The New Normal: How to Be Audit Ready All the Time

Speakers: Melanie Neumann, J.D., M.S. & Laura Nelson

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Today's Speakers

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Agenda

- Risks and Regulations
- Key Strategies: How to Reduce your Risks
- Leverage Technology to Drive Efficiencies
- Q & A

Risks and Regulations

Risks and Regulations: The Stakes Just Went Up

- Changing risk landscape and why the stakes are higher than ever
- Increased criminal and civil liability risks and the legal standards we are measured by
- FSMA requirements and how they compare to GFSI standards
- Key strategies industry leading companies are using to stay audit-ready, 24/7

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Risk Landscape

What is the Legal Standard?

- **Strict Liability**…is civil tort law, as well as a criminal law doctrine, that imposes liability on an individual (and corporations are deemed individuals in the eyes of the law) **regardless of negligence or knowledge**
- One is “strictly liable” provided that the injured party can prove the item was defective, it proximately caused the injury, and that the defect created an unreasonably dangerous product
- Automatic responsibility without having to prove negligence for damages
- **NO KNOWLEDGE, NO NEGLIGENCE NEEDED**

Park Doctrine: a 1975 Doctrine, Dormant Until Recently

- The **Park Doctrine**
  - Allows the government to seek a misdemeanor conviction against a company official for alleged violations of the FDCA without having to prove that the official participated in or was even aware of the violations
  - The government need only demonstrate that the official was ***in a position of authority to prevent or correct the alleged violation***
- Since 2010, FDA said it would increase misdemeanor prosecutions of food industry executives for violating the FDCA

Adulteration: the “What” that gets Companies in Trouble

- Under section 402(a)(4) of the FDCA, a food product is deemed “adulterated” if the food was “prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health”
- A food product is also considered “adulterated” if it “bears or contains any poisonous or deleterious substance which may render it injurious to health”
- **If you make people sick (“human illness standard”)**
- **Filth and insanitary conditions – sanitation conditions**

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Penalties

- Chapter III of the FDCA covers the legal violations--called "prohibited acts"
- A prohibited act is a violation of the FDCA and, depending on the nature and degree, can impose civil and/or criminal liability
- Civil and Civil penalties
  - Which charge depends on facts of the case
- Criminal violations look like any other crimes — felonies or misdemeanors

Felonies

- Felony violations include adulterating or misbranding a food, and distributing an adulterated or misbranded food in interstate commerce
- If there is “intent to defraud or mislead,” this rises to a felony punishable by more than one year, and up to numerous years in jail, and up to millions of dollars in fines, or both

Misdemeanors

- A misdemeanor conviction does not require proof of “intent to defraud or mislead” or any knowledge at all
- A person may be convicted if he or she **held a position of responsibility or authority in a firm such that the person could have prevented the violation**
- Misdemeanor convictions are punishable by not more than one year, or a fine of not more than $250,000, or both

The Hurdle is Getting Higher

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DOJ and FDA Forge Stronger Alliance

DOJ and FDA further solidifying alliance to conduct civil or criminal investigations against companies who distribute food associated with a foodborne illness

"…**we have to rely on the companies who manufacture and distribute food to ensure that the food we buy is safe.** In fact, most consumers give little thought to the safety of their food. I know I don't and I bet many of you don't either. **That is why food safety is a priority for the Justice Department. Our role in protecting consumer safety is at its apex when consumers can least protect themselves."**

"We are committed to continuing to vigorously prosecute food safety cases"

Principal Deputy Assistant Attorney General Benjamin C. Mizer
April 6, 2016

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Awe come on…

WHAT ARE THE CHANCES THIS WILL HAPPEN?

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Reality? Investigations & Charges…Some Unintentional Some Intentional…

Salmonella in low moisture foods

PARK DOCTRINE- CRIMINAL MISDEMEANOR

Community Service

QA Manager Liable/Prison

Felony

- ***Third party liability***

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FDA's New Approach: a More Litigious, Policing Lens

- FDA is training its "investigators"
  - Where did the "inspectors" go?
- Two-tiered FDA training approach
  - FSPCA training & Internal training
  - (looking for food safety culture—are you?)

- The regulatory standard?
  - Identify and manage known and reasonably foreseeable hazards with preventive controls
  - Manage remaining hazards / risks with cGMPs/PRP
  - War on Pathogens/Human Illness Standard
- If Food Safety Plans, testing, records, cGMPs are not reflecting a sound program, **"we are moving in"**
  - Joann Givens, FDA in speech to BRC Conference April 7, 2016

