FOOD & AGRIBUSINESS WEBINAR

HOW TO PREPARE FOR A **VISIT FROM THE FDA**

PRESENTED BY:
COTTINGHAM & BUTLER AND THE ACHESON GROUP

tag THE ACHESON GROUP

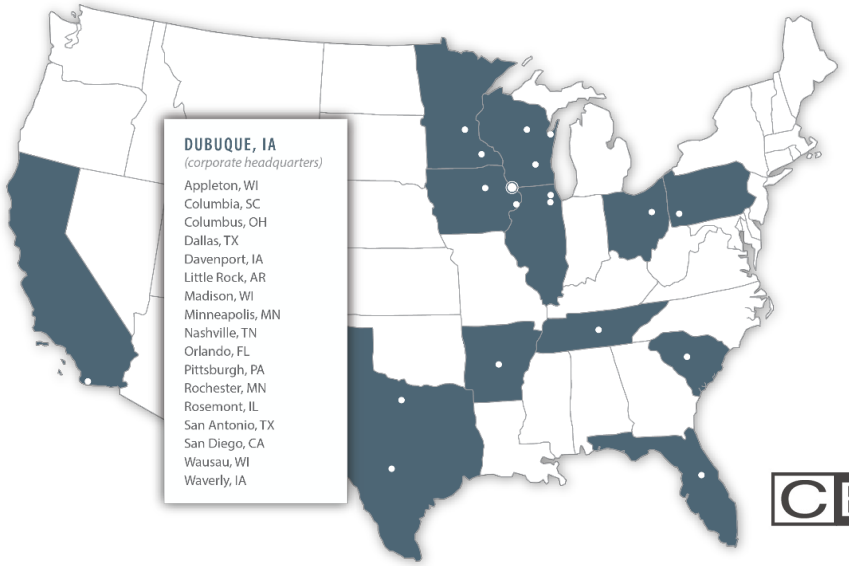
CB Cottingham & Butler

COTTINGHAM & BUTLER OVERVIEW

- Established in 1887
- Privately owned and operated
- Headquartered in Dubuque, IA, with operations in 20 states
- Over 1,000 team members
- 6th largest independent and privately held insurance broker in the U.S. (25th 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 115 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



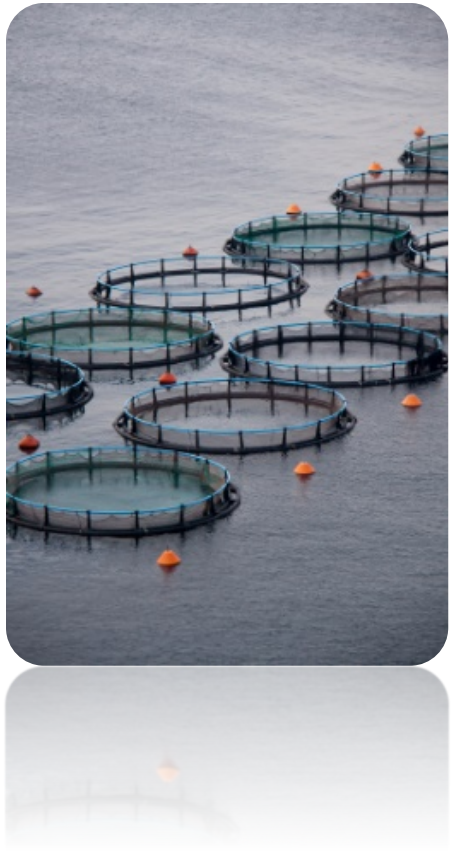
PRESENTER

DR. DAVID ACHESON

President & CEO of The Acheson Group

OVERVIEW

- Reasons for a visit
- How to prepare
- How to manage
- Follow up after a visit



ROUTINE INSPECTION

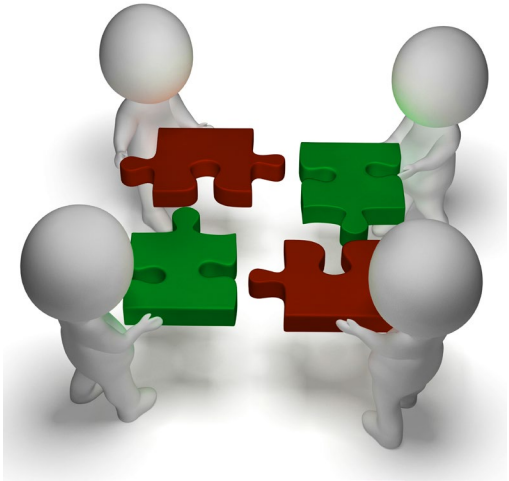
- Inspect every facility once ever five years
  - High risk every three years
  - Non-high risk every five years
- What you make
- Past history
  - Inspections
  - Recalls
- Rest of industry making the same products

