

A worker in a white lab coat and hairnet is using a tablet in a food processing plant. The worker is wearing blue gloves and is looking at the tablet. The background shows industrial machinery and conveyor belts. The foreground shows a large quantity of golden-brown, twisted snack pieces.

RECALL COMMUNICATIONS AND PROCEDURES

PRESENTED BY COTTINGHAM & BUTLER AND THE ACHESON GROUP



Cottingham & Butler

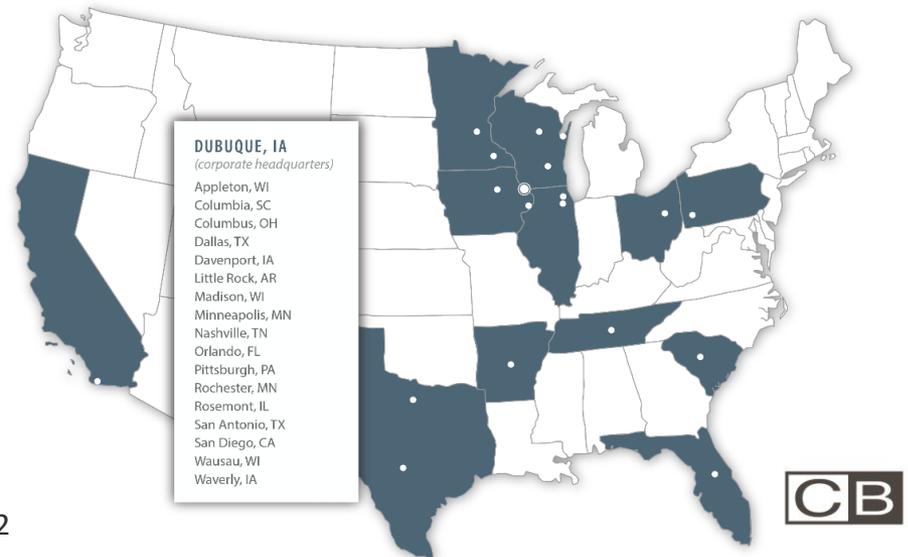


COTTINGHAM & BUTLER OVERVIEW

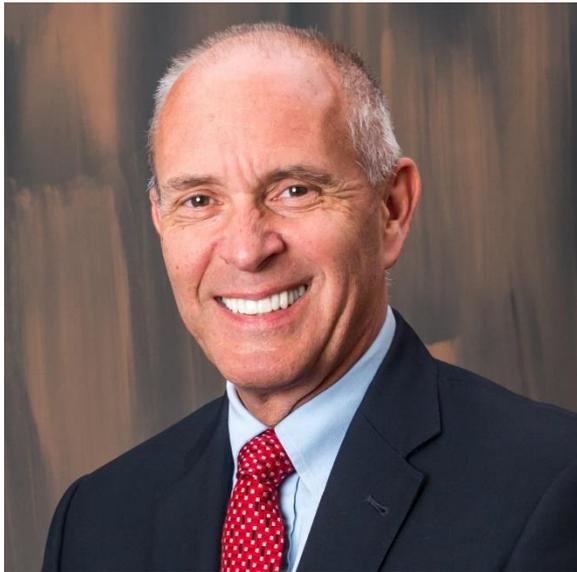
- Established in 1887
- Privately owned and operated
- Headquartered in Dubuque, IA, with operations in 20 states
- Over 950 employees
- 6th largest independent and privately held insurance broker in the U.S. (28th largest overall)
- Over 5,000 customers
- Handling over \$3 billion of our clients' money
- 96% retention rate across entire book of business v 90% industry average

C&B Food/Ag Practice

- Serving over 110 clients throughout the country
- Dedicated team of 13 specialists throughout 5 offices who specialize in:
 - Insurance coverage analysis, structuring and purchasing
 - Claims adjustment and advocacy
 - Safety Services: Workers, Facility, Food
 - Employee Benefits, Healthcare and Benefits



