



# Food Defense: How to Comply with FSMA's New Intentional Adulteration Rule

Speakers: John W. Larkin, Ph.D. & Holly Mockus  
August 17<sup>th</sup>, 2016



  
alchemy

# Today's Speakers



John W. Larkin, Ph.D.  
Research Director

Food Protection and Defense Institute

- Research areas include agent detection, supply chain, information sharing, risk analysis, and economically motivated adulteration
- 27 years of experience at FDA, managing research program on shelf-stable and extended shelf-life foods



Holly Mockus  
Food Industry Expert  
Alchemy



- 30+ years of experience in the food industry with companies including ConAgra, Kellogg, and Sara Lee
- Received 2013 SQF Outstanding Achievement Award and was named 2016 Food Logistics Champion



# Agenda

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- The Threat
- Voluntary Food Defense Program
- FDA Intentional Adulteration Rule
- Enforcement
- Frontline Employees – Your Best Defense
- Q & A

# THE THREAT

# Food Defense Threat

## **MOTIVATION**

Adversary's intent  
to do harm

## **CAPABILITY**

Adversary's capability,  
adulterant, and tactics



**FOOD  
DEFENSE  
THREAT**

## **VULNERABILITY**

Conditions of accessibility and likelihood that  
adulteration would cause an impact

# ISIS Fighter Urged French Jihadists to Use Trucks to Kill ‘Infidels’ in Pre-Nice Massacre Video

“Two weeks before 31-year-old Tunisian Muslim emigre Mohamed Lahouaiej Bouhlel massacred at least 84 people when he drove a rented 19-ton Renault truck for more than a mile along a Nice, France beachfront roadway filled with Bastille Day celebration crowds, a video was released using a Telegram channel managed by French ISIS fighters, likely in Mosul, in which an ISIS fighter called for French jihadists to use large trucks to carry out mass killings of “infidels.” \*

The ISIS fighter said in his video posted on Telegram June 29, "Go get a truck" - Sheikh Abu Muhammad Al Adnani Al Shami



\*Homeland Security Today.US 07/22/2016

# ISIS is Threatening a Mass Murder using Cyanide to Poison Food Supplies, Warns Indonesia's Security Minister

- Minister Luhut Pandjaitan claimed ISIS was seeking stocks of cyanide
- He suggested police and military were at particular risk of ISIS attack
- Indonesia has arrested some 20 suspected ISIS terrorists in recent weeks
- ISIS is attempting to recruit new Jihadis from Indonesia's prison population



DailyMail.com, Feb. 17, 2016, Darren Boyle



# TERRORISM

## Threats Against the Food System Expressed in Propaganda Video

DailyMail.com, November 20, 2014

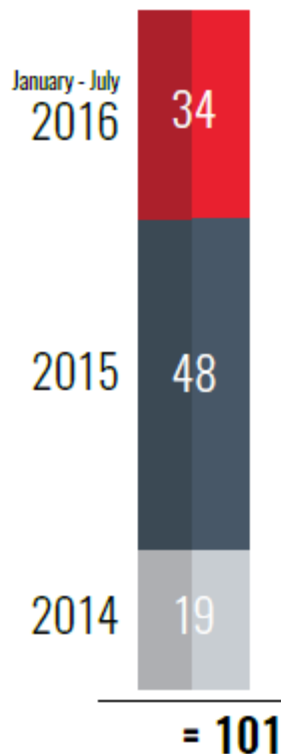
Abu Salman al-Faranci called for attacks, “poison is available, so poison the water and food of at least one of the enemies of Allah. Kill them and spit in their faces and run over them with your cars.”