ROUTINE INSPECTION

- Regular inspection – non FSMA focused
- FSMA compliance
  - Focus on specific areas of FSMA
    - Preventive controls
    - Recall plans
    - Supply chain
- GMP inspection

FOR CAUSE INSPECTION

- Following a recall you initiated
- Following a recall someone else initiated e.g. from Reportable Food Registry (RFR)
- Testing of your product by regulators
- Consumer complaint
- Epidemiological link to your product



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 lose control of it
  - Includes a third-party warehouse

EPIDEMIOLOGICAL LINK WITH YOUR FOOD

- Person gets sick with diarrhea and vomiting
- Visit to Doctor or hospital
- Stool sample taken
- Laboratory analysis of stool sample
- Diagnosis of Salmonella from testing
- Required to report it to the local health authority

INVESTIGATING FOODBORNE ILLNESS

- Local health authority
  - Salmonella isolate is sequenced using Whole Genome Sequencing by State laboratory
    - Entered into national genome database
    - Looking for matches
  - Interviews patient
    - What was eaten in the prior week
    - Where was it eaten

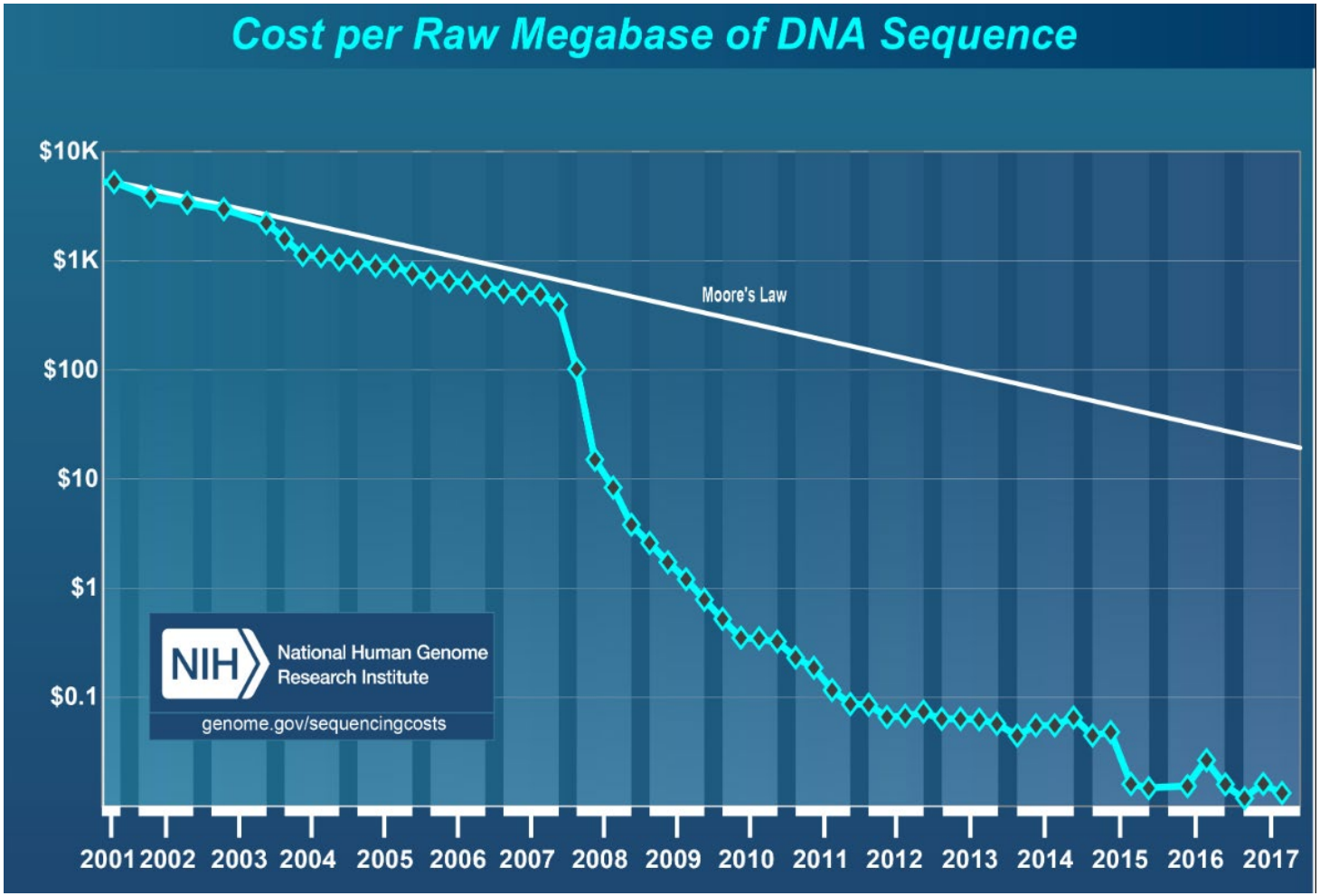
INVESTIGATING FOODBORNE ILLNESS

- More cases of Salmonella
  - Bacteria sequenced and put in database
- Same questions for patients
- Look for common patterns
  - Same food
  - Same restaurant
  - Same genetic identity
- Wide spread use of Whole Genome Sequencing

WHOLE GENOME SEQUENCING

- Massive increase in number of bacteria sequenced (8000/month)
- Regulators are mapping facilities
- Connecting human illness with facility isolates
- Aim to prevent outbreaks before they occur
- Expectations for food companies to be proactive
- Pros and cons of WGS for a food company

WHOLE GENOME SEQUENCING



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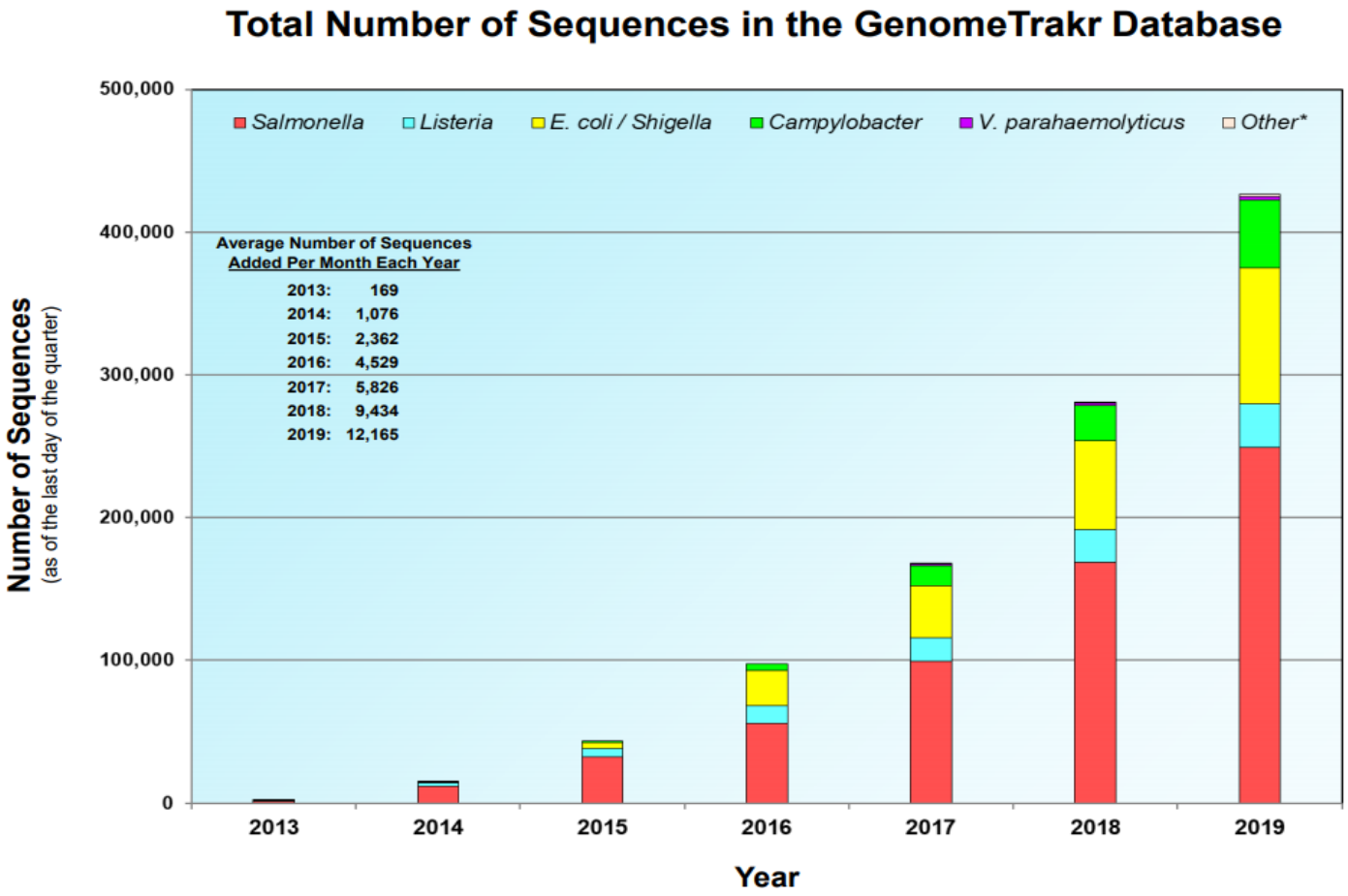