PRESENTER



DR. DAVID ACHESON
President & CEO of The Acheson Group

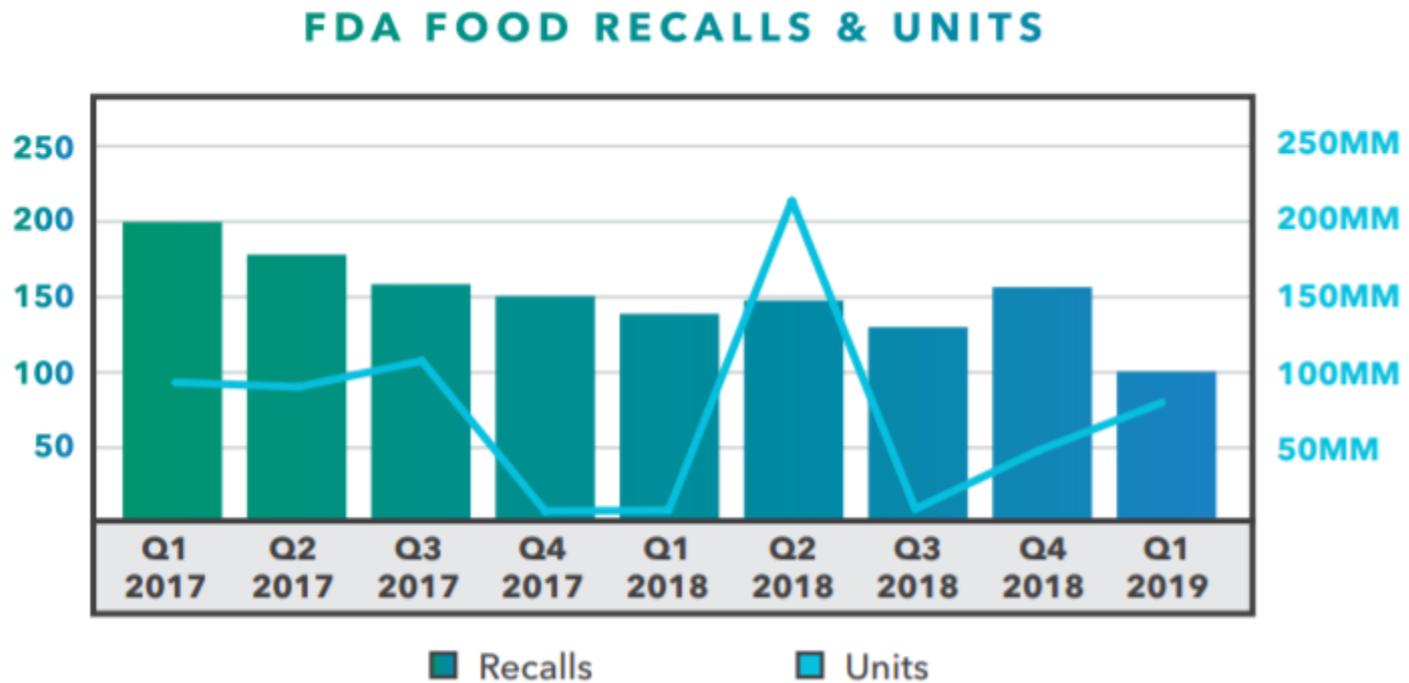
OVERVIEW

- Latest recall trends
- Impacts of recalls
- Approach to a recall
 - Identify the issue
 - Escalation as needed
 - Assessing risk
 - Involving regulators
 - Execution of the recall