# Terror Gone Viral – DHS Special Report\*

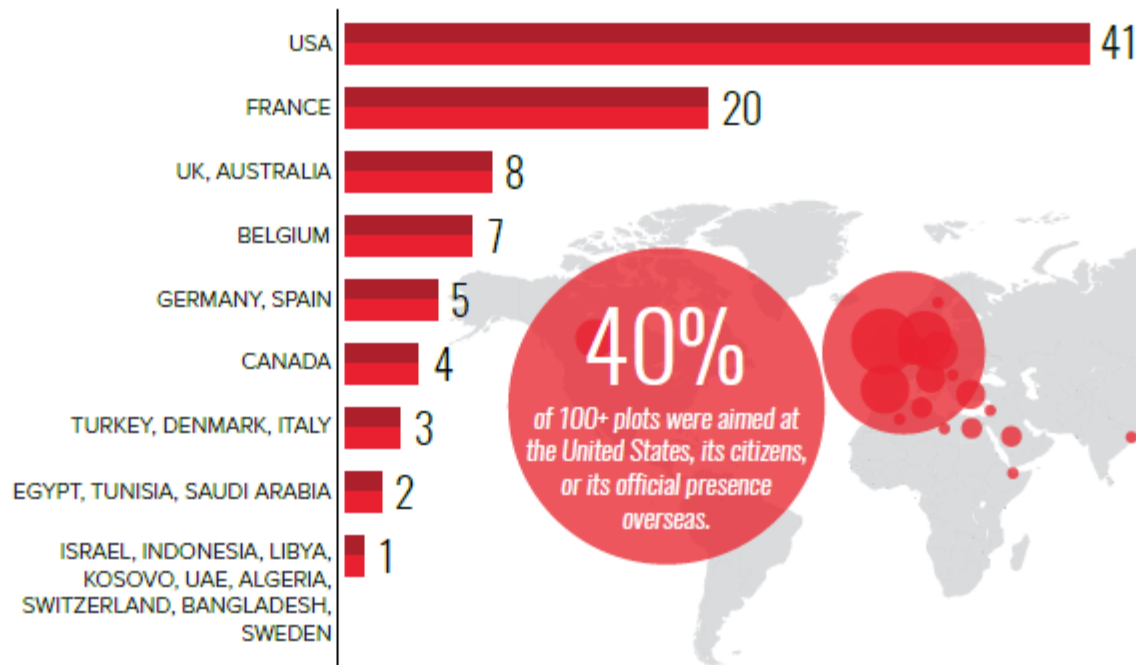
## 100+ ISIS-LINKED TERRORISM PLOTS AGAINST THE WEST

### TOTAL ISIS-LINKED PLOTS



### THE UNITED STATES IS THE TOP TARGET

NUMBER of ISIS-LINKED PLOTS PER COUNTRY

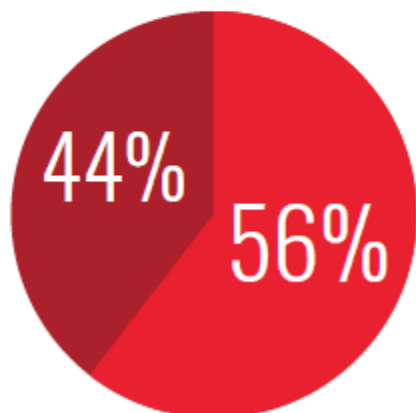


\*TERROR GONE VIRAL OVERVIEW OF THE 100+ ISIS-LINKED PLOTS AGAINST THE WEST, July 2016, HOUSE HOMELAND SECURITY COMMITTEE MAJORITY STAFF REPORT

# Terror Gone Viral – DHS Special Report\*

ISIS-LINKED PLOTS HAVE A GROWING—AND ALARMINGLY HIGH—SUCCESS RATE (2016)

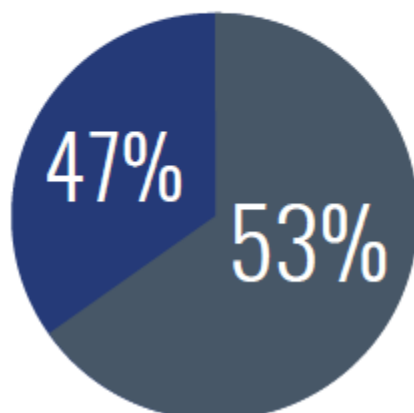
EXECUTED DISRUPTED



...up from 31% "executed" in 2015.

