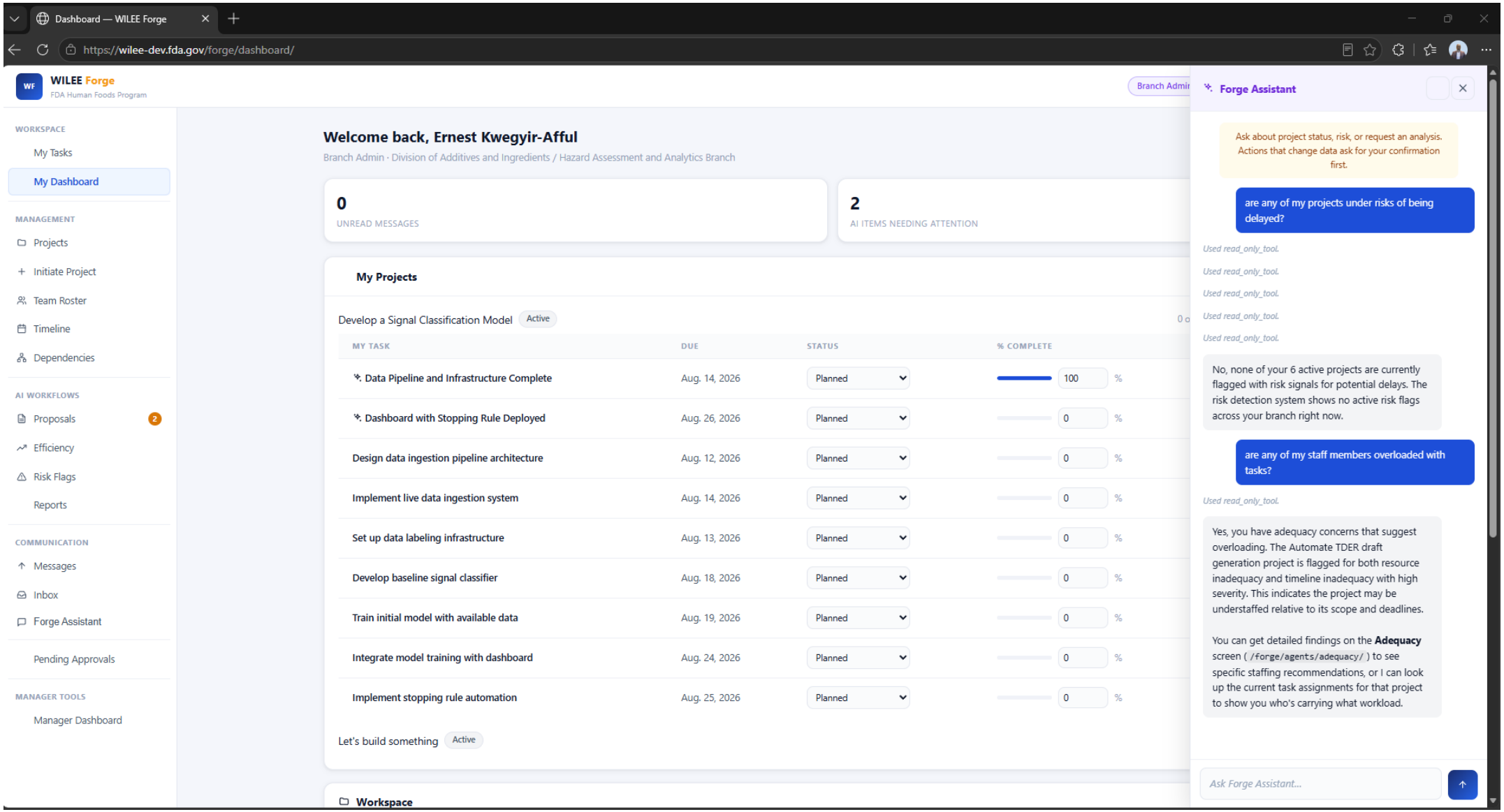
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6. Impurities: 4
7. Physical Description: 4
8. Stability: 4
9. Comments: 4
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WILEE Forge


