DHS SCIENCE AND TECHNOLOGY

Federal Laboratory Consortium Mid-Atlantic Region Annual Meeting- Human Interest Panel

DHS & Food Industry Collaboration to Develop Tools to Assess and Prevent Deliberate Contamination of Food

Homeland Security

Science and Technology

November 15, 2017

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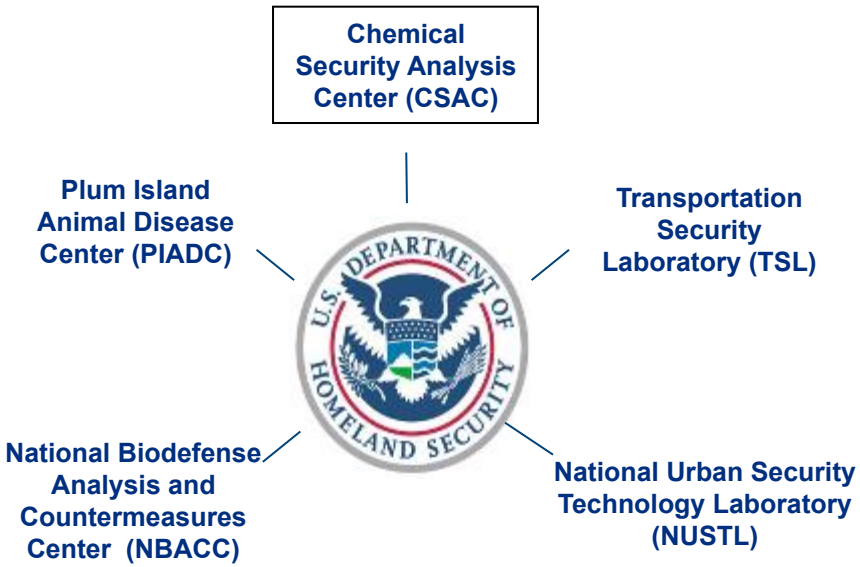
CHEMICAL TERRORISM RISK ASSESSMENT

Science and Technology Directorate

Chemical Security Analysis Center

DHS S&T Chemical Security Analysis Center



Chemical Security Analysis Center, Aberdeen Proving Ground – Edgewood Area (APG-EA), Edgewood, MD

- Established in 2006, CSAC is one of five DHS/S&T Laboratories
- Focus is on understanding & mitigating toxic chemical threats & hazardous chemical processes to support the national effort to secure the American homeland.
- Edgewood, MD location leverages Army expertise in the areas of chemical defense, chemical threat agents, and toxic industrial chemicals
- 2nd MOA signed in May, 2011 reinforces the cooperative relationship between DHS & DOD

The Problem/Challenge & Why it is Important to Address:

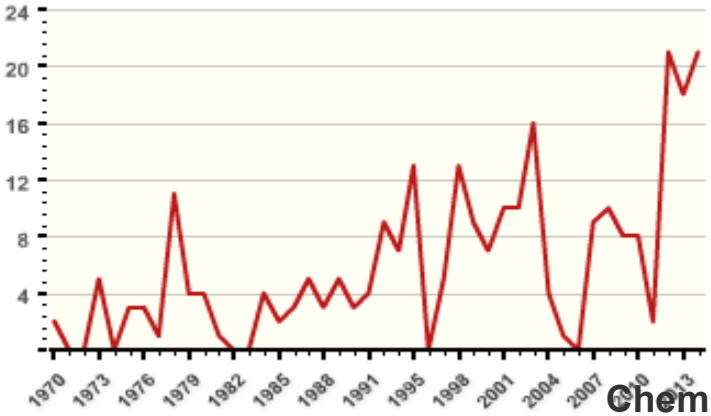
The Chemical Threat

- In April 2016 the CAS Registry had **110 million+ unique organic and inorganic chemical substances** of which **345,000 substances are regulated** in key markets across the globe.
- Large number of these chemical compounds are **highly toxic** and used in a number of industries throughout the country. They are **transported, stored, processed, sold, and disposed of in large quantities.**
- Accidental, intentional and criminal motivated **chemical events occur daily** across the country and the world.
- Each of these points provides potential for access or diversion of the material to become a **"weapon of opportunity."**
- There are **billions of possible scenarios** that involve these chemicals of opportunity.

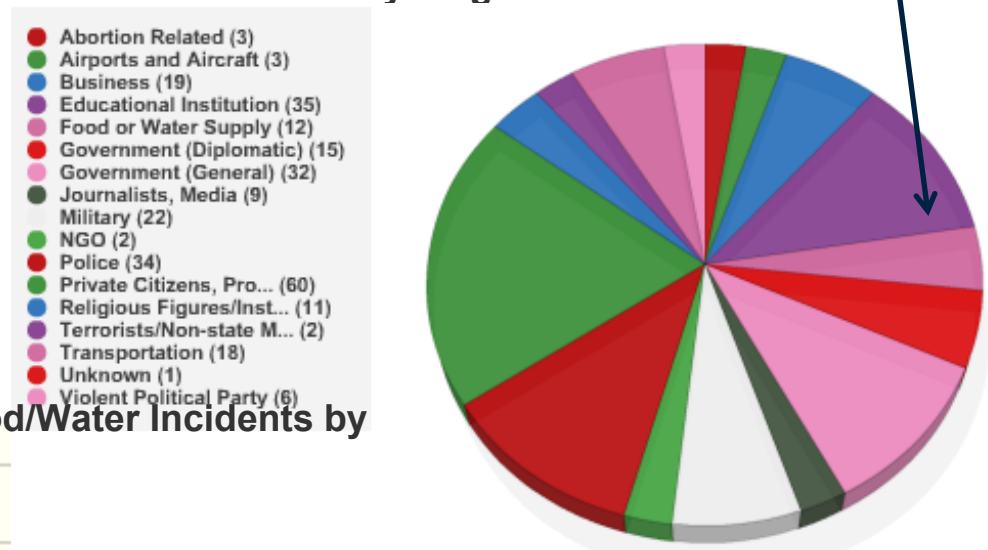
The Chemical Terrorism Threat

According to the Global Terrorism Database: 264 Incidents of Chemical Terrorism from 1970 to 2014

