

FOOD DEFENSE

John Larkin, PhD

Research Director,
Food Protection and Defense Institute

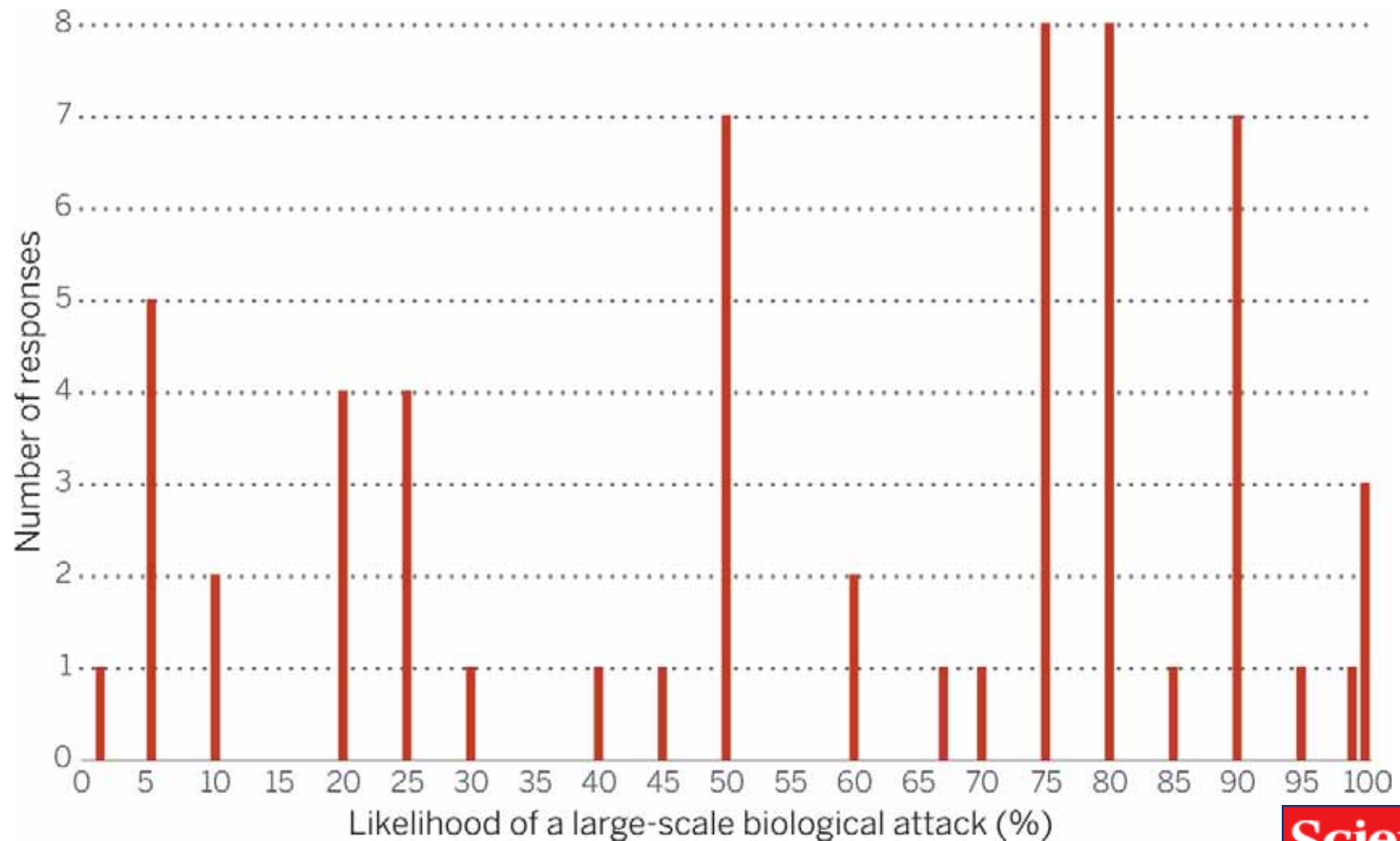


Assessing the Bioweapons Threat

- **Likelihood of large-scale biological weapons attack within the next 10 years?**
 - 1 to 100% likelihood, with a mean of 57.5%
 - Overt state bioweapons use considered less likely than covert use by state or by nonstate group
 - Religious extremists judged most likely to perpetrate attack, followed by rightwing violent nonstate actor or disgruntled or mentally ill individual

(Science, August 2015)

Likelihood of attack.