2019 RECALLS

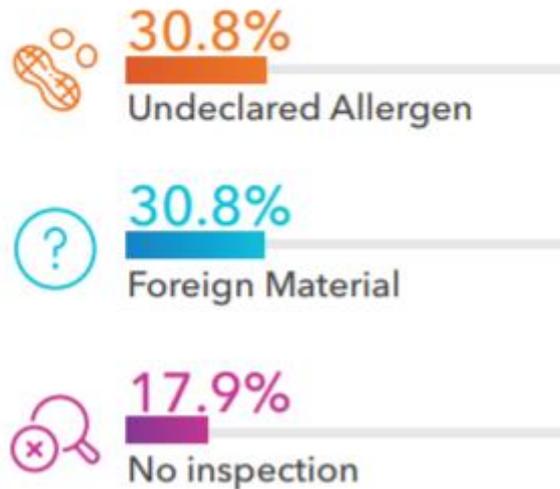
Stericycle Recall Index 2019 Q1



2019 RECALLS

Stericycle Recall Index 2019 Q1

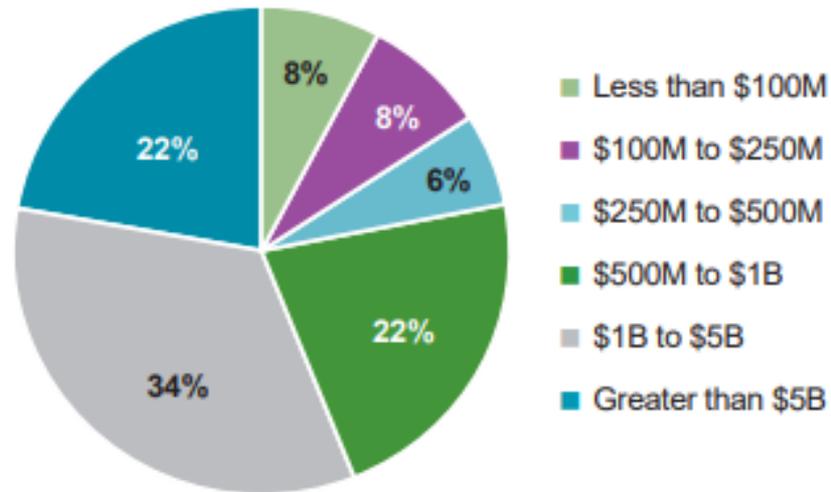
TOP USDA REASONS BASED ON RECALLS



COST OF RECALLS

- Grocery Manufacturers Association 2011
- Surveyed 36 members

Figure 2 - Company Sizes Represented



COST OF RECALLS

- Grocery Manufacturers Association 2011

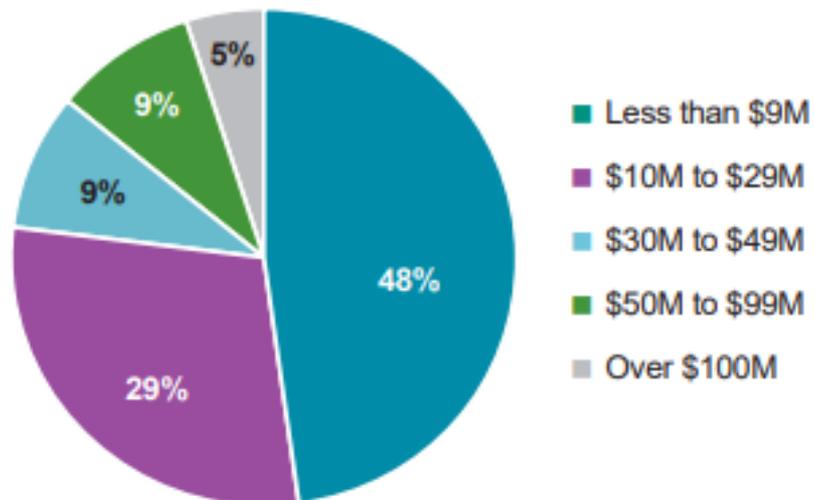
Key Survey Results

- ▶ 81% respondents deem financial risk from recalls as significant to catastrophic
- ▶ 58% have been affected by a product recall event in the last five years
- ▶ 78% manage the risk by procuring insurance
- ▶ 77% experienced recalls that had a financial impact of less than \$30 million
- ▶ The largest recall costs came from business interruption and product disposal
- ▶ The highest recoveries came from insurance proceeds