LOOKING FOR WGS MATCHES

- Isolate viewer software from NCBI:
- https://www.ncbi.nlm.nih.gov/pathogens/isolates/#/search/

THE FDA VISIT

- Usually during working hours
- Form 482 “Notice of Inspection”
- May be one or several investigators
- May be a few hours or a week or more
- Opening meeting
- Site visit – may be taking swabs
- Closing meeting

GENERAL APPROACH

- Be courteous
- Be open minded
- Do not be defensive but point out any misinterpretations FDA may be making
- Give them what they ask for – no more and no less
- Listen to what they say
- Stay with them at all times
- Do not be adversarial

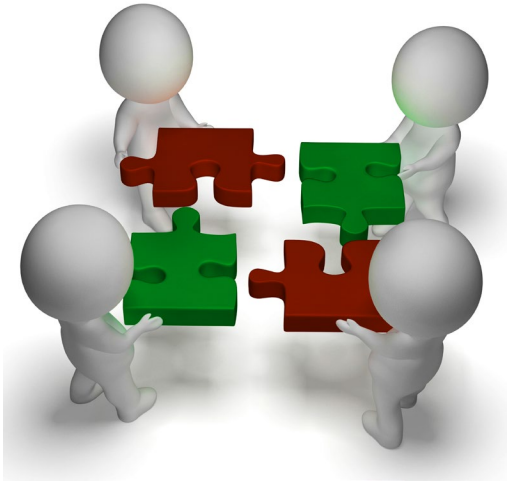
SCENARIO # 1

Two FDA Inspectors arrive at your plant's guard center at 8am on a Monday morning

- What would you do?

PREPARING FOR FDA VISIT

- Have a SOP on how to manage the visit
  - Arrival
  - Who is involved at the plant
  - Who needs to be informed at corporate
  - Where do you take them initially
- Who will be leading from the Company side
- Who will accompany the FDA
- What do you give them when they ask



SCENARIO # 2

During the introductory meeting the FDA inspectors ask to see your Food Safety Plan

- What would you do?

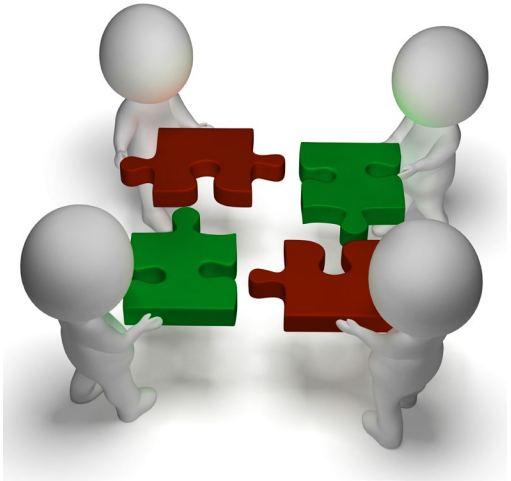
SCENARIO # 3

As you show the inspector your Food Safety Plan, the inspector asks to see the scientific explanations and rationale behind why certain agents are considered to be a hazard that requires a preventive control, and others that do not

- What would you do?