Crystal Boddie et al. Science 2015;349:792-793

Published by AAAS



Assessing the Bioweapons Threat

- **Probability that intelligence information will provide actionable indications and warning preceding the attack?**
 - Most believed intelligence agencies are unlikely to provide actionable information or warnings before a biological attack
 - Realities of classification of information make a fully informed analysis of biological threat impossible—a fact that several participants acknowledged

(Science, August 2015)

SECURITY, SAFETY, AND DEFENSE

FOOD CONTINUUM PARADIGM

Food Security: Supply sufficiency –
access to nutritionally adequate and
safe food

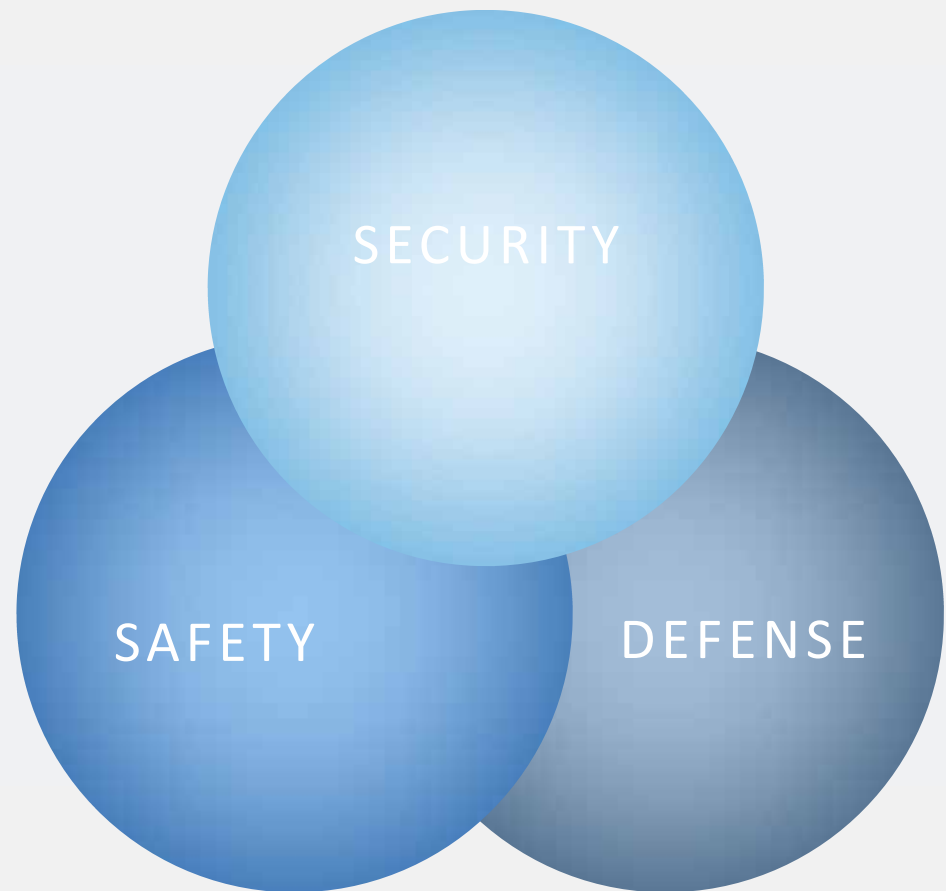
Food Safety: System reliability –
reducing exposure to natural
hazards/errors/failures

Food Defense: System resiliency –
reducing the impact of system attacks

Food Quality: Supply desirability

Food Protection: Safety & Defense
continuum

FOOD SYSTEM PROTECTION



FOOD SAFETY

System Failure
Microbial & Chemical Agents
Known Agents
Low levels/ concentration
Reasonably Likely
FDA / USDA enforcement
Regulation exists

VS

FOOD DEFENSE

System Attack
Microbial & Chemical Agents
Unexpected Agents
High levels/ concentration
Unlikely
Criminal investigation
Recent regulation put in place

CHALLENGING TO KNOW WHY
FOOD WENT BAD

How do we know what happened?

NOVEL STRAIN OF
E. COLI O104:H4
BACTERIA RESULTS IN
BLOODY DIARRHEA
WITH HEMOLYTIC-
UREMIC SYNDROME
(HUS)

751 PEOPLE AFFECTED
WITH SALMONELLA
TYPHIMURIUM
RELATED TO EATING
AT SALAD BARS

600 DEATHS OF
PATIENTS ADMITTED
WITH PNEUMONIA
SYMPTOMS

How do we know what happened?

NATURAL

NOVEL STRAIN OF
E. COLI O104:H4
BACTERIA RESULTS IN
BLOODY DIARRHEA
WITH HEMOLYTIC-
UREMIC SYNDROME
(HUS)