COST OF RECALLS

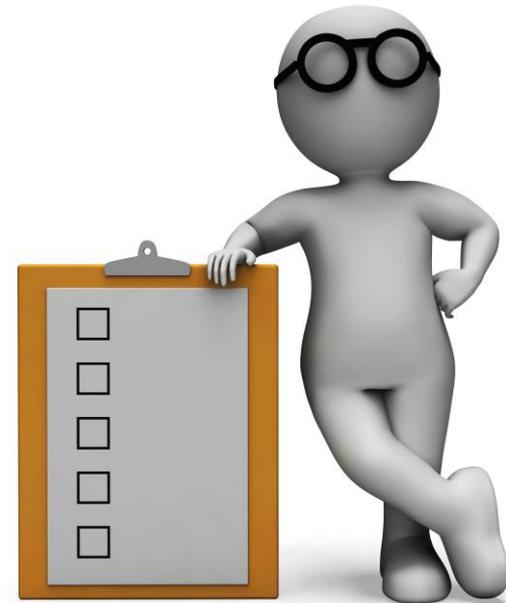
- Grocery Manufacturers Association 2011

Figure 3: What do you estimate the financial impact (sales losses, direct recall costs, etc.) to your company was as a result of the recall?



HOW TO MANGE A RECALL OR CRISIS

- Identifying the issues
- Elevation in the organization
- What action should you take
- Regulatory implications
- Managing the situation
- Importance of communications



HEARING ABOUT THE ISSUE

- How will you hear about an issue?
- Who will be notified?
 - Your Toll free number
 - Plant manager
 - QA person
 - Sales and marketing
 - Senior executives
 - Others
- Call from a supplier
- Call from a regulator