ISIS FOLLOWERS CONDUCT MOST ATTACKS, BUT THE NUMBER OF ISIS-DIRECTED PLOTS IS ON THE RISE

DIRECTED INSPIRED



...up from 35% "directed" in 2015.

**MOST SUSPECTS ARE MILITARY-AGE MALES**

GENDER

89%  
MEN



11%  
WOMEN


AGE OF SUSPECTS

80% were under the age 30  
Average age: 26

**ISIS-LINKED PLOTS ARE GETTING MORE DESTRUCTIVE**

2016  58 casualties\* per attack/875 people total so far

2015  48 casualties per attack/720 people total

2014  3 casualties per attack/30 people total

\* casualties = killed and wounded

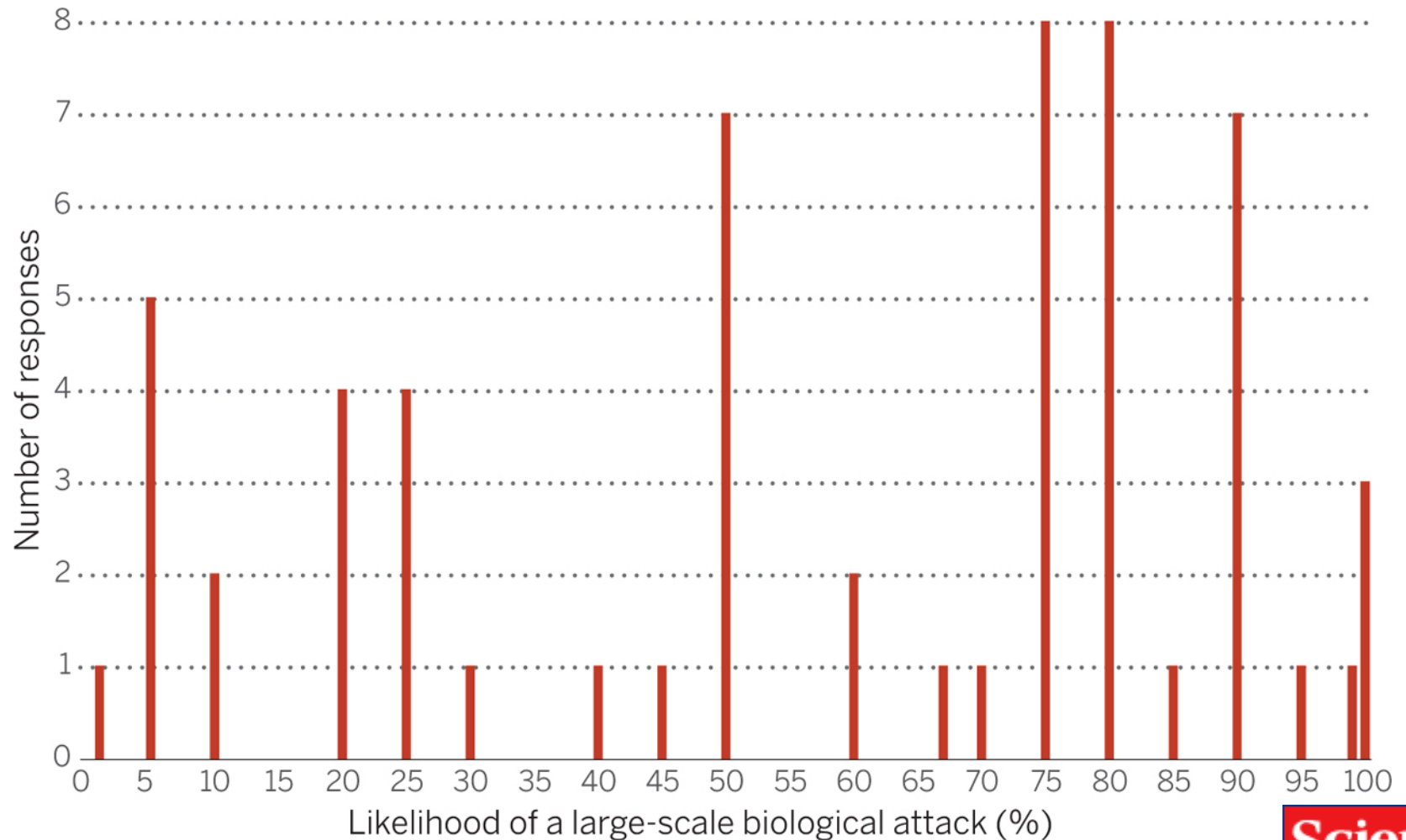
\*TERROR GONE VIRAL OVERVIEW OF THE 100+ ISIS-LINKED PLOTS AGAINST THE WEST, July 2016,  
HOUSE HOMELAND SECURITY COMMITTEE MAJORITY STAFF REPORT