TERRORISM

751 PEOPLE AFFECTED
WITH SALMONELLA
TYPHIMURIUM
RELATED TO EATING
AT SALAD BARS

ECONOMICALLY MOTIVATED ADULTERATION

600 DEATHS OF
PATIENTS ADMITTED
WITH PNEUMONIA
SYMPTOMS

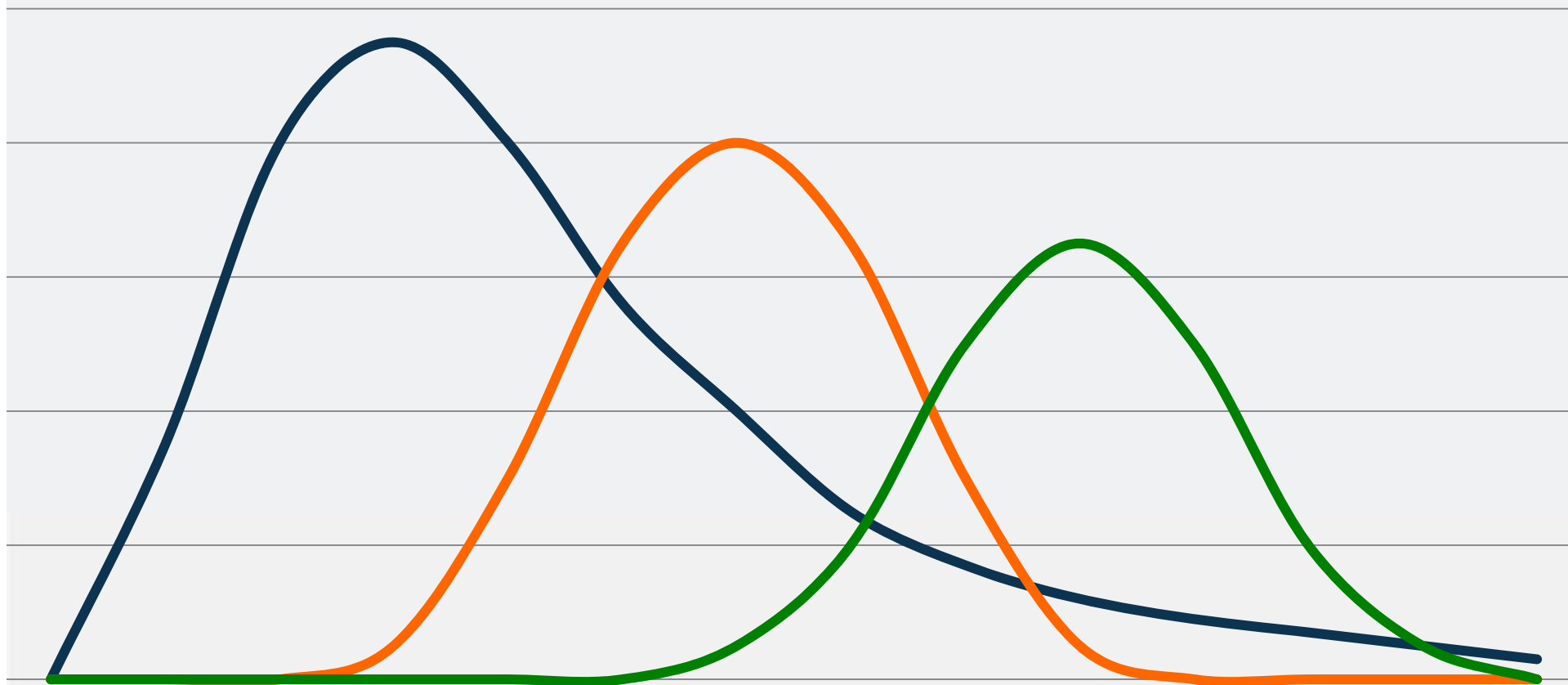
When did it happen?