Projects — WILEE Forge
https://wilee-preprod.fda.gov/forge/projects/
WILEE Forge
FDA Human Foods Program
Return to WILEE
Branch Admin
+ New Task
MANAGEMENT
Projects
Initiate Project
Team Roster
Timeline
Dependencies
AI WORKFLOWS
Proposals
Efficiency
Risk Flags
Reports
COMMUNICATION
Messages
Inbox
Forge Assistant
WORKSPACE
My Tasks
My Dashboard
Pending Approvals
MANAGER TOOLS
Manager Dashboard
Approved Anthony.Kumah — they can now sign in.
Projects
8 projects in your Branch
+ Initiate project
PROJECT
STATUS
RAG
BRANCH
CREATED BY
CREATED
TESTING WILEE FORGE - tracking problemat... Draft Green Division of Additives and Ingre... DSCHMIT 2026-09-08 Timeline Activate
Test project Draft Green Division of Additives and Ingre... Ernest.Kwegyir-Afful 2026-09-01 Timeline Activate
build updates to forge Active Green Division of Additives and Ingre... Ernest.Kwegyir-Afful 2026-09-01 Timeline
Ongoing Vocab Review Active Green Division of Additives and Ingre... Teresa.Crone 2026-08-26 Timeline
Docket Prep - GRN and GRN amendments Active Green Division of Additives and Ingre... Teresa.Crone 2026-08-26 Timeline
Docket Prep GRN XXX1 Active Green Division of Additives and Ingre... Zachary.Riley 2026-08-26 Timeline
Promote Ask WILEE to production Active Green Division of Additives and Ingre... Nathan.Smith 2026-08-25 Timeline
Test Project Active Green Division of Additives and Ingre... HWoodall 2026-08-25 Timeline

WILEE Forge


Dashboard — WILEE Forge
https://wilee-dev.fda.gov/forge/dashboard/
WILEE Forge
FDA Human Foods Program
Branch Admin
WORKSPACE
My Tasks
My Dashboard
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Projects
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Team Roster
Timeline
Dependencies
AI WORKFLOWS
Proposals
Efficiency
Risk Flags
Reports
COMMUNICATION
Messages
Inbox
Forge Assistant
Pending Approvals
MANAGER TOOLS
Manager Dashboard
Welcome back, Ernest Kwegyir-Afful
Branch Admin · Division of Additives and Ingredients / Hazard Assessment and Analytics Branch
0
UNREAD MESSAGES
2
AI ITEMS NEEDING ATTENTION
My Projects
Develop a Signal Classification Model
Active
MY TASK
DUE
STATUS
% COMPLETE
Data Pipeline and Infrastructure Complete
Aug. 14, 2026
Planned
100
Dashboard with Stopping Rule Deployed
Aug. 26, 2026
Planned
0
Design data ingestion pipeline architecture
Aug. 12, 2026
Planned
0
Implement live data ingestion system
Aug. 14, 2026
Planned
0
Set up data labeling infrastructure
Aug. 13, 2026
Planned
0
Develop baseline signal classifier
Aug. 18, 2026
Planned
0
Train initial model with available data
Aug. 19, 2026
Planned
0
Integrate model training with dashboard
Aug. 24, 2026
Planned
0
Implement stopping rule automation
Aug. 25, 2026
Planned
0
Let's build something
Active
Workspace
Forge Assistant
Ask about project status, risk, or request an analysis. Actions that change data ask for your confirmation first.
are any of my projects under risks of being delayed?
Used read_only_tool.
Used read_only_tool.
Used read_only_tool.
Used read_only_tool.
Used read_only_tool.
No, none of your 6 active projects are currently flagged with risk signals for potential delays. The risk detection system shows no active risk flags across your branch right now.
are any of my staff members overloaded with tasks?
Used read_only_tool.
Yes, you have adequacy concerns that suggest overloading. The Automate TDER draft generation project is flagged for both resource inadequacy and timeline inadequacy with high severity. This indicates the project may be understaffed relative to its scope and deadlines.
You can get detailed findings on the Adequacy screen (/forge/agents/adequacy/) to see specific staffing recommendations, or I can look up the current task assignments for that project to show you who's carrying what workload.
Ask Forge Assistant...



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