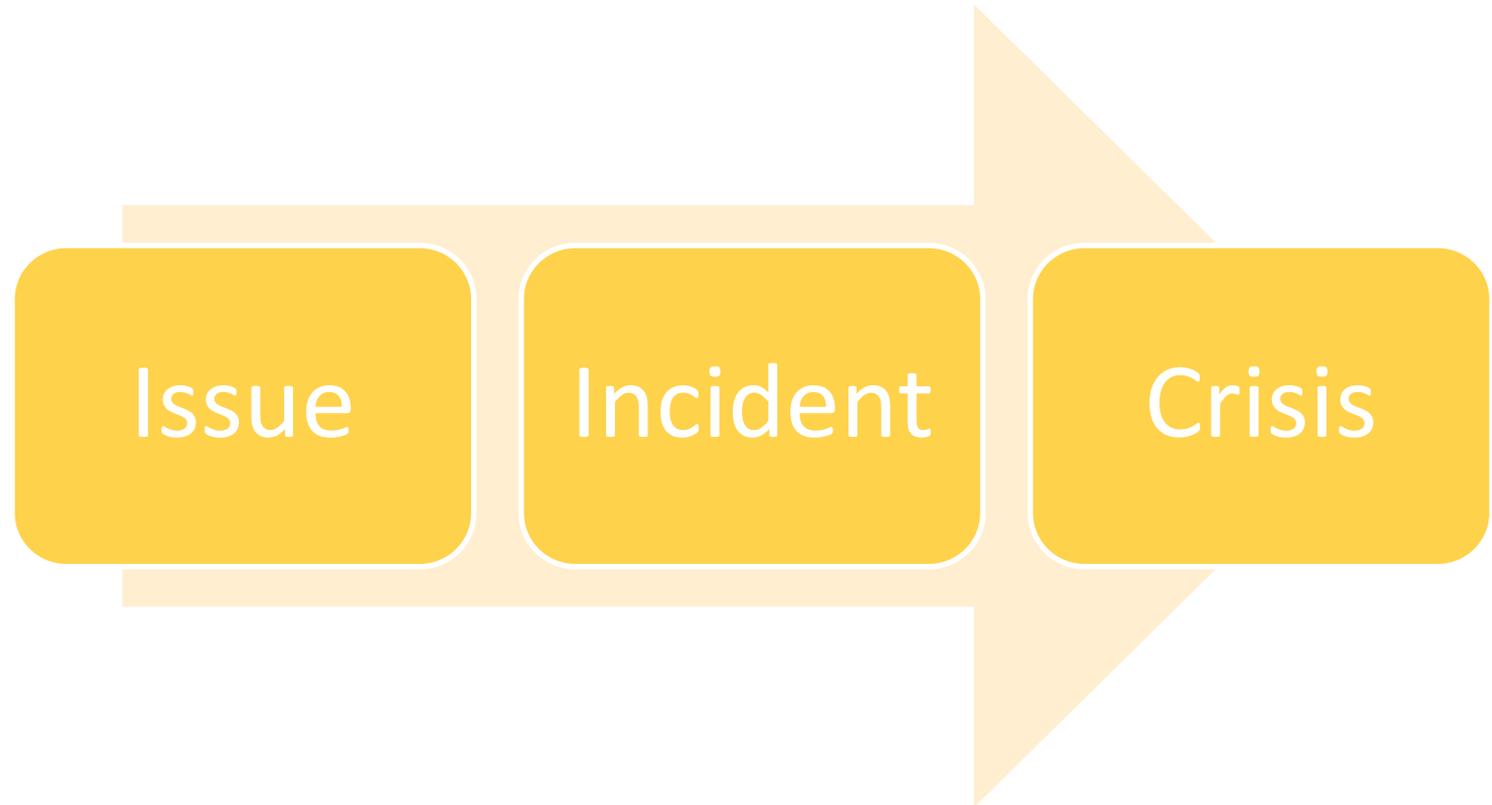


FIRST ASSESSMENT

- How serious is the issue?
- Does it need to be elevated?
- Who needs to know?
- Speed really matters!



ELEVATING THE ISSUES



MANAGING A SITUATION

- When does an incident become a crisis?
 - System for rapid elevation of issues
 - Is it an incident?
 - When does it become a crisis?
 - What is the difference?
 - Who is involved?
 - What are the risks?



ELEVATING THE ISSUES

- What are the criteria for elevation?
- Who needs to know at each level?
- What is the process/people that need to be involved at each level?



IMPORTANT POINTS

- Need to have a written procedure
- People need to know their roles
- Create a single message and stay on message
- Appropriate communication
- Clear process for addressing questions
- Do you have the right contact information?
- Do you have outside experts lined up if needed?
- Practice



ASSESSMENT

- Public health risk
- Employee risk
- Financial risk
- Regulatory risk
- Brand risk
- How much trouble are we in?



PUBLIC HEALTH RISK

- Does the situation pose a risk to the public?
- What is the degree of that risk?
 - Reasonable probability of a serious adverse health consequence or death
 - Remote possibility of a serious adverse health consequence or death; or reversible medical issue
 - No significant medical consequences
- How are you going to determine this?
- How will this drive your actions?

CONTACTING REGULATORS

- Do you need to contact regulators?
- How fast do you need to contact regulators?
- What should you tell them?
- Do you need to file a Reportable Food Registry event?
- Do you need to contact your FSIS District Office
- Are you facing the need to take an action?
 - Recall
 - Market withdrawal
 - Stock recovery



ACTIONS

- **Recall:** A firm's voluntary removal of distributed products from commerce when there is reason to believe that such products are adulterated or misbranded. "Recall" does not include a market withdrawal or a stock recovery.
- **Market Withdrawal:** A firm's removal or correction by its own volition of a distributed product that involves a minor infraction that would not warrant legal action by the applicable regulatory agency or that does not involve a health hazard.
- **Stock Recovery:** A firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm. For example, product is located on premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use.