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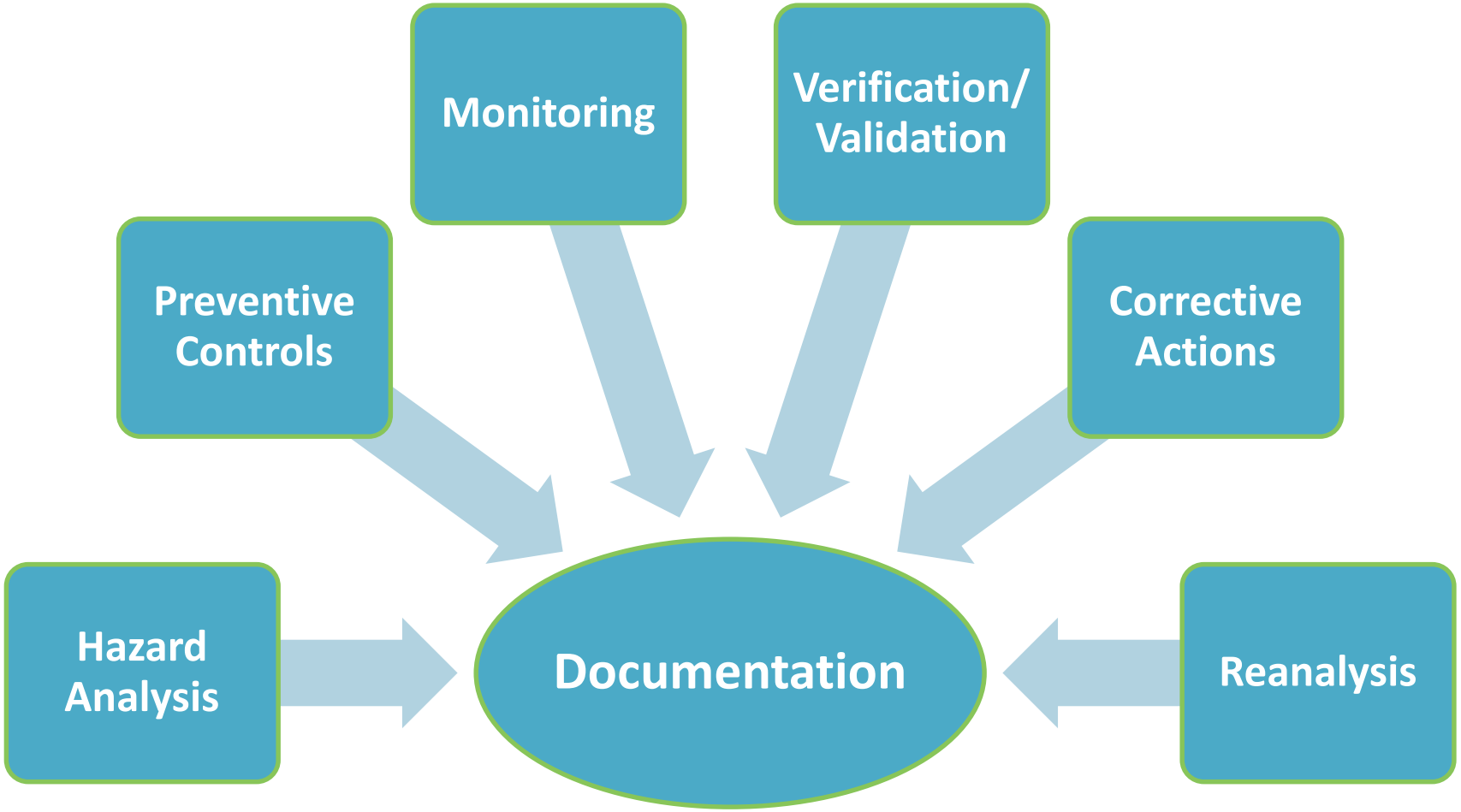
Where Does FSMA Fit into Increased Liability Risk?

- FSMA gives the FDA more opportunity to establish a violation of the law because now there are many more requirements for manufacturers to have to follow, such as:
  - Having a food safety plan
  - Establishing preventive controls for hazards requiring them
  - Validating process controls, etc.
- **Hence more "prohibited act" opportunities**

FSMA's Food Safety Plan: Required Contents



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FSMA & GFSI – How the GFSI Standards are Measuring Up

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Analysis Structure

vs.

- Looking for whether a FSMA Rule section addresses a GFSI Scheme Standard requirement
- Point of if any major requirement of FSMA was missing from GFSI Scheme Standard
- Rate as follows:
  - Exceed, Comparable or Different
    - Exceed: GFSI Scheme clause exceeds FSMA expectation
    - Comparable: GFSI Scheme clause is comparable to FSMA expectation
    - Different: GFSI Scheme clause is not as prescriptive, detailed or stringent as the corresponding FSMA Rule requirement, or asks for something fundamentally different from the FSMA requirement

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Global Theme and Struggle Across Schemes

- The need for the “PCQI”
- HACCP “team” approach in GFSI
- PCQI “Individual” approach in FSMA
- Requirement of what is now known and referred to in the Rule as a “Food Safety Plan”
  - Verses a traditional HACCP Plan based on Codex principles
- Establishment and use of what are now known as “Preventive Controls”
  - Rather than traditional critical control points (CCPs)