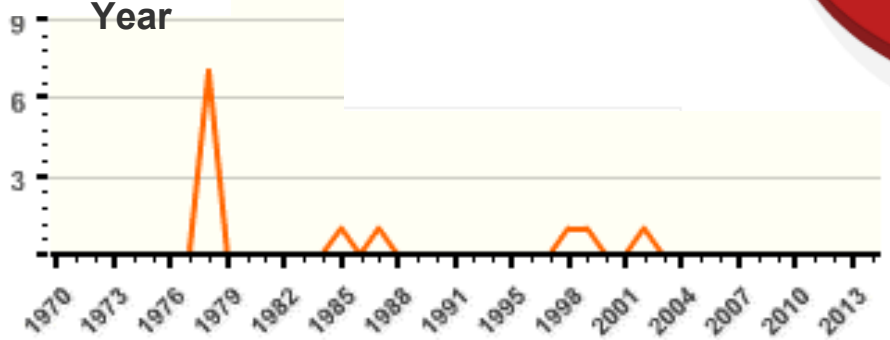
Chemical Incidents Over Time



Chemical Incident by Target



Chemical Food/Water Incidents by Year

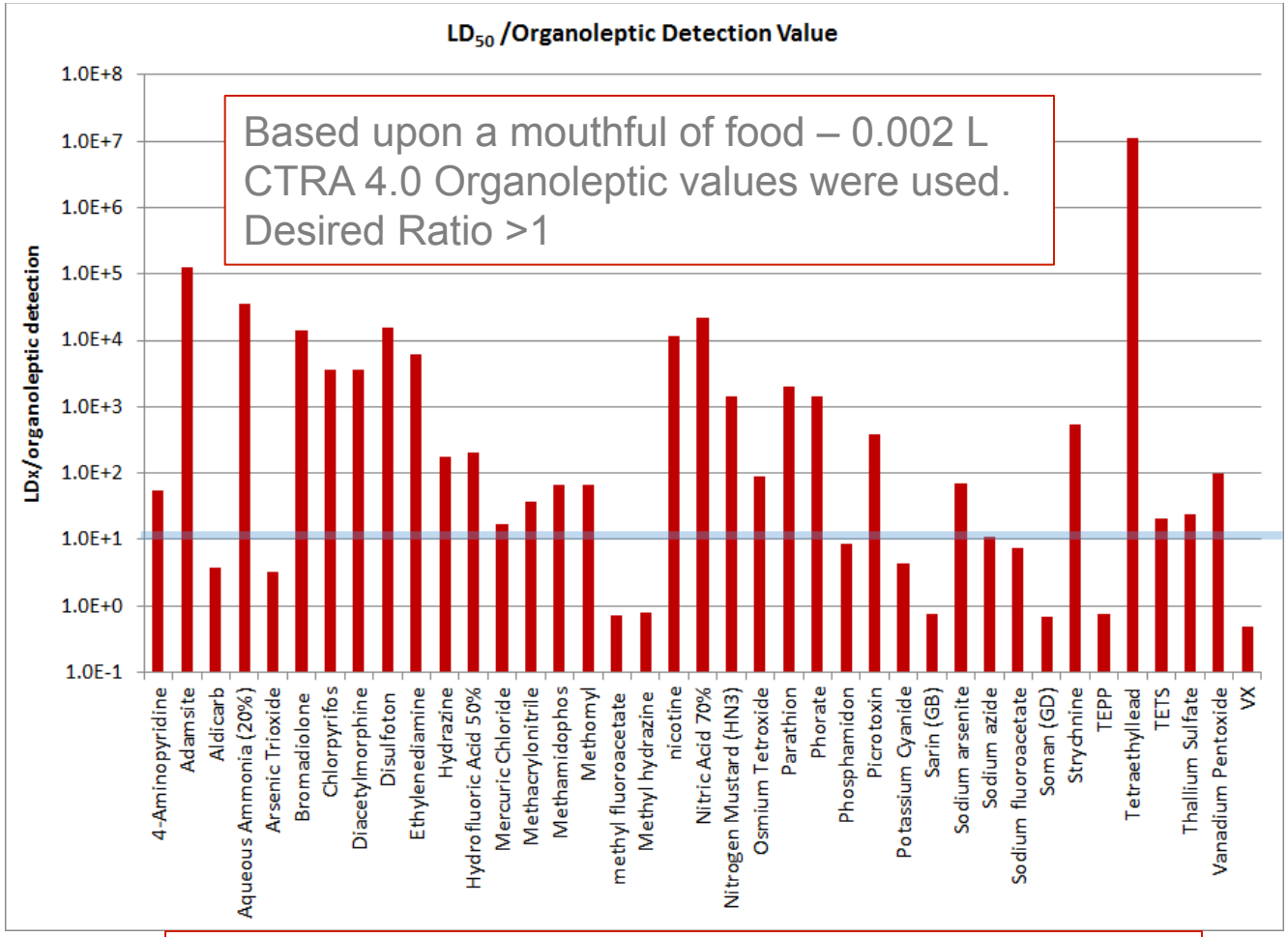


National Consortium for the Study of Terrorism and Responses to Terrorism (START). (2013). Global Terrorism Database 21 April 2016. Retrieved from http://www.start.umd.edu/gtd

Organoleptic Warning?

Indicates that organoleptics (taste, smell, solubility, one mouthful) would NOT warn for

- Aldicarb
- Arsenic trioxide
- Methyl fluoroacetate
- Methyl hydrazine
- Phosphamidon
- Potassium cyanide
- Sarin
- Sodium azide
- Sodium fluoroacetate
- Soman
- TEPP
- VX



Issue: people often ignore 'funny' or 'different' tastes and continue to eat.

Highlighted Historical Food Incidents

Year	Location	Agent	Food	Motivation	Perpetrator	Outcome
1999	Germany	Insecticide	Nestle Products	Terrorism & Blackmail	Robin Foods	No Injuries, but massive recalls
2003	USA (Kent County Michigan	Nicotine	Ground Beef	Revenge-Packaging	Supermarket Employee	92 victims, massive recalls
2008	China (Shijcazhuang)	Melamine	Milk & Infant Formula	Economic-During R&D	Corporate	300,000 victims including 54,000 infants
2009	USA (Lenexa, Kansas)	Methomyl	Salsa	?- Point of Sale	2 Restaurant Employees	2 incidents, 48 victims
2010	USA	Ricin and/or Cyanide	Buffet & Salad Bars	Terrorism	Al Queda in the Arabian Peninsula	Credible Threat but no Incident
2013	Japan (Gunma)	Malathion	Frozen Products	Revenge-during production	Disgruntled Employee	2,800 became sick, no fatalities, 6.3 million products recalled

How this Challenge is Being Addressed Through Government, Industry and Academia Collaboration

DHS CBRN Terrorism Risk Assessments

- HSPD 10, 18, 22 Mandated
- End-to-end probabilistic risk assessments that identifies, assesses, and prioritizes the CBRN terrorism risks facing the U.S. homeland.
- Risk results include the threat, vulnerability and consequences of all potential scenarios.
- SECRET

[Risk] = [Threat] x [Vulnerability] x [Consequences]

[Risk] = [Likelihood] x [Consequences]