Food Event Identification Timing Considerations

— Consumption

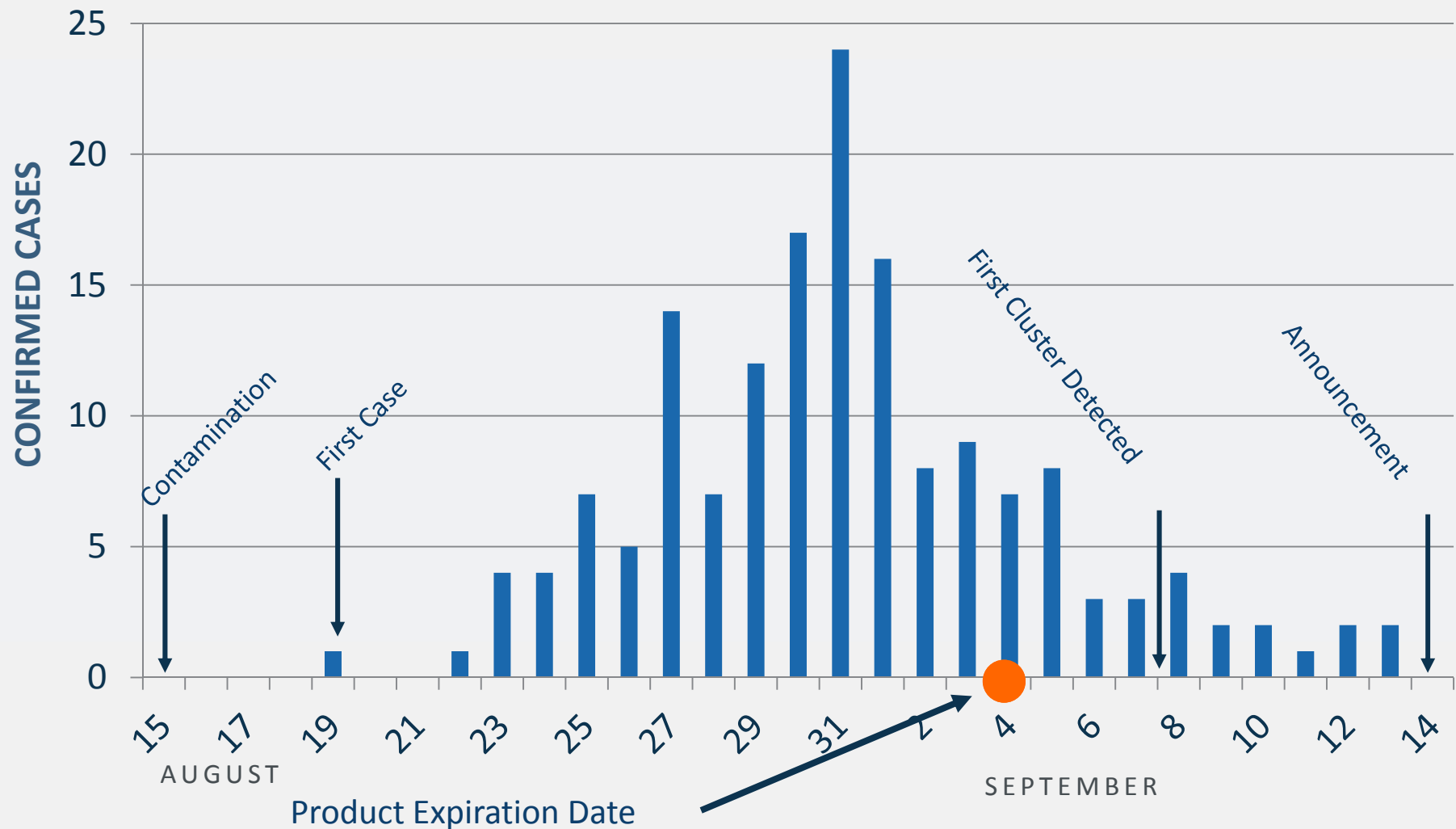
— Illness Presentation

— PH Recognition

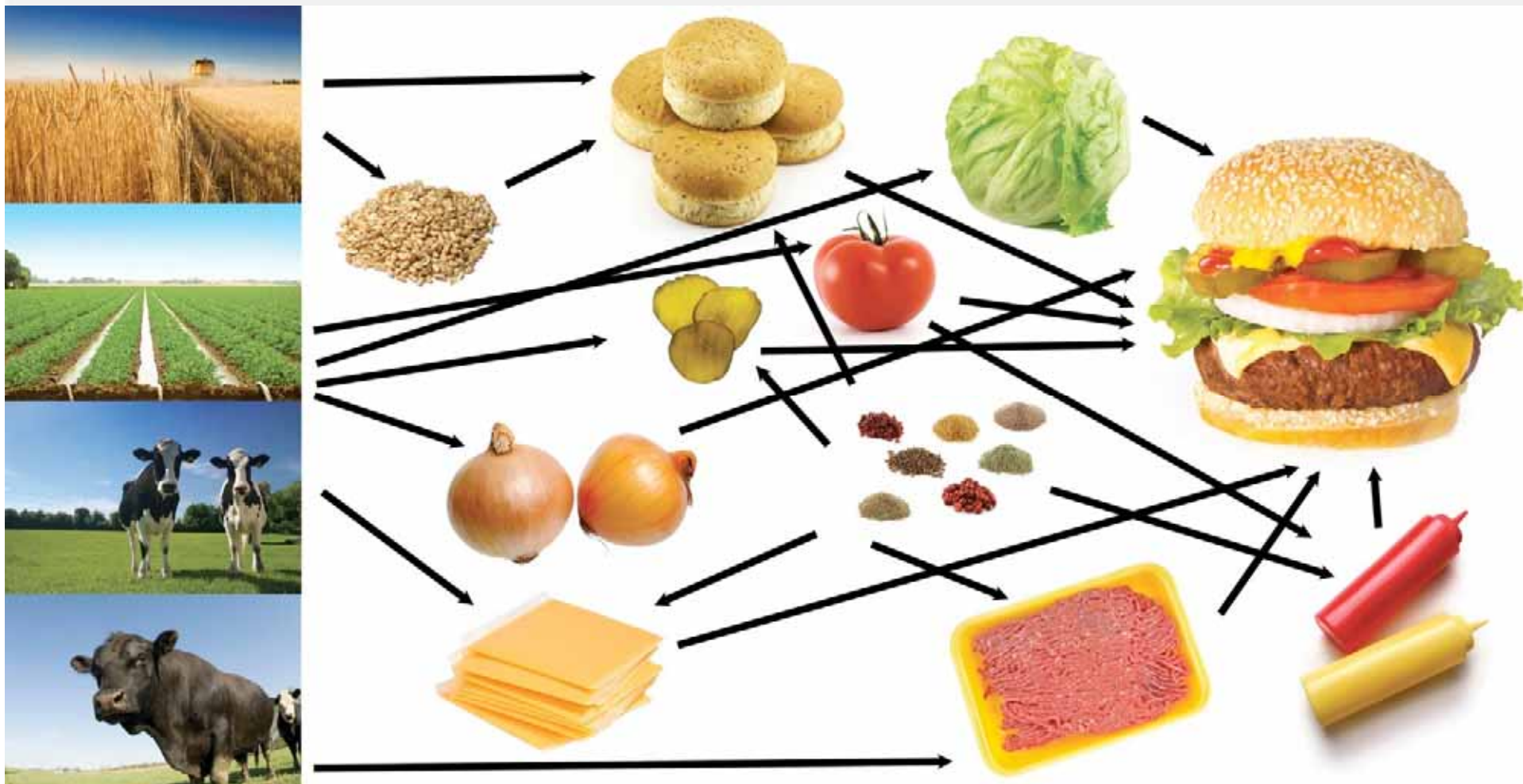


Challenges of Event Detection

Spinach E. coli 0157:h7 Contamination



The Supply Challenge

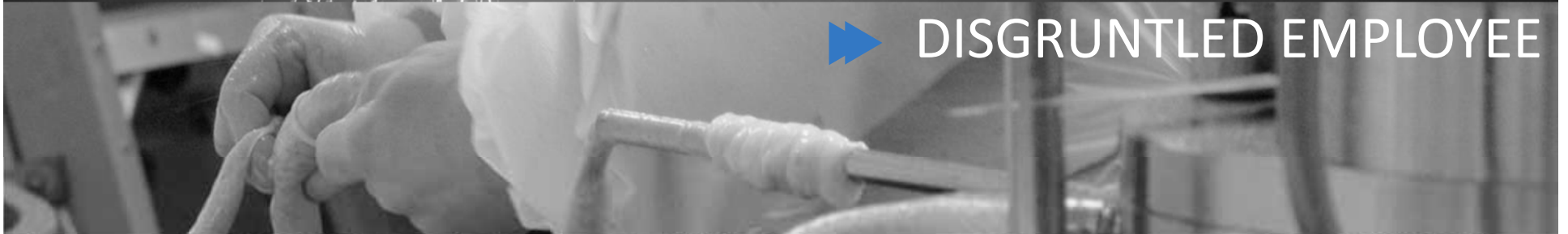




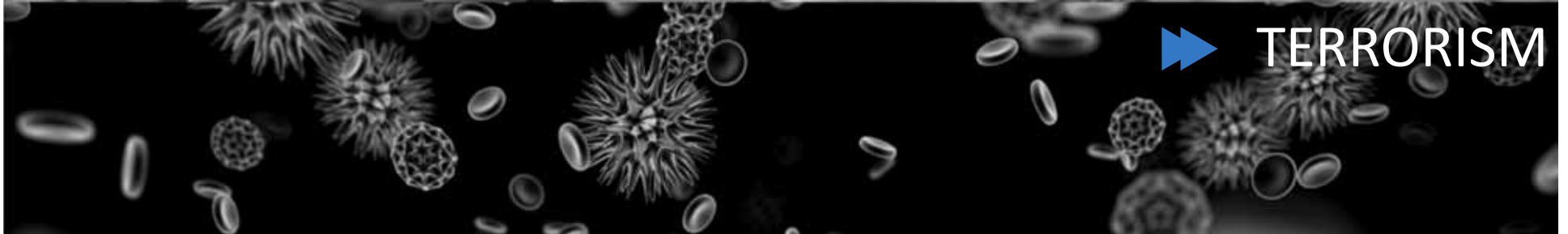
ACCIDENTS



MOTHER NATURE



▶ DISGRUNTLED EMPLOYEE



▶ TERRORISM



▶ ECONOMICALLY MOTIVATED ADULTERATION



Intentional Contamination History

Historical Military Weapon (Troops/Civilians)

590 B.C.

Athenians use hellebore to poison wells and contaminate Kirrha's water supply

1937

WWII Japan in China/Manchuria with *Bacillus anthracis*, *Shigella* spp, *Vibrio cholerae*, *Salmonella paratyphi*, and *Yersinia pestis*

Terrorist/Criminal Acts in the U.S. and Abroad

1984

Rajneeshee cult members contaminate ten salad bars with *Salmonella enterica* Typhimurium in Dalles, Oregon (752 ill)

1996

Lab technician poisons 12 co-workers with *Shigella dysenteriae* laced pastries in Dallas, Texas