# 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)*



# Intelligent Adversary

- ✓ Observes the system
- ✓ Finds vulnerabilities
- ✓ Gains Access
- ✓ Evades detection
- ✓ Works around mitigation strategies



# Gold'n Plump In-house Tampering 27 Tons of Chicken – June 6-9, 2016



ELIZABETH FLORES/STAR TRIBUNE

Production at the Gold'n Plump Poultry production facility, Tuesday, April 20, 2016 in Cold Spring, MN.



# Gold'n Plump In-house Tampering

- Gold'n Plump notified USDA Food Safety and Inspection Service (FSIS) that sand and black soil were found in some of their products
- Recall notice was issued for consumers to return product or dispose
- A worker believed to be behind the tampering was fired
- No confirmed reports of adverse reactions due to consumption of these products

ELIZABETH FLORES/STAR TRIBUNE

Production at the Gold'n Plump Poultry production facility, Tuesday, April 20, 2016 in Cold Spring, MN.

# VOLUNTARY FOOD DEFENSE PROGRAM

# USDA Food Defense Program

- Voluntary program
- Numerous published guidance documents
- Food defense program must include:
  - outside security
  - inside security
  - personnel security
  - incident response
- Targeted 90% of industry with functional food defense plan by 2015

# USDA Voluntary Adoption for all Segments\*

## 2015 Food Defense Plan Survey Results

As shown below, the adoption of functional food defense plans has consistently increased since initiation of the survey in 2006

Establishment Size	Percent of Establishments with a Functional Food Defense Plan			
	Meat & Poultry Establishments	Processed Egg Products Plants	Import Inspection Establishments	Overall
Large	98%	100%	N/A	98%
Small	92%	96%	N/A	92%
Very Small	78%	50%	N/A	78%
Total	85%	92%	85%	85%

\*<http://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-and-emergency-response/food-defense-plan-survey/survey-results>

# FDA INTENTIONAL ADULTERATION RULE

# Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR part 121)

- Published May 27, 2016
- Does not include produce farms subject to FD&C Act section 419
- For companies with > \$10,000,000/yr average sales
- Mitigation strategies must be established for significant vulnerabilities that might result in a wide-scale health hazard
- Includes threats from inside and outside the facility

# 21 CFR 121 Requirements

- Food Defense Plan
  - Written vulnerability assessments
  - Written mitigation strategies
  - Written monitoring procedures
  - Written corrective action plans
  - Written procedures for food defense verification
- Reanalysis
- Documentation
- Training



# Take a DEEP BREATH



## Take the 2-2.5 years to Implement

# Getting Started

- Management support, authority in emergencies?
- Facility implementation - separate or melded with Preventive Controls?
  - Employee training
  - Records
  - Facility culture
- Food Defense Team
  - Diversity and training
  - Internal person or outside consultant (facility familiarity?)