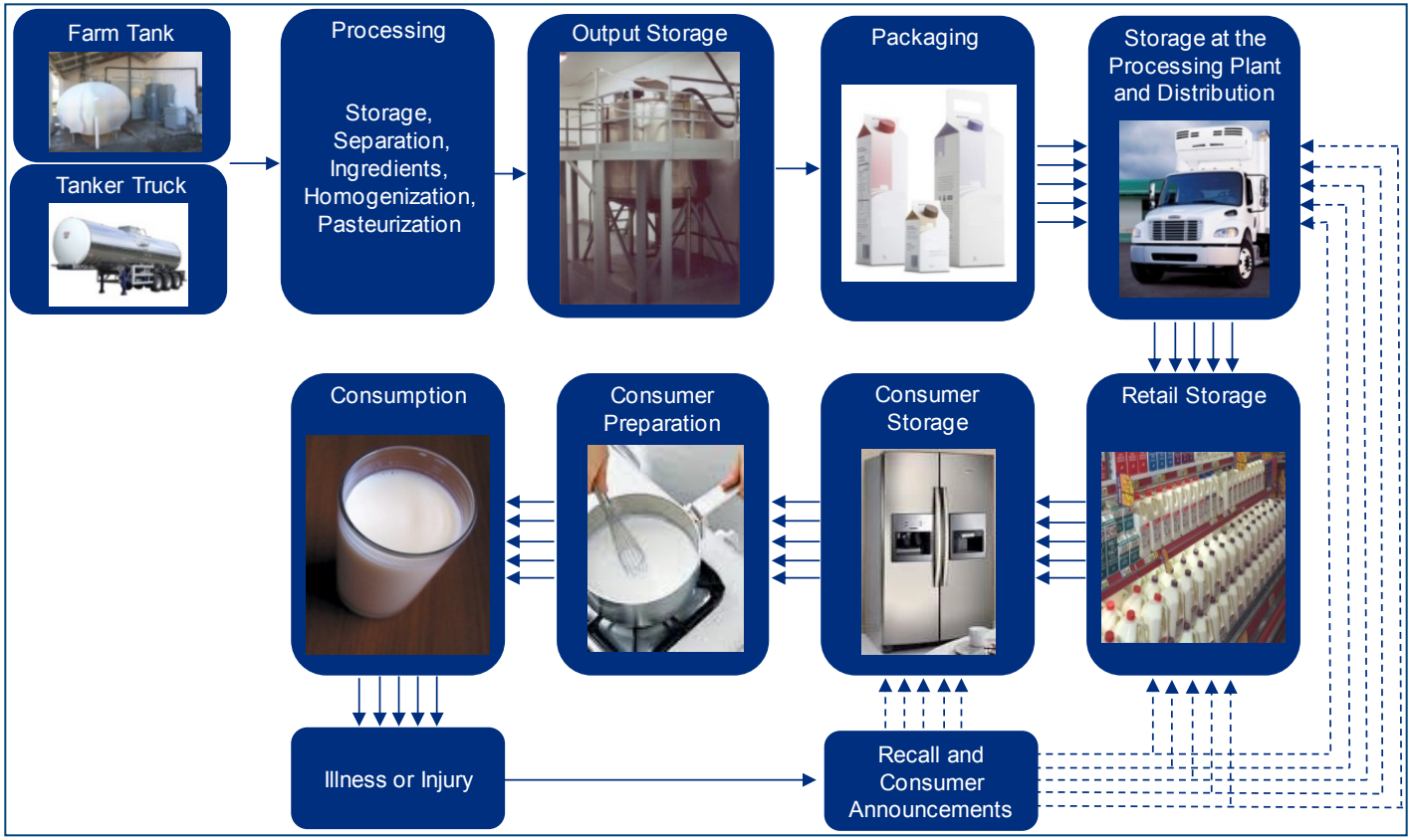
[Risk] = [Frequency] x [Consequences]

3 Primary Outputs: Critical Vulnerabilities, Critical Data/ Knowledge Gaps and Risk Rankings of Compounds, targets, classes, etc.

DHS Food Defense Efforts Ingestion Modeling – Food

Stock-and-Flow model incorporates

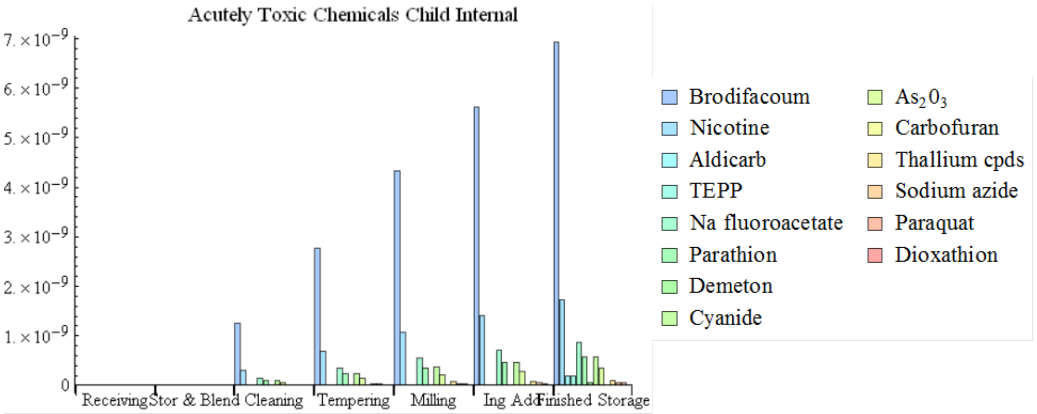
- **food processing and distribution for 11 exemplar foods representing thousands of food products**
- **CBR threat agent stability and effects;**
- **recalls and timing**



Provides high risk food scenarios for intentional contamination, vulnerabilities and critical knowledge gaps that can inform planning, preparedness, mitigation, response & recovery

Food Defense at Archer Daniels Midland

- ADM has a substantial Food Defense Program
- Active participant in the Food Ag Sector Coordinating Council and provided subject matter expertise for the CTRA Food Model Development
- Received SAIC designed Risk-Based Model in 2010 to aid Food Defense efforts
  - Agents Considered
    - Microbes (16)
    - Biological Toxins (16)
    - Acutely Toxic Chemicals (14)



Food Safety Modernization Act-Intentional Adulteration Rule

- FSMA enables FDA to better protect public health by strengthening the food safety system and focus more on preventing food safety/defense problems rather than relying primarily on reacting to problems after they occur.
- IA Rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply.
- Implement a written **Food Defense Plan that identifies vulnerabilities and actionable process steps, mitigation strategies**, and procedures for food defense monitoring, corrective actions and verification.

FDA FOOD SAFETY MODERNIZATION ACT

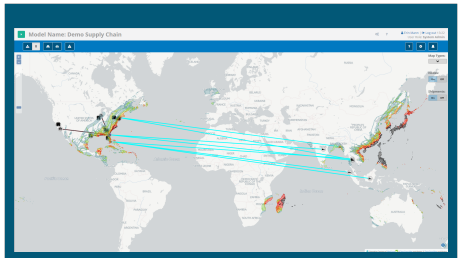
THE FUTURE IS NOW

- **Proposed rule was issued in December 2013 and Final Rule was published in May 2016**
- **3-5 years phased compliance**

The Food Protection and Defense Institute (FPDI)

DHS Emeritus Center of Excellence Established in 2004 at the University of Minnesota

FPDI Product Lines



RESEARCH

Exploratory, Basic, and Applied Research by Themes

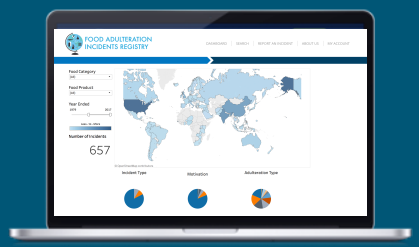
- » *Predictive Analytics*
- » *Supply Chain Resiliency*
- » *Intentional Adulteration*
- » *Information Sharing*
- » *Consortium Building*

EDUCATION

Education and training for students & professionals both domestic and international

Credit and Non-Credit Offerings Delivered Through

- » *Classrooms*
- » *Online Courses*
- » *Seminars*
- » *Collaborative Exchanges*



INFORMATION TECHNOLOGY

IT development to transition research to end-users and maintain CoreSHIELD operations

- » *FIDES*
- » *CRISTAL*
- » *FAIR*
- » *FoodSHIELD*
- » *Laboratory Portals*
- » *Risk Assessments*

SERVICE DELIVERY

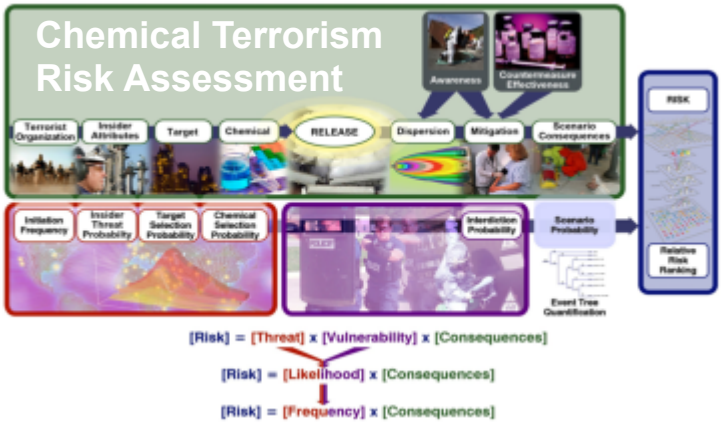
Delivery of service to advance the profession through though leadership and service projects

- » *Exercises*
- » *Consultation*
- » *Preparedness*
- » *Thought Leadership*
- » *Technical Reachback*

SUPPORT SERVICES

HR, Finance, Admin, Communication, Marketing

ADM & CSAC Cooperative Research and Development Agreement



- Originally signed September 2014, extended in March 2016 and in August of 2017.
- Collaboration in areas of Food Defense risk assessment and consequence estimation.
- Combine ADM's process risk modeling (FDRAP) with CSAC's public health consequences modeling (CTRA Food Defense Module).
- Provide a collaborative Food Defense Risk Assessment Tool which can be distributed to the U.S. Food & Ag Sector to aid meeting the IA rule requirements and decreasing enterprise risk.