RECALL CLASSIFICATION - FDA

Classification is driven by level of health risk

- **Class I:** a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- **Class II:** a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III:** a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

REPORTABLE FOOD REGISTRY

- The RFR requires that a company submit a report **within 24 hours** when there is a **transfer** of an FDA regulated food product **outside of the manufacturing company AND** there is **reasonable probability** that the use of, or exposure to, an article of **food will cause serious adverse health consequences or death to humans or animals** (i.e. lead to a Class I recall situation).
- When you receive product
- When you ship product and loose control of it
 - Includes a third party warehouse

FSIS REGULATED

- § 418.2 Notification. Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce.



CRITICAL QUESTIONS

- How did the problem occur?
- What is your root cause?
- What is the scope of the issue?
 - When did it start and end?
 - Defining implicated product
- What is your action going to be?
- What is your timing?
- What information do you need and how can you get it quickly?



EMBARKING ON A RECALL

- Try to do just one recall
 - Maybe a challenge
 - Data gaps
- Engaging with the regulators
 - Recall committee – FSIS
 - Recall coordinator
- Understanding the most important part of a recall
 - Coming out of the other side with the least damage possible
- Disposition of product



DISPOSITION

- What has been done with the product?
 - Cooked
 - Re-worked
 - Destroyed
 - Relabeled
- Keep accurate records



RECALL EXECUTION

- Having a clear written process for recall execution
 - Who is on the recall team?
 - Who do you need to contact?
 - What is the message?
 - How do you communicate the message?
- Communication is critical



WHO IS YOUR AUDIENCE?

- Consumers
- Customers
- Employees
- Suppliers
- Regulators
- Investors
- The media
- Food industry



COMMUNICATIONS

- One of the most important components
- One of the most difficult to get right
- What is your message?
- Who are you delivering it to?
- Who is sending the message?
- Who speaks for the Company?



CHALLENGES

- Simple messages about complex issues
- Good communication
- Being confident but not arrogant
- Be careful if you accuse someone else
 - CDC
 - Media



RECORDS

- Keep comprehensive records
- Who have you contacted?
- How did you contact them?
- When did you contact them?
- Have they confirmed they are taking action?
- Accounting for the product
 - You have some
 - Customers have some
 - Rest gone to consumer level
- Financial records including time spent



WHAT ARE THE BIG THREATS?

- Your brand is your biggest asset
 - Communication challenges
 - Key stakeholders
- Do you have a communication plan in place?
 - Are you monitoring what is being said?
 - Have you practiced how to respond?



ARE YOU READY FOR A RECALL OR CRISIS?

- Being prepared
- Written procedure
- Having the right people available (internal and external)
- Having the right systems
- Practice



SUMMARY

- Recalls are costly and frequent
- Make sure you will hear about issues quickly
- Elevate appropriately
- Have the team ready and knowing what to do
- Understand regulatory needs
- Keep very comprehensive records
- Have a communication strategy ready to go
- Make sure you practice and test the system at least annually



QUESTIONS?

HOW WE ADVISE AND MANAGE – CUSTOM PROGRAMS

MAJOR COSTS AND CONCERNS RELATED TO PRODUCT RECALL



Time and Expense



Business
Interruption and
Loss of Revenue



Brand Reputation



Supplier Relations



Increased Regulatory
Authority and
Enforcement

C O T T I N G H A M & B U T L E R

RECALLSMART

Cottingham & Butler's RecallSmart is designed especially for food, beverage and agribusiness companies that produce consumable products. The coverage is flexible and tailored to each company's specific needs.