FSMA Has New Training Requirements

- Differs from GFSI training requirements
- **Preventive controls qualified individual** means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system
- **Qualified individual** means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment

Reminder: Role of PCQI

Broader than HACCP Coordinator/Manager

- Employee or third party consultant
- Oversees or Performs:
  - Food Safety Plan
  - Validation of preventive controls
    - Justify >90 days of production
    - Determine if validation not required
  - Records review
    - Justify >7 days review for monitoring and corrective action records
  - Reanalysis
    - Justify >90 days of production for additional or changes of preventive controls
  - MUST successfully complete training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA
    - Document training, date, content
- GFSI certified firms need to prove that PCQI status has been achieved for US facilities or foreign facilities exporting to US

GSFI Certified? You're almost home but you still have to hustle!

GFSI Schemes Exceed in Many Areas!*

- Senior management involvement/management review
- Customer focus/expectations
- Non-conforming product/quarantine
- Internal audit
- Product release
- Crisis management/communications
- Product complaints
- Loading areas
- Outsourcing to co-mans

These are just the key areas*

Where FSMA Appears to Exceed…

Corrective Actions	FDA requires the establishment of written corrective action procedures that must be taken if PCs are not properly implemented/fail, including specific procedures to address the presence of pathogens in ready-to-eat products or environmental pathogens detected through environmental monitoring.
Calibration	FDA requires calibration of monitoring & verification instruments and has requirements on what records must be kept, how frequently those records must be reviewed. GFSI requires that calibration be performed against recognized standards/methods and records be maintained. However it does not specifically state that calibration be performed against recognized "regulations" which would cover the FDA requirement, nor does it require that these records be reviewed or specify how frequently to review records relating to calibration (required by the PCQI). However the PC Rule does not require calibration against a national/int'l reference standard

Where FSMA Appears to Exceed…

Documentation (certain areas)	…Regarding documentation of the implementation of the Food Safety Plan appear more prescriptive and detailed. For example, documentation of calibration of process monitoring & verification instruments, product testing, and environmental monitoring.
Process Validation/Process Control	The Prev.Controls Rule contains detailed guidelines for monitoring and validation of preventative controls that are more prescriptive than the process validation and control requirements in most GFSI Standards.
Training	FDA requires training for the first time in history-PCQI and Qualified Individuals, Qualified Auditors and Supervisory Personnel, all defined in the Prev. Controls Rule.

Key Strategies: How to Reduce your Risks

Block and Tackle: Know the Game and the Playbook

- Have an Inspection Policy
- Know your Duties
  - Duty to Report-RFR
  - Duty to Test-EMP, Product Testing
- Know your Playbook
  - Laws, Standards
- Know your Players
  - Regulators/ Lawmakers
  - Consumers
  - Customers
  - Suppliers
  - Co-manufacturers
  - Media/Social Media
- Keep your Scorecards
  - Documentation
- Leverage Technology
- Create a Culture of Food Safety

Importance of Data/Recordkeeping

- Regulatory compliance
- Leverage Technology
  - Traceability
  - Visibility
  - Training
- Contracts: Liability / Indemnification
- Trending
  - To identify emerging risks
  - Proactive v reactive use of data
  - Improve quality
  - To achieve brand protection
- KPI's/Performance Metrics
  - At Corporate; suppliers; plants
  - "Food safety culture"
- Audit against requirements
  - 2nd party or 3rd party
  - Helps you be audit ready

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Inspection Policy

- Pre-Inspection
  - Train employees!
  - Conduct self-inspections
  - CAPAs
- During
  - Define roles/responsibilities for inspections
    - What is the communication plan
    - Who greets/asks for credentials/escorts
    - Who answers questions
    - Who responds to the inspection report
  - Define what the inspector has access to review
    - FSMA Records access Final Rule FDA
    - FSIS Directive 5000.2 & FSIS Notice 74-13
    - Define how to manage requests for copies of records
      - Stamped confidential
      - Keep a copy yourself of all documents released
  - What is the reason for the visit?
    - Potential answers
      - Information gathering
      - For cause
  - If it is “for cause” make sure you ask why!
- Pre/Post Inspection
  - Document everything! Swabs, photos, records agency copies, compliance with procedures,…. “confidential”
  - Audit against established procedures