Evolution of Food Defense – Joint

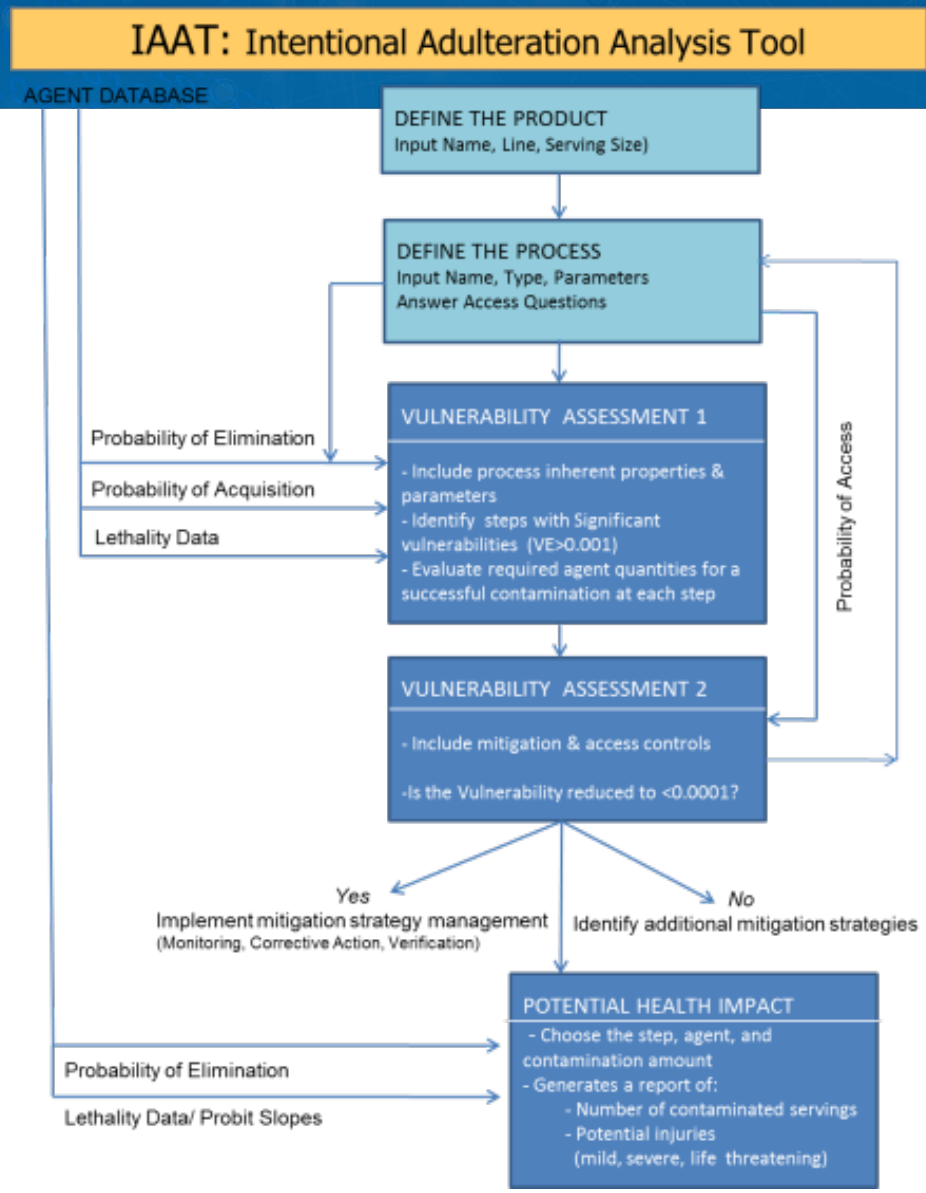
- Alignment of existing ADM Model with existing DHS Programs
  - CTRA – chemicals
  - BTRA – biological agents (bacteria, viruses and toxins)
- Incorporate requirements of the May 27, 2016 FSMA Rule
  - Consider Risk vs. Vulnerability
- Retain the ADM in-process vulnerability focus
- Generate a stand-alone, laptop-based Intentional Adulteration Assessment Tool that is applicable to a variety of food production processes
- Calculate the inherent and mitigated vulnerability of a process from the manufacturing facility incoming raw materials until the packaging of the final product.
- Intentional Adulteration Assessment Tool (**IAAT**) software coding, web hosting and download support from FPDI, U. Minnesota.

Food Protection and Defense Institute
A Homeland Security Center of Excellence

Technology Developed and Transferred to Address this Problem and Positive Outcomes

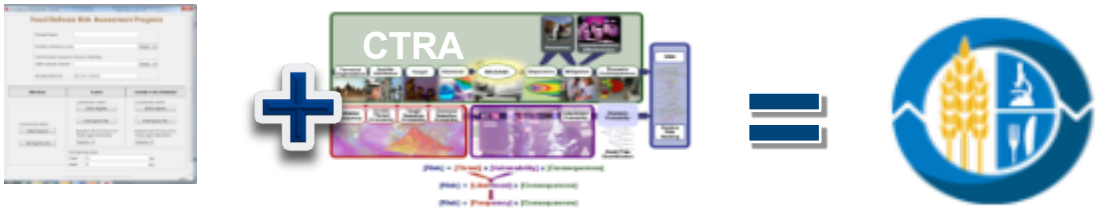
Intentional Adulteration Assessment Tool

- Software tool for risk-based decisions:
  - Identify vulnerabilities
  - Calculate risk
  - Calculate the effect of the mitigation
  - Inform Food Defense Plan and Mitigation Strategies
- Downloaded from FoodShield; run on a stand-alone computer so industry proprietary info is protected
- Intended for a variety of processes within the food sector
- Customizable by the user



Details of the IAAT

- Vulnerable = open to attack or damage
- Risk = Threat x Vulnerability x Consequences
- Risk Estimate = pAq x pAc x $(1\text{-}pElim_{n-(n-2)})$ x $(1\text{-}pElim_{n-(n-3)})$ x ... x$(1\text{-}pElim_{n})$
- **pAq = probability of acquisition of the agent**
  - From CTRA for chemicals
  - Considers commercial availability of the chemical plus prior use
- **pAc = probability of access**
  - = 1 in the default, total vulnerability state ("inherent")
  - Changed to give a risk estimate after the mitigation (doors, locks etc.) is considered
- **pElim = probability of elimination**
  - Will the agent be destroyed by heat, removed by filtering etc.
  - Need agent-specific and process-specific data in order to calculate this
    - Process Steps and data are entered by the user
    - The agent data are built into the software