TERRORISM

INTENT

Terrorize

Create Fear

Disrupt Normal Way of
Living

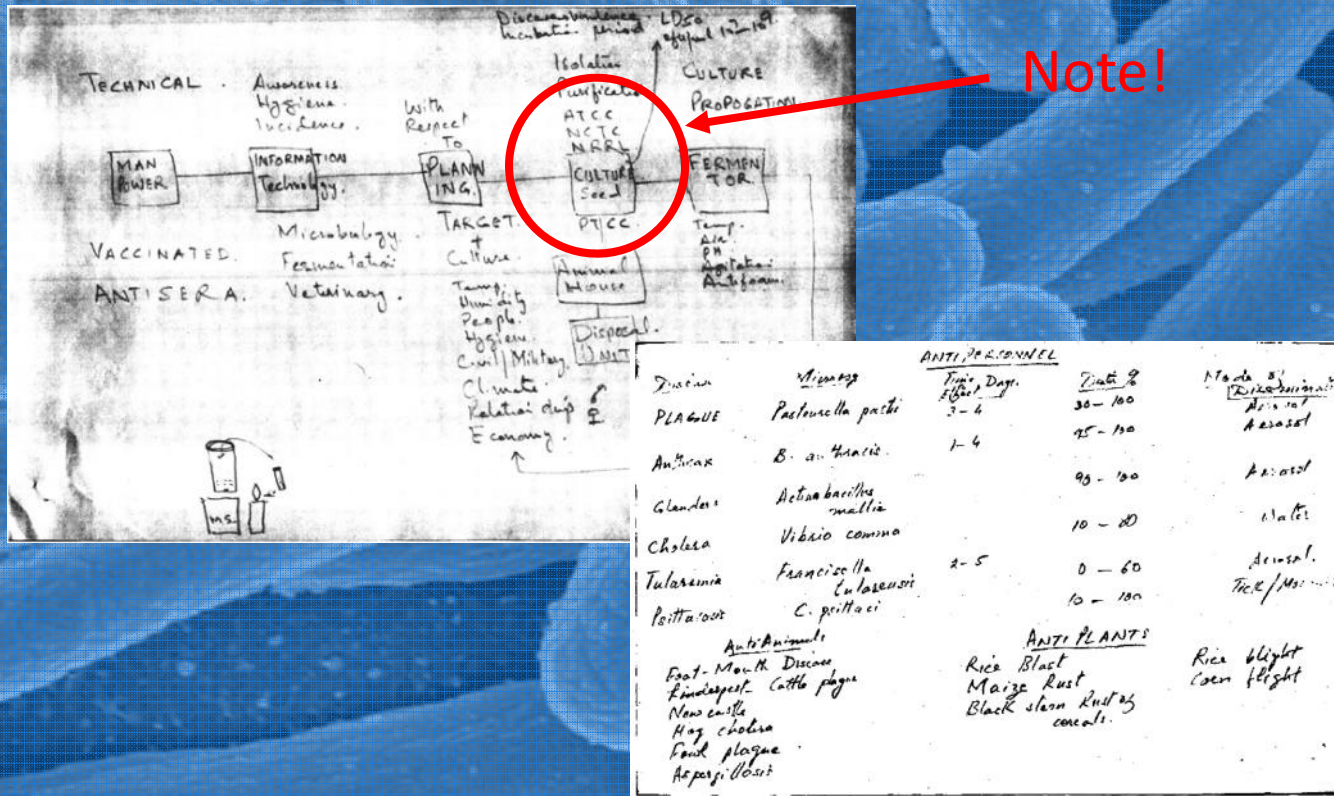
ISSUE

Existing Cells

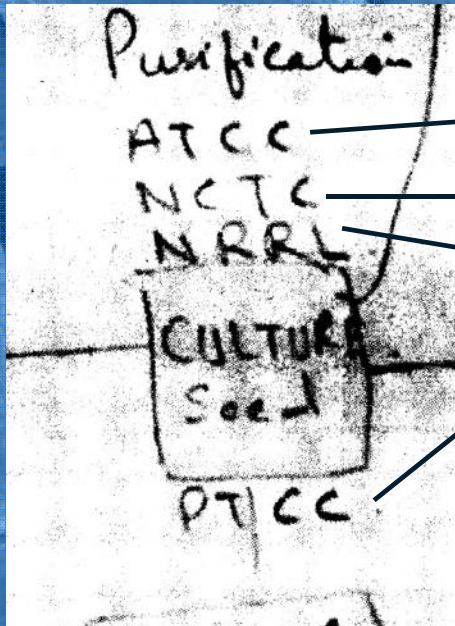
Have Considered Before

TERRORISM

Key Documents were seized by US forces from Al Qaeda camps in Afghanistan in 2002 Reference or Target Agriculture Sector



TERRORISM



American Type Culture Collection



National Collection of Type Cultures



Northern Regional Research Laboratory



Pakistan Type Culture Collection



NRRL is a USDA Facility

Facility Info on the Web!