COVERAGE HIGHLIGHTS

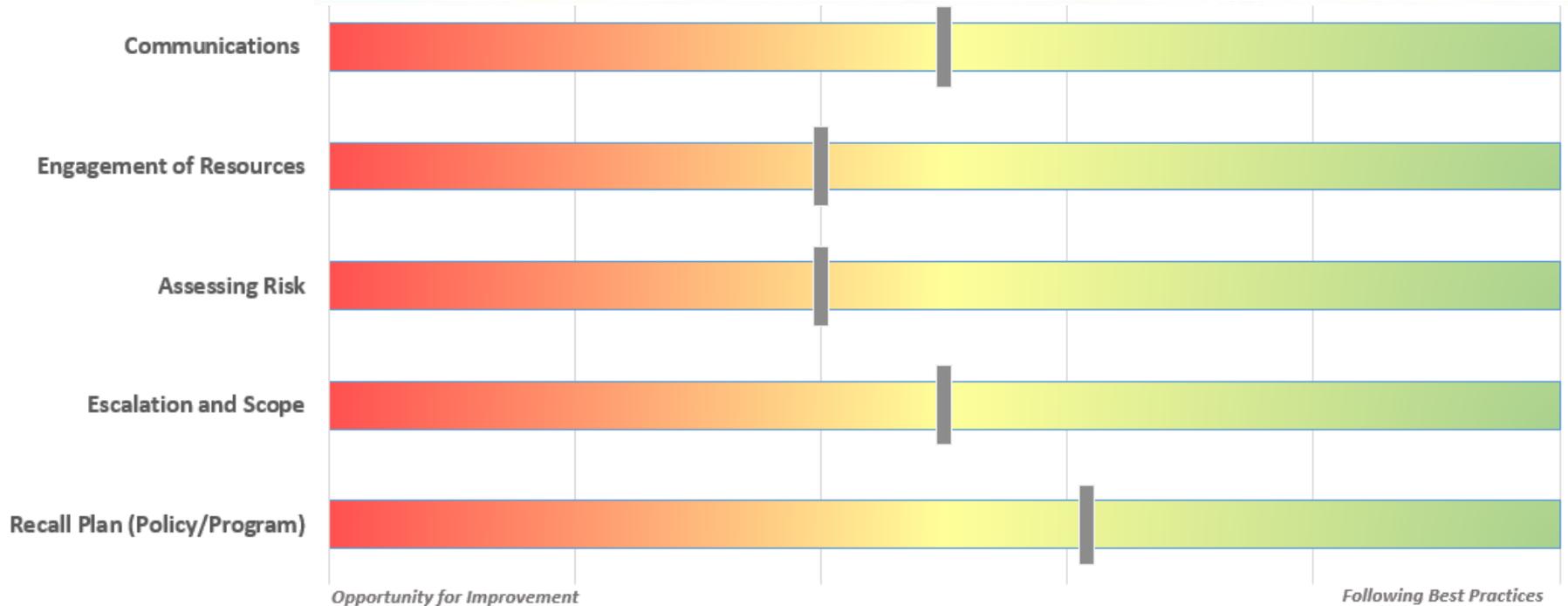
- Broad Coverage Trigger – not just Contamination based and will respond to defect, deficiency, inadequacy or breach of warranty of an Insured Product
- Coverage for Product Refusal
- Coverage for Product Restoration Costs
- Coverage for False Positives
- Social Media PR Events Trigger Coverage
- Coverage can be extend to non-food products if applicable
- Acknowledgement that a product recall limit on a GL policy erodes the policy retention
- Cottingham & Butler recall clients can allocate a percentage of recall premium to pre-loss and recall mitigation consulting services.

FOOD SAFETY DIAGNOSTICS

Complete the C&B online Food SafetySMART Diagnostics to benchmark your current practices with industry best guidelines in the following categories:



FOOD SAFETY DIAGNOSTICS - OUTPUT



FOOD AND AG – RISK MANAGEMENT ASSESSMENT



Program Design & Structure

- Benchmark current program pricing
- Alternative Risk options and feasibility
- Marketplace feedback

Coverage Review

- Identify coverage deficiencies
- Gaps in coverage identified
- Recommendations to correct w/cost implication

Claims Analysis

- Current claim trends and observations
- Comparison to 'best in class'
- Brokerage Advocacy Claim Support, ClaimSmart

Safety Assessment

- Assessment of current carrier/broker services
- Identified areas of opportunity
- C&B/SMSC support services

PLEASE DON'T HESITATE TO REACH OUT!



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Upcoming Webinars

July 16

Preventative Controls for Human Food

September 17

Pros and Cons of a Third Party Audit

November 19

Big Box Retailers

QUESTIONS?