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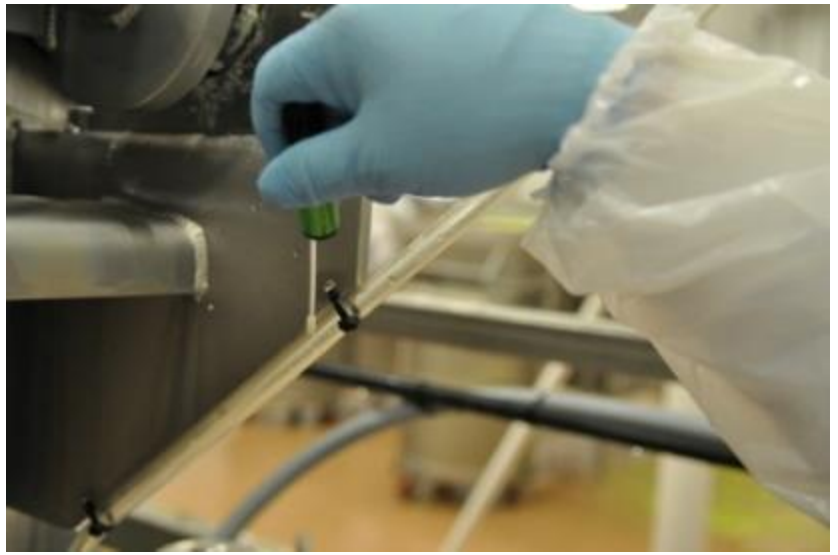
Inspection Policy: Photos and Swabs

- Have a policy-Define if you allow photographs or the criteria to which you allow photographs
- Define what actions you will take if the inspector want to take environmental samples or product samples
  - Take duplicate swabs
  - Take split samples (if allowed) or take samples before and after those collected
  - Do not take swabs or samples
- Define the communication plan to the items identified in the report
- Define how to respond to the inspectors report
  - Immediate
  - Long term
- Define inspector training and who needs to attend
  - Leadership that deal with inspectors directly
  - General front line employee training



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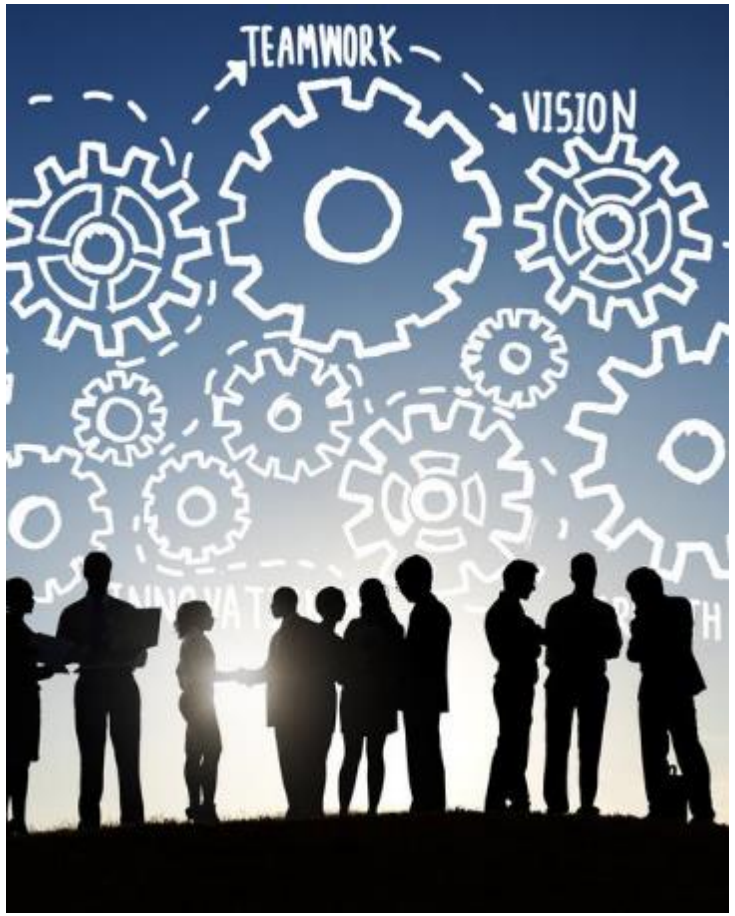
Be Part of a Team

- Trade Associations
- Smaller Industry Sector Groups/Information Sharing Groups
- Intra-company teams
- Software partners
- **Network!**
- **Food Safety is not a trade secret**



Parting Message

- Understand the regulations and your exposure risk
- Focus on your food safety culture
  - Food safety vs. procurement/ price
- Understand where your risk is
  - Internally
  - Externally / Supply chain
- Team up: the C Suite, Legal and Food Safety should work together and realize there is an ROI to Food Safety
- Don’t let compliance be your food safety goal
- Establish good relations with regulators
- **Leverage Technology to Manage Your Risk!!!**
- Recognize that you are **never done—Food Safety Risk Management is a journey not a destination**

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Leverage Technology to Drive Efficiencies

Training/ Education

Audit Readiness

Three Training Keys to Optimizing Your Workforce

1. Align training content with critical food safety risks
2. Provide your employees the tools they need
3. Empower your frontline supervisors