Microbial Genomics and Bio-processing Research Unit
National Center for Agricultural Utilization Research
1815 N. University Street
Peoria, IL 61604USA
Telephone: (309) 681-6397 Fax: (309) 681-6672

TERRORISM

Threats Against the Food System Expressed in Propaganda Video

DailyMail.com, November 20, 2014

Abu Salman al-Faranci called for attacks, “poison is available, so poison the water and food of at least one of the enemies of Allah. Kill them and spit in their faces and run over them with your cars.”

DISGRUNTLED EMPLOYEES

INTENT

Brand Damage,
Attack Colleagues

ISSUE

Internal Access,
Familiar with Processes

DISGRUNTLED EMPLOYEES

OCTOBER–NOVEMBER, 2013, JAPAN

- Sprayed frozen pizzas, croquettes and pancakes with malathion pesticide
- 2,800 illnesses
- Recall of more than 6 million packages
- Sentenced to 3 ½ years in prison

Economically Motivated Adulteration

INTENT

Economic gain,
Intentional,
Not to be detected

ISSUE

Can be health hazard,
Can evade mitigation
steps



Economically Motivated Adulteration

Melamine was added to milk for fraudulent economic gain

- 2008-09 in China
- Melamine imitates protein in milk
- 300,000 illnesses, 6 deaths

Food Fraud Methods



Dilution
Partial replacement



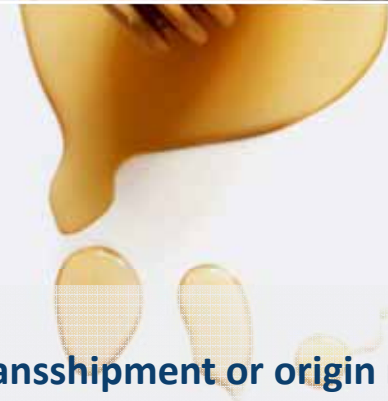
Substitution
Complete replacement



Artificial enhancement
Unapproved additives



Mislabeling
Quality, harvesting, processing



Transshipment or origin masking
Fraudulent geographic origin



Counterfeit
Fraudulent brand-name



Theft and resale
Re-introduction into commerce



Intentional distribution of a contaminated product
Unintentional contamination

FOOD SAFETY MODERNIZATION ACT - U.S. GOVERNMENT REGULATIONS

FOOD SAFETY MODERNIZATION ACT

Passed in 2011

Vulnerability assessment and mitigation strategies will be required for intentional adulteration

www.FDA.gov/FSMA



*PROPOSED RULES

Focused Mitigation strategies to Protect Food Against Intentional Adulteration	Final Rule Due May 2016
Foreign Supplier Verification	Final Rule Due October 2015
Preventive Controls for Human Food	Final Rule Issued
Preventive Controls for Animal Feed	Final Rule Issued
Standards for Produce Safety	Comments Closed December 2014
Accreditation of Third Party Auditors	Final Rule Due October 2015
Sanitary Transportation of Human and Animal Food	Final Rule Due March 2016

U.S. Preventive Control Rule (21 CFR part 117)

- Published September 17, 2015
- Requires food safety plans for all foods
- Preventive controls must be established for known or reasonably foreseeable hazards that have the potential to cause illness or harm
- Hazards that might be present in the food
 - Intentionally introduced for purposes of economic gain

U.S. 21 CFR part 117 subpart G

Supply-Chain Controls

- Must establish a risk-based supply-chain program for supply-chain controlled hazards (i.e., Economically Motivated Adulteration)
- Can only receive ingredients from approved suppliers
- Corrective actions must take place when a receiving facility finds out the supplier is not controlling the hazard

RESPONDING TO THE NEED FOR FOOD DEFENSE

FOOD DEFENSE PREPAREDNESS

Presidential Policy Directive 8

- 1.Prevent
- 2.Protect
- 3.Mitigate
- 4.Respond
- 5.Recover

A comprehensive food defense strategy includes all 5 frameworks

Food Defense Essentials

- Place high priority on breaking down the communication barriers
- Government must be the leader
- Investments are not temporary (sustainability)
- Need to build infrastructure
 - Government to Government (U.S. GCC)
 - Government to Academia
 - Government to Industry (U.S. SCC)

Prevent/Protect/Mitigate

- CARVER+Shock risk assessment tool
- U.S. FDA Defense Plan Builder
- U.S. FDA mitigation database
- Agent detection methods
 - Validated methods
 - Availability of supplies/kits
- National laboratory system (FERN)
 - Trained analysis
 - Data information sharing
- Monitoring program

Respond/Recover

- Develop a culture from Management to Employee
 - Assume it will happen
- Exercised your plan and people
 - Recall Plan
 - Emergency response plan
- Recovery will be to a “New Normalcy”

A man with a neutral expression is seated at a rustic, weathered wooden table. He is wearing a light gray, textured sweater. In his right hand, he holds a black-handled knife, and in his left hand, he holds a silver fork. On the table in front of him is a black, octagonal tray. The background is a solid, muted blue.