IAAT Embedded Threat Agents

Metallic compounds
Arsenic Trioxide
Mercuric Chloride
Osmium Tetroxide
Thallium Sulfate
Vanadium Pentoxide

Microbes
Y Pestis
V Cholerae
Hepatitis A
C norovirus
L monocytogenes
Brucella ssp

Toxins
Anatoxin
Picrotoxin
Ricin
Saxitoxin
SEB
Aflatoxin

Acids & Alkalis
Aqueous Ammonia
Nitric Acid
Hydrofluoric Acid

Opioids

Other
4-Aminopyridine
Brodifacoum
Cyanides
Methyl Hydrazine
Sodium Fluoroacetate
Sodium Azide
Nicotine
Strychnine

Cholinergic

Organophosphorus Pesticides
Chloropyrifos
Disulfoton
Methamidophos
Parathion
Phorate
Phosphamidon

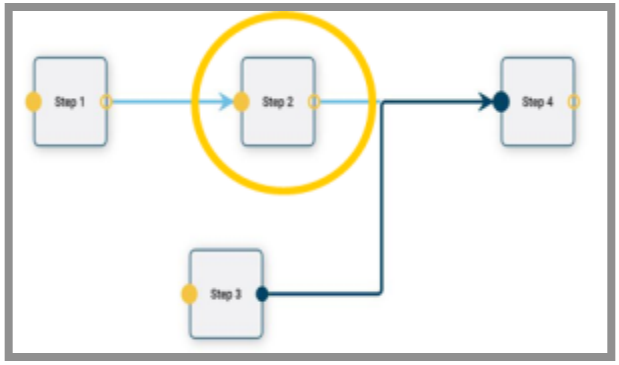
Nerve Agents
GA
GB
GD
VX

Carbamate Pesticides
Aldicarb
Methomyl

The Tool has embedded properties for ~50 threat agents; expandable if needed

Data Used by The IAAT

- Each Process is defined as series of steps:
  - a) access
  - b) effect



Processing Parameters – from the USER
Never seen by FPDI or the web

- Temperature
- pH
- Aw
- Centrifugation
- Mass-balance reduction

Microbes Data – from BTRA

-Thermal Death Temperature
-Aw (death?)
-pH
-Spore or Vegetative

Toxic Chemicals & Natural Toxins – from CTRA and BTRA

- LD_{50}, LD_1 and probit slopes
- Thermal denaturation
- Water solubility

IAAT Outputs

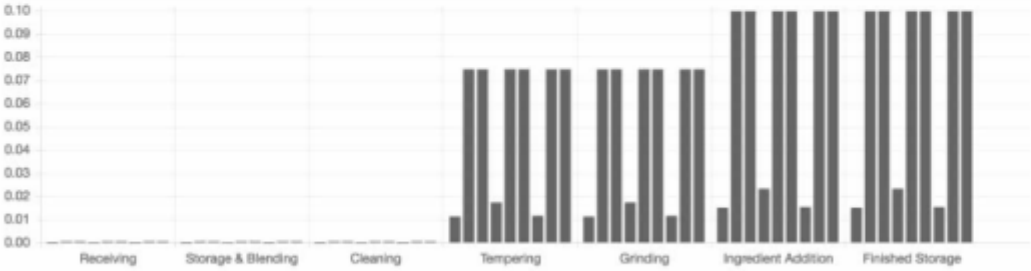
- Prepares a Vulnerability Assessment which satisfies the IA Rule
  - Size of Contamination Risk (number of packages, servings impacted)
  - Potential Public Health Impact (mild, severe, life-threatening injuries)
  - Likelihood of a successful contamination
- Process Risk Estimates
- Provides Food Defense Professionals a basis to seek funds for changes that reduce vulnerabilities

IAAT

Vulnerability Assessment 1

Internal Aggressor (no mitigation steps included)

Receiving	Storage & Blending	Cleaning	Temp
0.000114	0.000114	0.000116	0.011
0.000758	0.000758	0.000758	0.075
0.000758	0.000758	0.000758	0.075
0.000178	0.000178	0.000178	0.017
0.000758	0.000758	0.000758	0.075
0.000758	0.000758	0.000758	0.075
0.000119	0.000119	0.000119	0.011
0.000758	0.000758	0.000758	0.075
0.000758	0.000758	0.000758	0.075



Outcome of This Technology Transfer

- Developed a software tool informed by government, industry and academia that provides a quantitative assessment of the vulnerability of food products for intentional contamination.
- Successfully transitioned this tool to Industry to utilize and help meet the FSMA Intentional Adulteration Rule Requirements.
- The CRADA with industry and the contract with FPDI were critical for this transition. The collaboration in Food Defense with ADM and FPDI is ongoing as all parties see the continued benefits of the work.
- This technology transfer has impacted food defense and enabled the food industry to protect our food supply through risk informed decisions.
- This technology development and transition was a success that has reduced the vulnerability of an intentional adulteration so they American Public can enjoy a safe and protected food supply!

For More Information

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  410-417-0910

- CSAC HSDN Website*
  http://www.csac.dhs.sgov.gov/
  * All published reports and presentations available for download