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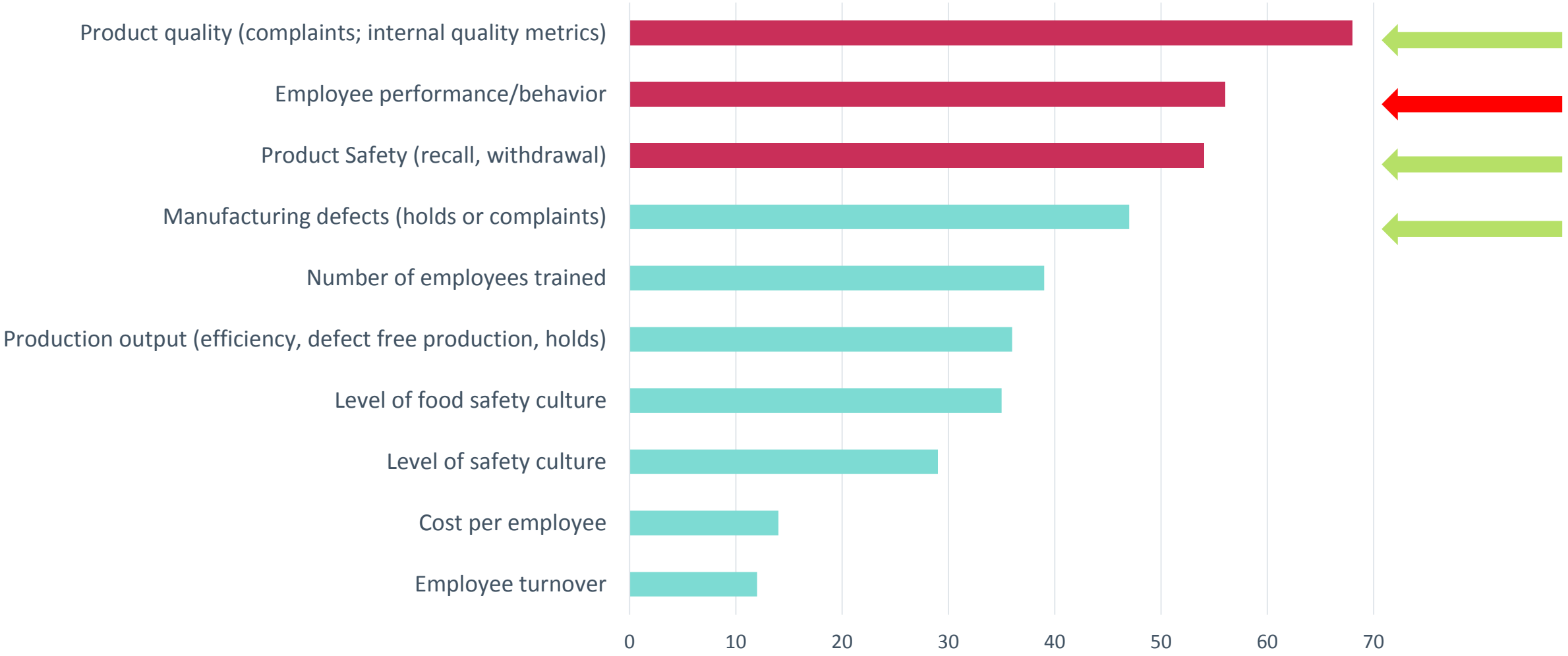
How the value of training is measured



Source: Global Food Safety Survey conducted by Alchemy Systems and Campden BRI (2016)