FPDI Tools & Capabilities



CRITICALITY SPATIAL ANALYSIS (CRISTAL) SOFTWARE PLATFORM

PURPOSE Supply chain documentation and risk assessment

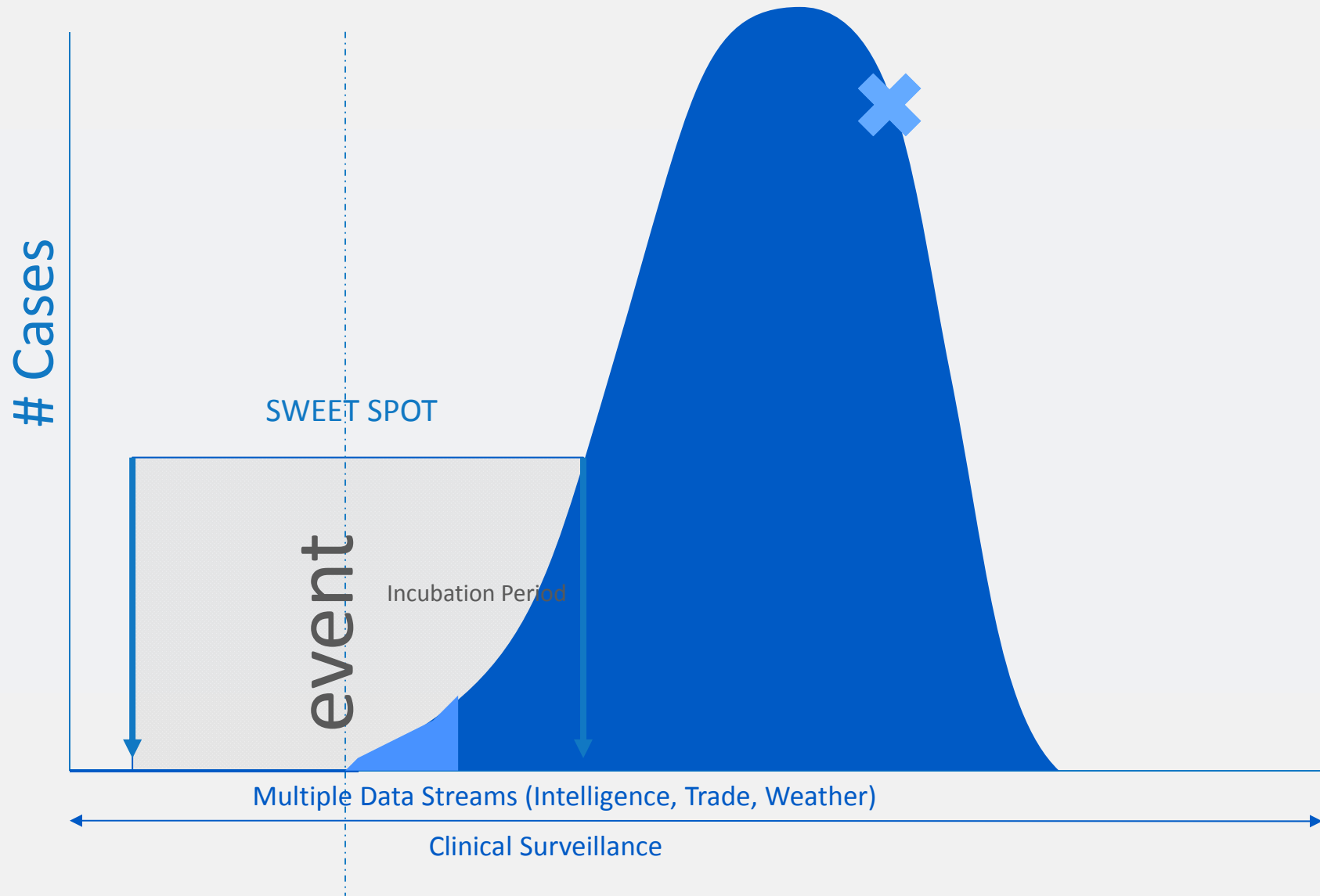
SPONSOR DHS funded project

USERS Private sector food companies

RELEASE DATE Winter 2015 (beta-testing)

CONTACT Tim Boyer
boye0087@umn.edu

Finding the Sweet Spot





ECONOMICALLY MOTIVATED ADULTERATION

PURPOSE Understand EMA and Build Capability to Mitigate

SPONSOR DHS funded project

USERS All food protection stakeholders

RELEASE DATE February 2013

CONTACT Karen Everstine
ever0152@umn.edu

“If you don't know where
you are going, you might
wind up someplace else.”
- **Yogi Berra**