# Vulnerability Assessment

- Re-evaluate your processes and bring your flow diagrams up-to-date, including each point, step, or process that will be included in your vulnerability assessment
  - You will not want to try to maintain two different flow diagrams (PC vs. IA)
- Each facility is most likely going to be different
- Key to your food defense plan – make it a high priority

# Vulnerability Assessment

- Consider each point, step, or process without any mitigation controls (including current ones)
- Record why and why not for each point, step, or process
- Become familiar with tools that can be used to aid you in your assessment.
  - \* Coming \* - Intentional Adulteration Assessment Tool (IAAT) from DHS and ADM

# Mitigation Strategy

- Use HACCP type procedures to establish
  - Measuring, monitoring, correcting, and verification
- For process design changes – take into account hygienic design

# Monitoring/Corrective Actions

- Must be of sufficient frequency to demonstrate control
- Consider burden vs. control
- Minimal likelihood of an event may result in knowledge loss when action is required
- Seek to develop behavioral skills
- Develop a culture of mandatory compliance

# Food Safety Plan Impacts

- Changes to the Recall plan
- Changes to the Emergency and Disaster Recovery plan



ENFORCEMENT

# Enforcement

- Not for 3 years (May 2019)
- Progressive enforcement
  - Verification it is in place when conducting preventive controls inspection
  - Minimum detailed inspections
- Training being developed in conjunction with Food Safety Preventive Controls Alliance
- Guidance targeted for 1 year before enforcement

# Resources

- FDA Technical Assistance Network (TAN)  
(<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>)
- FSPCA Technical Assistance Network  
(<https://fspca.force.com/FSPCA/s/>)
- FPGI – Food Defense Readiness Assessment 2.0  
(<https://foodprotection.umn.edu/innovations/prepare-dness/food-defense-readiness-assessment-20-coming-soon>)
- USDA Food Defense and Emergency Response  
(<http://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-and-emergency-response>)

# Frontline Employees – Your Best Defense

# Best Defense

What to look for:

- **Environment**
  - Unattended parcels
  - Unlocked doors
  - Out of ordinary conditions
- **Materials**
  - Unusual packaging
  - Signs of tampering
  - Off odors, colors, etc.
- **People**
  - Strangers
  - Unattended ‘visitors’
  - Behavior difference

## See Something...Say Something!

- Importance of plant security
- How to report
- Who to report to



Don't create an entrance for unwanted visitors.

# Good Offense

- Frontline employees see it all!
  - Teach them what to look for
  - Extend training onto the plant floor
    - Active
    - Passive
  - What's in it for them?
  - Reinforce reporting
    - Culture of **trust**
    - Telling is not tattling!
  - Use industry and plant examples as teaching moments
  - Include in investigation and problem solving activities



Report suspicious visitors.



They're restricted for a reason.

# Partnering



- Mock event
  - Test Procedures regularly
  - Set goals
  - Retrieval, disposal
  - Include recovery from the beginning!
  - Formal write up
  - Retrospective
  - Action items
- Form business relationships now!
  - Local law enforcement
  - DHS
  - USDA
  - FDA
  - State Health Department
  - Dept. Natural Resources



# Employees Are your Best Defenders

- Learning:
  - Consistency
  - Ensure employees know what to look out for so they will speak up when they see something concerning
- Communications:
  - Drive retention through reinforcement
- Performance:
  - Coach and observe employee behavior on the production floor





# Recordkeeping & Documentation: Best Practices for Compliance

**Date:** Wednesday, September 28<sup>th</sup> | 12:00-1:00 pm CT

**Speakers:** Holly Mockus (Alchemy) & Kristin Kastrup (Alchemy)

Compliance in the area of recordkeeping and documentation continues to be a top challenge facing food industry professionals. It can be daunting to stay on top of FSIS, FSMA, and all the other changing requirements surrounding it. However, proper recordkeeping and documentation is critical because it can prevent a recall and protect you and your company against regulatory enforcement actions. Join two food industry experts with real-world experience from companies including ConAgra, Kellogg, and Sara Lee, who have faced these challenges first hand. They will point you to some of the regulations requiring documentation, explain why airtight records matter, and share best practices to ensure compliance.

**Learning Objectives:**

- Discover why records matter
- Understand the latest recordkeeping requirements
- Determine the biggest risks of poor documentation
- Learn industry best practices to ensure compliance

# Q & A



# THANK YOU

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