Homeland Security

Science and Technology

References

- American Chemical Society, CAS Registry 21 April 2016. Retrieved from https://www.cas.org/
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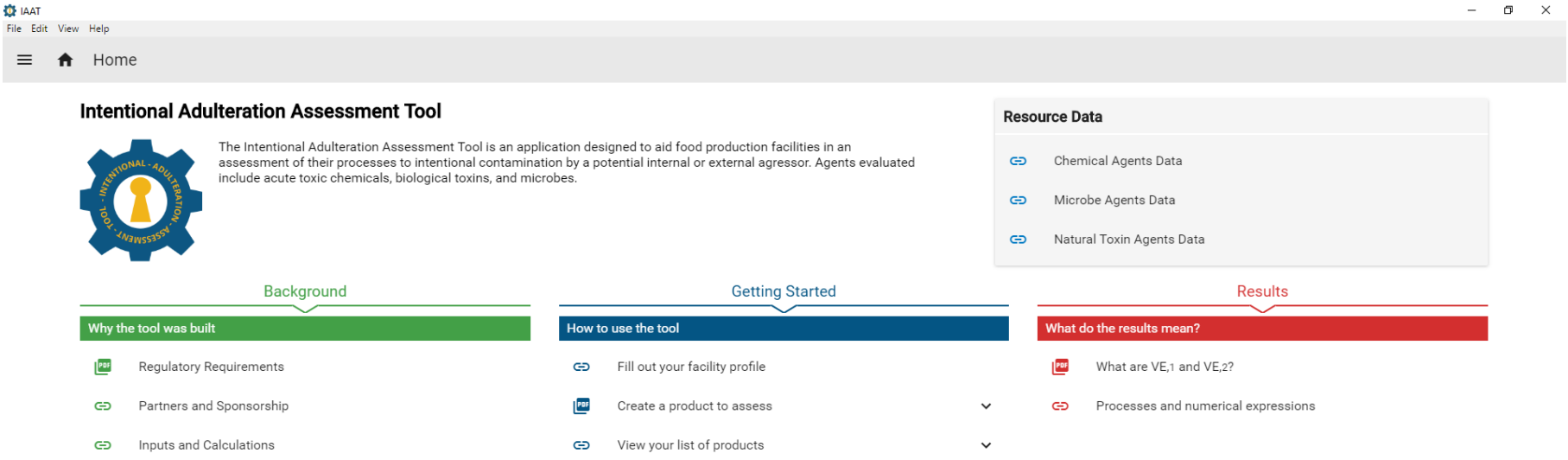
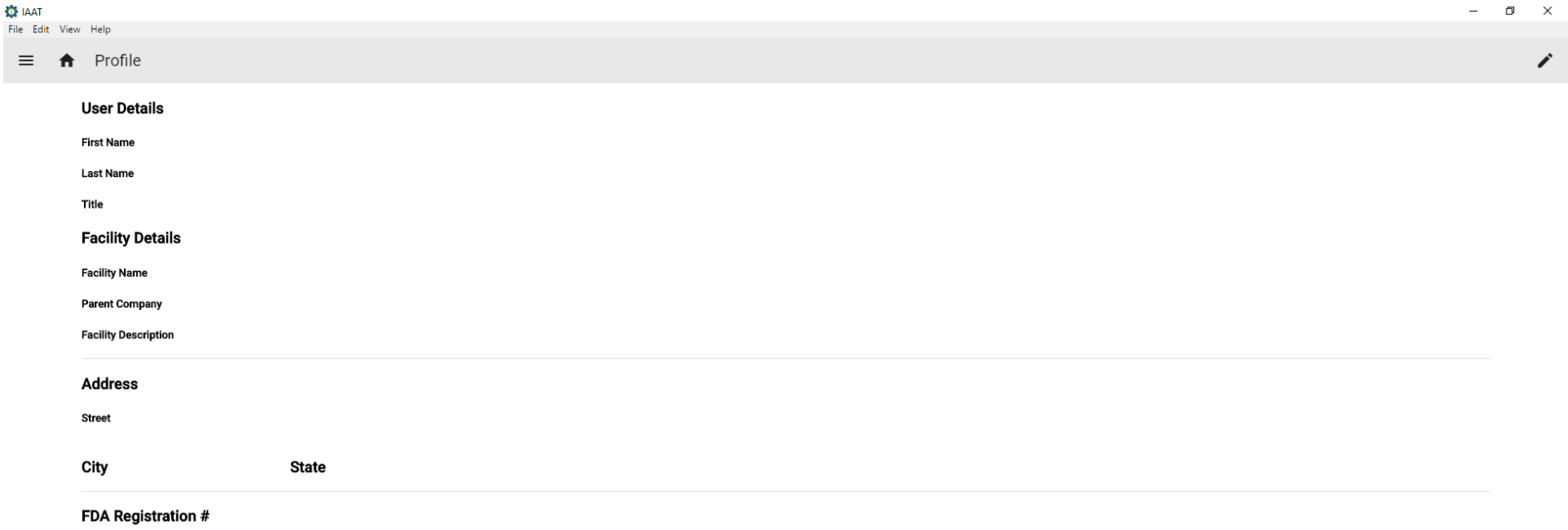
- Environmental Protection Agency. Toxic Substances Control Act (TSCA). Retrieved from https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory#whatdoesitmean
- FEMA. Threat Hazard Identification and Risk Assessment (THIRA) 26 June 2017. Retrieved from https://www.fema.gov/threat-and-hazard-identification-and-risk-assessment
- National Consortium for the Study of Terrorism and Responses to Terrorism (START). (2013). Global Terrorism Database 21 April 2016. Retrieved from http://www.start.umd.edu/gtd
- FSMA Intentional Contamination Final Rule. 21 CFR 121.130(c) May 26, 2016.

IAAT Home Page



Registration Page



IAAT Product List:

- List can be sorted and searched.
- Can delete a product, create a product, copy a product, and download a *json file of the product

Create a new product in the IAAT

Create New Product

Product Name *

Process Line *

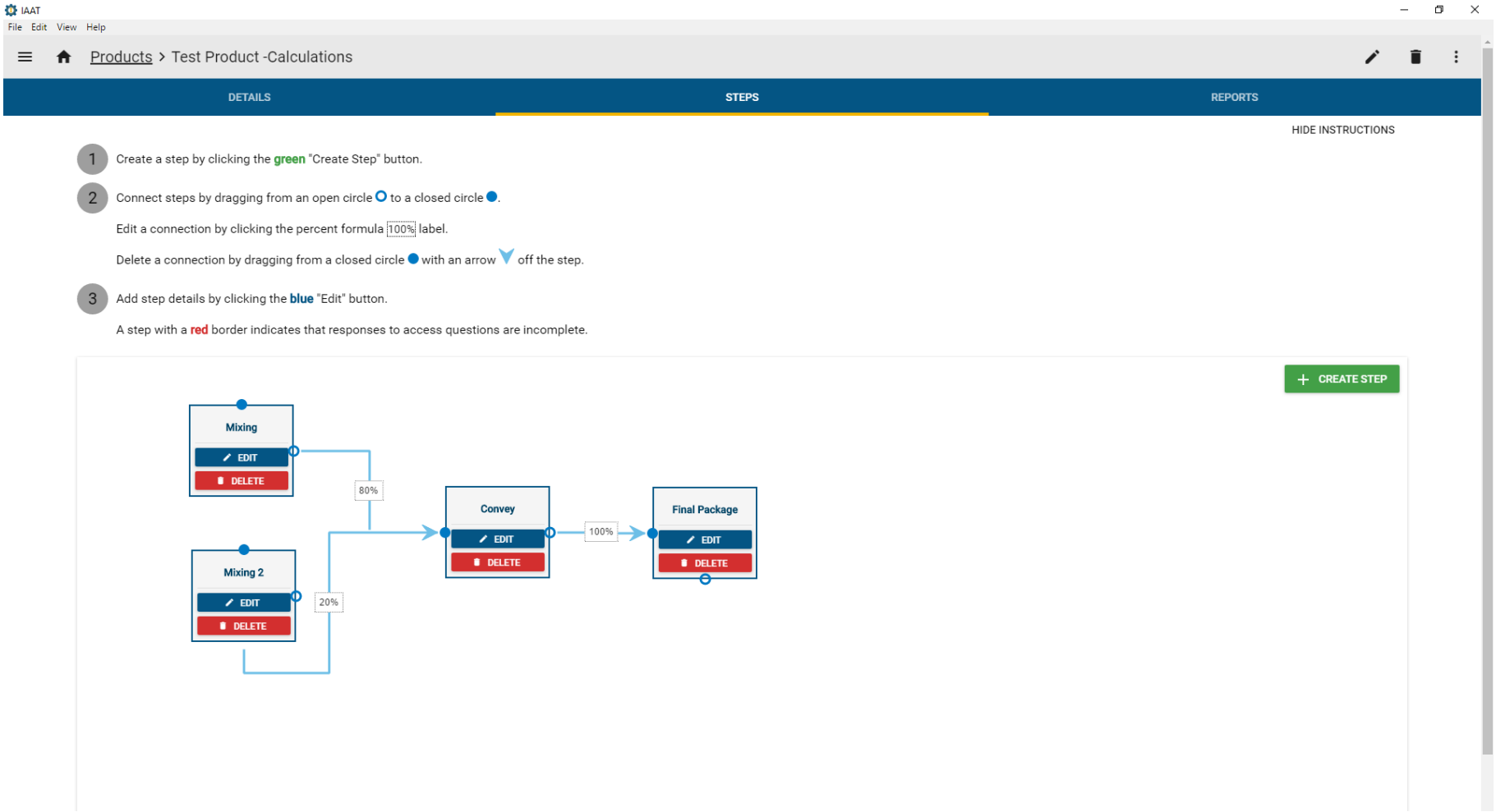
Serving Size (g) *

Product Description

* Denotes required field

CANCEL SAVE

IAAT Example Steps and Process



IAAT Step Wizard: Details

IAAT

File Edit View Help

Mixing Edit Wizard

SAVE

1 Details — 2 Access — 3 Elimination — 4 Review

Enter all information that you have. Not all fields are required.