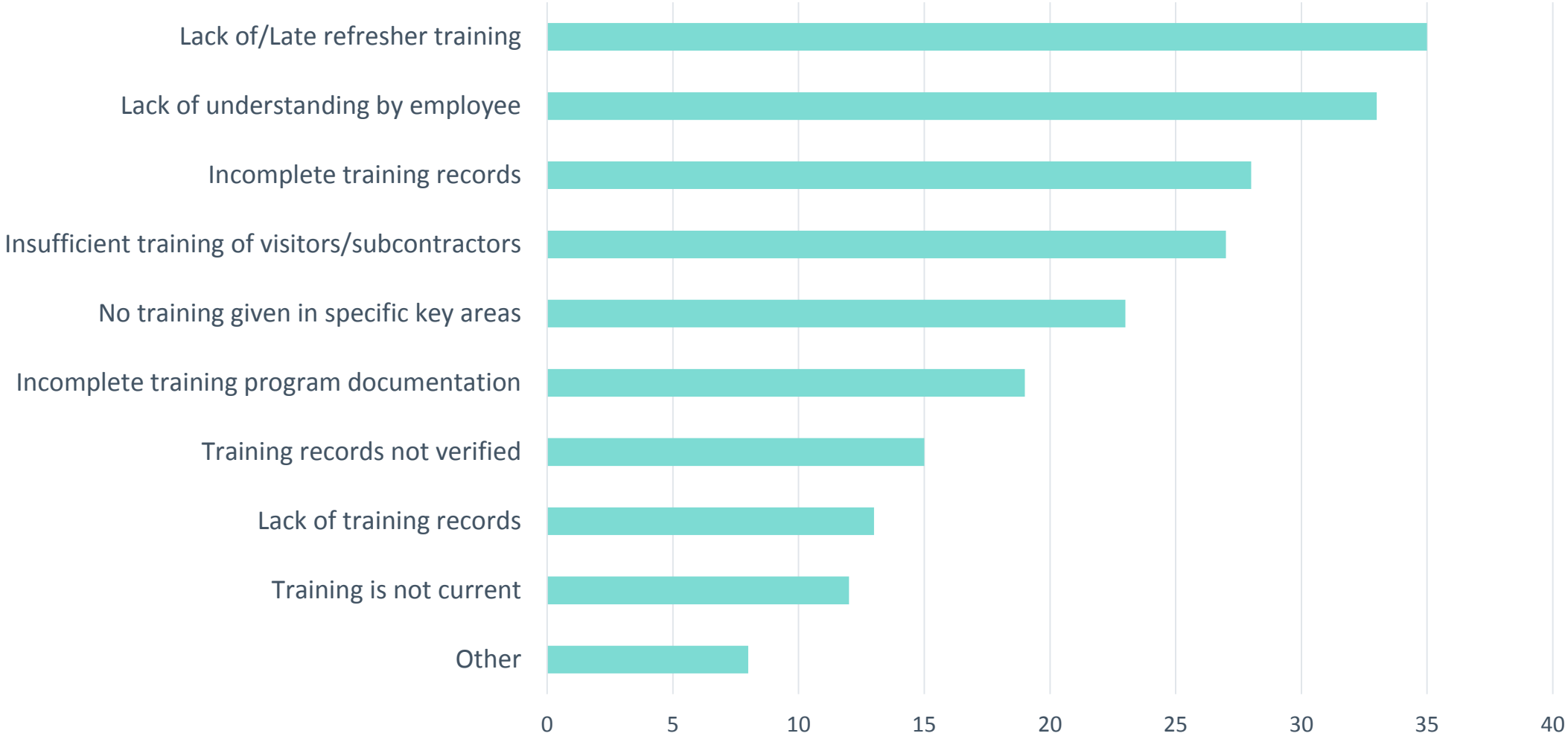
1. Connect Appropriate Behaviors to Process Outcomes

Example: Proper Sanitation

- ✓Damaged equipment
- ✓Facility conditions
- ✓Temporary fixes
- ✓Equipment storage
- ✓Cleaning during processing

- Train employees to bring attention to issues that require immediate action

Types of training deficiencies noted during audit



Source: Global Food Safety Survey conducted by Alchemy Systems and Campden BRI (2016)

Supervisor and Employee Feedback on Training

19.8% of workers say they received ***too little onboarding training.***

Almost one in five workers start their jobs without confidence that they know the proper procedures.

37.2% of workers and 42.7% of supervisors say that ***training is too complex and difficult to understand.***

Given the critical role frontline workers play in safety and productivity, poor training can create safety risks and compromise quality and brand standards.

Source: The Mind of the Food Worker study by Alchemy Systems and CRPP (2015)

2. Provide Employees with the Tools they Need

- **Who?**
  - Ex. Specific learning plans per job task
- **When?**
  - Ex. 15-20 minute training events
- **Where?**
  - Ex. Classroom AND on the plant floor
- **Why?**
  - Ex. Explain negative outcomes from employee perspective
- **How?**
  - Ex. ILT, huddle talks, posters, multiple languages

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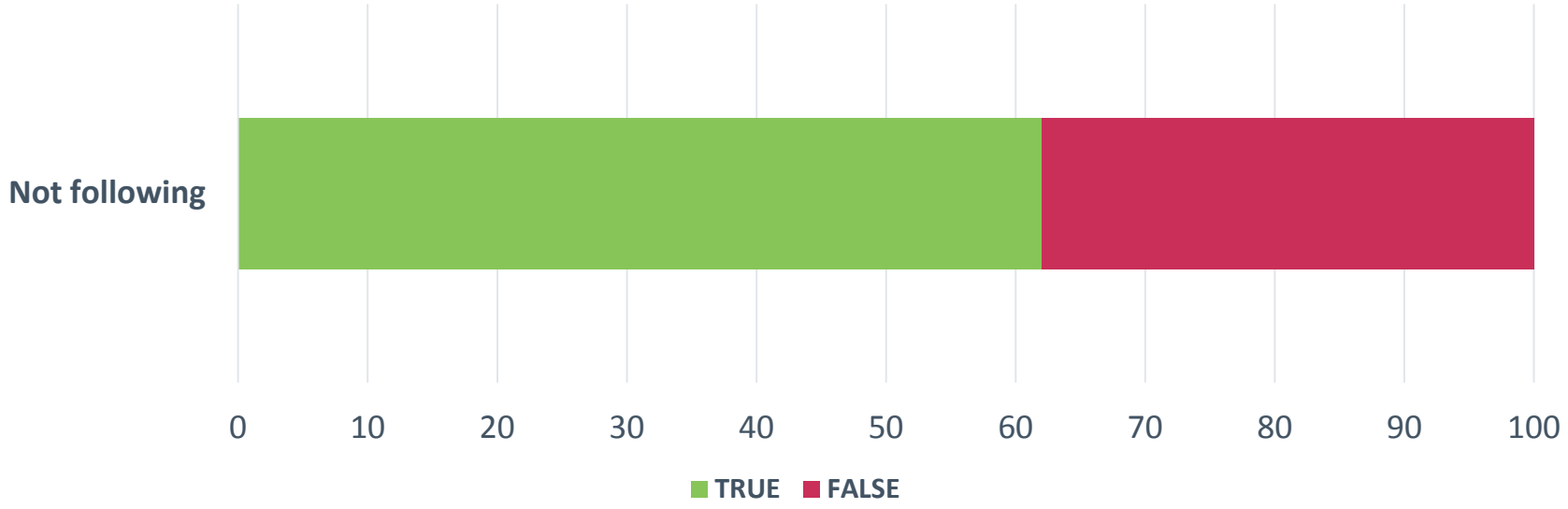
✓ Have the Knowledge