Details

Step Name *

Mixing

Batch or Continuous

- (●) Batch
- ( ) Continuous

Batch Size

This field is only required for the final step.

Minimum Mass (kg)

Step Type

Choose all that apply.

- [ ] Cleaning
  Washing produce, Not equipment sanitation
- [ ] Drying
  Freeze Dryer, Spray Dryer
- [ ] Heating
  Cook kettle, Pasteurizer, Oven
- [ ] Ingredient Addition
  Chocolate chip addition, Seasoning addition
- [ ] Package / Fill
  Wrapper, Liquid filler
- [ ] Transfer
  Conveyor belt, Pump
- [ ] Cool
  Cooling tunnel, Refrigerator
- [ ] Freeze
  Spiral freezer, Walk-in freezer
- [ ] Hold / Storage
  Bulk tank, Surge tank
- [x] Mix / Blend / Homogenize
  Ribbon blender, Extruder, Mixer
- [ ] Separation
  Distillation, Filtration
- [ ] Other

* Denotes required field

NEXT >

IAAT Step Wizard: Access

IAAT

File Edit View Help

Mixing Edit Wizard

SAVE

1 Details — 2 Access — 3 Elimination — 4 Review

This section asks questions about access to the process step. All questions are required to calculate the Probability of Access for this process step.

Copy responses from another step

Is it impossible to add a contaminant to this process step while in operation?

Examples: operates under pressure or vacuum, sealed, etc.

- ○ Yes
- ◉ No

Is this process step outside?

Examples: grain dump pit, storage tanks, loadout, etc.

- ○ Yes
- ◉ No

Are the building's external entrances/exits continuously access controlled?

Examples: card swipe, locks, etc.

- ◉ Yes
- ○ No

How many hours per day is this process step in operation?

Hours (0.01-24) *

20

How many hours per day is this process step in operation with no employees present?

Hours (0-24) *

10

* Denotes required field

BACK

NEXT

IAAT Step Wizard: Elimination

IAAT

File Edit View Help

Mixing Edit Wizard

SAVE

1 Details — 2 Access — 3 Elimination — 4 Review

This section collects details about the process step that may result in elimination of agents. All fields are optional.

Some fields are hidden based on the selected step types. SHOW ALL FIELDS

Maximum Temperature

Degrees Celsius *

25

Minimum pH

pH (0-14)

Maximum pH

pH (0-14)

Mass Reduction

Total mass reductions as caused by physical filtration, traditional filtration, dry cleaning, sorting/grading, non-evaporative dewatering, etc.

Percent (0-99.9)

* Denotes required field

BACK

NEXT

IAAT Step Wizard: pElim and pAccess Review

IAAT

File Edit View Help

Mixing Edit Wizard

SAVE

1 Details — 2 Access — 3 Elimination — 4 Review

Probability of Access

The probability that an individual could gain access to a point in the process at which a contaminant could be added. The model assesses a pAc value for both internal (pAc,int) and external aggressors (pAc,ext). pAc values are calculated for each process step based on the accessibility questions.

Scenario	pAc
Internal (no mitigation)	0.833
External (no mitigation)	0.833
Internal	0.000133
External	0.000001

Probability of Elimination

The probability that an agent, after having been added to the process, will be reduced by the processing parameters it will encounter. Examples of processing that could reduce the level of an agent include denaturation of a toxic with heat, inactivation of the microbe with heat, or physical removal through cleaning.

Chemicals

Chemical	pElim
Aniline	0
Fentanyl	0
Carfentanil	0
2-Fluoroethanol	0
3-Quinuclidinyl benzilate (BZ)	0
4-Aminopyridine	0
Acrolein (Acrylaldehyde)	0
Adamsite (Diphenylaminechloroarsine, DM)	0

IAAT Reports

IAAT

File Edit View Help

Products > Test Product -Calculations

DETAILS | STEPS | REPORTS

Process Summary

A grid view of the process step data and calculated probability of access values for each step.

RUN REPORT

VE,1 Assessment

A complete assessment of all VE,1 calculations for each Step/Agent combination.

RUN REPORT

VE,1 Summary

Summary of Step/Agent combinations that have a VE,1 that indicates a significant risk. Output is the same as VE,1 Assessment, but only Step/Agent combinations with VE,1 > 0.001 are reported.

RUN REPORT

VE,2 Assessment

A complete assessment of all VE,2 calculations for each Step/Agent combination.

RUN REPORT

VE,2 Summary

Summary of Step/Agent combinations that have a VE,2 that indicates a significant risk. Output is the same as VE,2 Assessment, but only Step/Agent combinations with VE,2 > 0.0001 are reported.

RUN REPORT

Public Health Impact Report

Define a intentional adulteration scenario and generate a report of the potential number and type of injuries based on the agent type, contamination step, and contamination amount.

RUN REPORT

IAAT Example Process Summary Chart

Test Product -Calculations Process Summary

Process Summary

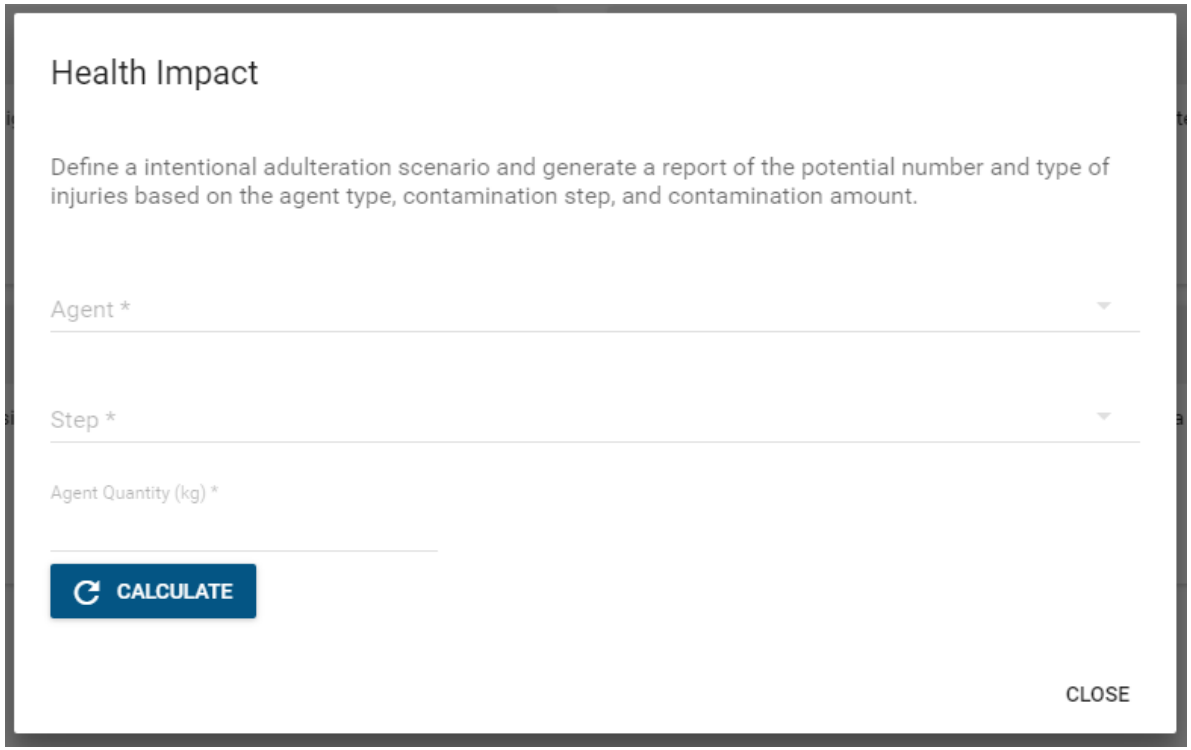
Product Name: Test Product -Calculations

Process Line: 1

Serving Size: 100(g)

	Mixing 2	Mixing	Convey	Final Package
Batch or Continuous	Batch	Batch	Batch	Batch
Batch Size (kg)				3000
Production Rate (kg/hr)				
Production Run Time (hr)				
Types	Mix Blend Homogenize	Mix Blen Homogenize, Mix Blend Homogenize	Transfer, Heating	Package Fill
Process Parameters				
% Mass Balance Reduction				0
% Product Formula	20	80	100	100
Temperature (C)			100	25
pH (min)				
pH (max)				
Accessibility				
Closed	No	No	Yes	No
pAc, int (no mitigation)	0.833	0.833	0.000001	0.833
pAc, ext (no mitigation)	0.833	0.833	0.000001	0.833
pAc, int	0.000133	0.000133	0.000001	0.000133
pAc, ext	0.000001	0.000001	0.000001	0.000001

IAAT Public Health Impact Entry



Reports # of potential serving contaminated

For ATC:
Reports probability and people impacted
- Life Threatening
- Severe
- Mild

For Toxins and Microbes:
Reports if the scenario is > ID or
LD1, LD50 values

FSMA Final Requirements

- Written food defense plan that includes:
  - **Vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps***
  - Mitigation strategies, including required explanations
- Food defense monitoring procedures
- Food defense corrective actions procedures
- Food defense verification procedures
- Training and qualifications of supervisors and personnel
- Records to be prepared and kept:
  - **Vulnerability assessment to identify significant vulnerabilities and actionable process steps****
  - For each point, step, or procedure in the facility's operation, you must evaluate:
    - **The severity and scale of the potential impact on public health, if a contaminant were added**
    - **The degree of physical access to the product**
    - **The ability of an attacker to successfully contaminate the product**
    - **Mitigation strategies for actionable process steps- Identify and implement mitigation strategies at each actionable process step to significantly minimize vulnerabilities, and include a written explanation of how the strategy minimizes the vulnerability.**

(U) Chemicals of Concern for Food Targets

4-Aminopyridine	Methyl Acylonitrile	Thallium Sulfate
Aldicarb	Phorate	Vanadium Pentoxide
Arsenic Trioxide	Phosphamidon	VX and other CWAs
Disulfoton	Picrotoxin	
Fentanyl	Potassium Cyanide	
Mercuric Chloride	Sodium Azide	
Methamidophos	TEPP	
Methomyl	TETS	

CTRA 4.0 Exemplar Food Scenarios

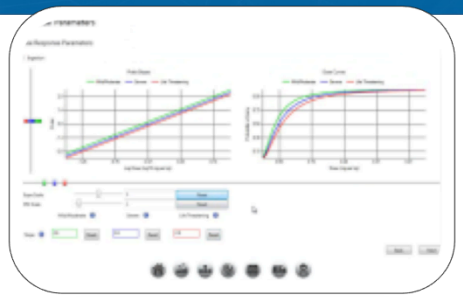
Food Cluster	Example Food Products	Point(s) of Contamination
Multi-component assembled foods, thermally processed in the home	Frozen meat pizza, flavored rice, soup	2
Packaged, processed, cold chain RTE	Processed cheese, margarine, lunch kits	1
Assembled companion dishes	Bagged Leaf salad, fruit salad, pickles, potato salad	2
Main dishes, single component foods	Ground beef, turkey, beef, pork	2
Produce	Grapes, nuts, eggs, fruits, vegetables	2

Food Cluster	Example Food Products	Point(s) of Contamination
Multi-component assembled foods, not thermally processed in the home	Seasoned snacks, Baby food, cookies, crackers, gelatin	2
Ready to eat, primary component foods	Fluid milk, lunch meat, hot dogs	3
Beverages	Apple Juice, Fruit juices, soda, water	2
Industrial ingredients	Liquid eggs, spices, additives	2
Home ingredients	Pasta sauce, flour, sugar, salt, oils	1

Consequence Module

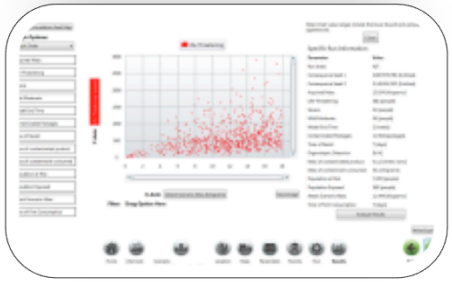
Scenario Selection & Modeling Interface

- Interface for users to adjust the CTRA scenario input parameters
  - Agent and Target Selection- 37 targets with multiple contamination points
  - Scenario Specific Parameters- Pt values or ranges for a wide range of variables
  - Medical Mitigation Parameters- CM quantities, efficacies, etc.
  - Agent Specific Parameters- Toxicity & chemical properties
  - Mass- Specific or uniform distribution
  - Run- Millisecond runt time allows real time focused follow-up studies



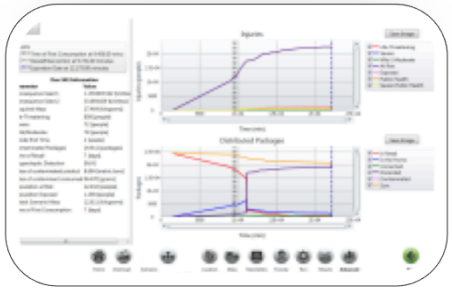
Results Interface

- Interface for users to analyze data graphically and numerically
  - Pie, Histogram and Scatterplot Outputs
  - Data Filtering
  - Correlation Heat Mapping
  - Excel Export of data and images



Advanced Analytics

- Interface for users to do in depth time resolved analysis for a single simulation to analyze critical points along the scenario timeline
  - Event Trigger times recorded and outputted
    - Awareness, Stop Entry, Evacuation, 1st Consumption, Recall, etc.
  - Animated Injury Tracking
  - Variables by time graphs- injuries, packages, concentration, etc.



This module allows the analysis of pertinent consequence parameters for any given scenario to examine the impact of individual parameters on consequence results .

Frequency Module

Adversary Characteristics Module

- Interface for users to adjust the characteristics of adversaries (terrorists)
  - Group Type – Individual/Small Group, Domestic, International
  - Financial Backing – Low, Medium, High, Very High
  - Technical Capability – Low, Medium, High
  - Operational Capacity – Low, Medium, High
- Status: Draft Completed

Results Module

- Interface for users to explore and parse CTRA 4.0 (and sensitivity study) results
  - View and manipulate graphs that display the user-desired information
  - Graph types include: Doughnut, Side by Side Bar, Stacked Bar, Treemap, Box and Whisker
- Status: Draft Completed

Adversary Decision and Interdiction Modules

- Interface for users to adjust threat parameters associated with the adversary decision model and vulnerability parameters associated with the interdiction models
- Status: In Progress

This module allows the analysis of pertinent frequency parameters for any given scenario, revise event tree inputs and examine the impact of individual event tree levels on frequency results .

Risk Module

- Provides the ability to view the impacts of frequency and consequences on the risk in an interactive fashion
- Allows for customizable graphical display of risk data
- Integrates the frequency and consequence modules to allow for targeted risk analysis and visualization

CTRA Desktop Risk Suite