✗ Have the Equipment

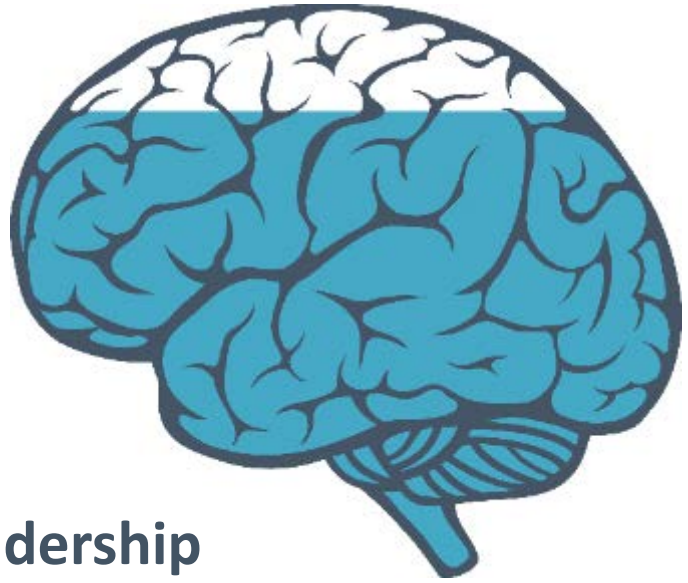
Are Employees Following your Food Safety Program?

Despite our efforts in employee food safety classroom training, we still have employees not following our food safety program on the plant floor.



Source: Global Food Safety Survey conducted by Alchemy Systems and Campden BRI (2016)

How Much Information are Employees Retaining?



Leadership

Workers

Leaders suggest that only **19.7%** of workers ***remember*** all or most of their initial training versus **79.2%** of workers.

Source: The Mind of the Food Worker study by Alchemy Systems and CRPP (2015)

3. Empower Your Frontline Supervisor

Coaching & Mentoring Employee Behaviors for Key Risk Functions

Validate

Verify Training Efficacy On-the-job

- Document on-the-job training and sign-offs
- Ensure SOPs and work instructions are practiced on the floor

Communicate

Drive One-on-One Communication

- Provide remediation feedback and sign-offs
- Facilitate supervisor and employee communication

Audit Readiness

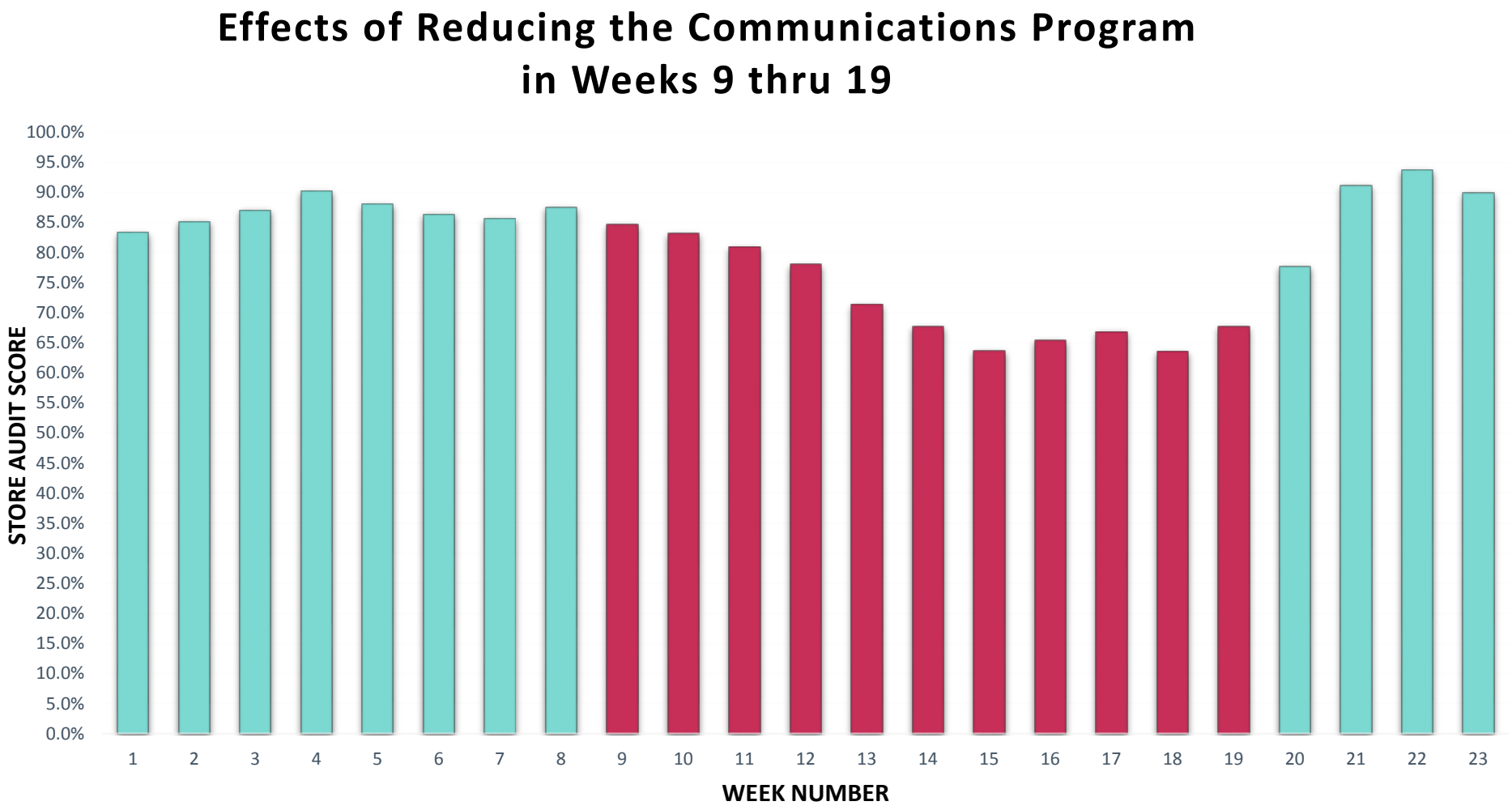
Perform Observations

- Document and track corrective observations
- Ensure compliance with regulatory requirements

"Coach is an essential tool for our supervision team. It drives one-on-one time with our employees, it also drives employee participation and involvement."

Rudolph Foods

Impact of 24/7 Awareness on Retail Food Chain



Source: Global Food Safety Survey conducted by Alchemy Systems and Campden BRI (2016)

Comprehensive Solution to Optimize your Workforce

Coach and monitor behavior

Streamline & Create Consistency

Reinforce and Engage

Food Fraud:
What You Don't Know *Can* Hurt You

Date: Wednesday, July 20th | 12:00-1:00 pm CT

Speakers: Karen Everstine, Ph.D. (US Pharmacopeial Convention) & Jorge Acosta (Alchemy)

Horse meat in hamburgers, fillers in parmesan, Italian olive oil that is not from Italy – these are just a few recent examples of food fraud. Food fraud is a real issue that threatens the viability of your company and safety of your consumers. Companies who fraudulently manufacture, label, or sell their product face potential regulatory and legal consequences. Tune in to our webinar to learn all about food fraud, the new regulatory requirements that surround it, and discover strategies to mitigate the risk. Don't wait for food fraud to emerge in your company – educate yourself now to preserve the integrity of your brand and to ensure the safety of your consumers.

Learning Objectives:

- Explore what food fraud is and why it is so important
- Discover new tools and strategies to reduce your vulnerability to food fraud
- Understand the new FSMA and GFSI requirements regarding food fraud and economically motivated adulteration

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Resource: PCQI Onsite Training

BACKGROUND

- New FSMA regulations require that key personnel in charge of managing the Food Safety Plan at a company must be a "Preventive Control Qualified Individual."
- The Food Safety Preventive Controls Alliance (FSPCA) has partnered with the FDA to develop course curriculum to meet the "Preventive Control Qualified Individual" requirements.
- Companies have a specific amount of time to comply depending on their size.
- Alchemy will offer an FSPCA-approved classroom training to be PCQI certified.

WHO SHOULD ATTEND

- QA Directors and Managers
- QA Supervisors
- Operations Managers
- SQF/BRC Practitioners and Auditors

LOCATIONS

Chicago, IL
June 15-17 SPACE LIMITED!

Austin, TX
July 19-21

Denver, CO
August 16-18

Visit link below for more details and locations

Register at: www.alchemysystems.com/PreventiveControl

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