PREPARING FOR FDA VISIT

- Check your compliance documents
  - Food safety plan
    - Hazard analysis
    - Preventive controls
  - Supply chain approval
  - Foreign Supplier Verification Program if applicable
  - Monitoring is current
  - Corrective actions are current
  - Validations are current
  - Recall plan
  - Preventive Control Qualified Individual (PCQI)



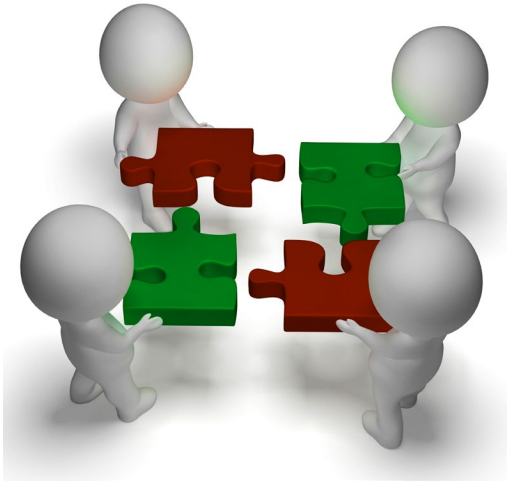
SCENARIO # 4

During a FSMA inspection, the inspector asks to see the validation studies related to your allergen control program, environmental control program and your preventive controls

- What would you do?

PREPARING FOR FDA VISIT

- Understand what FDA can ask for
- Allergen control and Environmental monitoring don't have to be validated
  - FDA can ask for everything other than
    - Recipes
    - Personnel records
    - Financial records
- Have a process to make copies of documents
- Must be available within 24 hours
- Two years of records



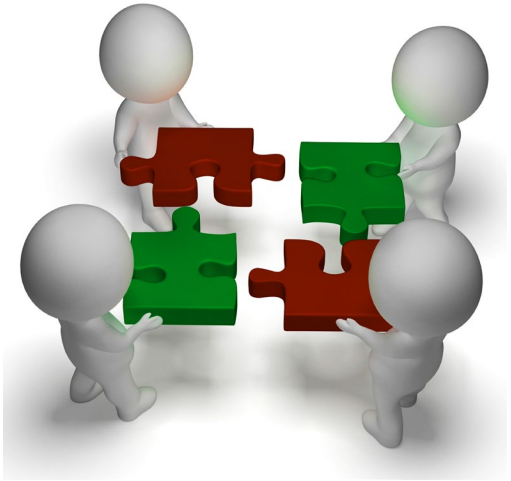
SCENARIO # 5

During the inspection the FDA inspector indicates he wants to take photographs

- How do you react to this request?

PREPARING FOR FDA VISIT

- Understand what FDA has the authority to do
- Decide where to pick your battles – if any
- Do you have a photograph policy
- If you don't allow photographs how would you handle this request
- FDA believes they have the authority to take photographs



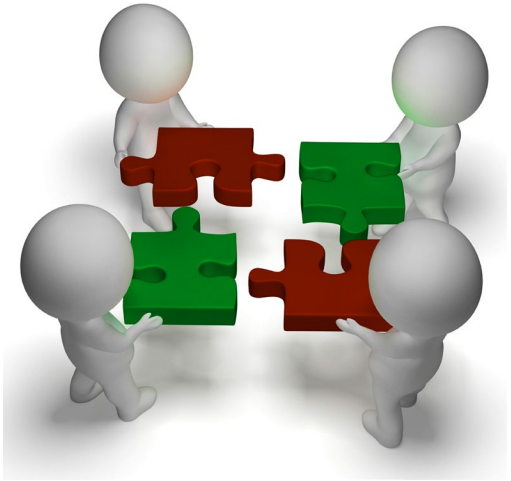
SCENARIO # 6

During the inspection the FDA inspector indicates he wants to take swabs

- How do you react to this request?

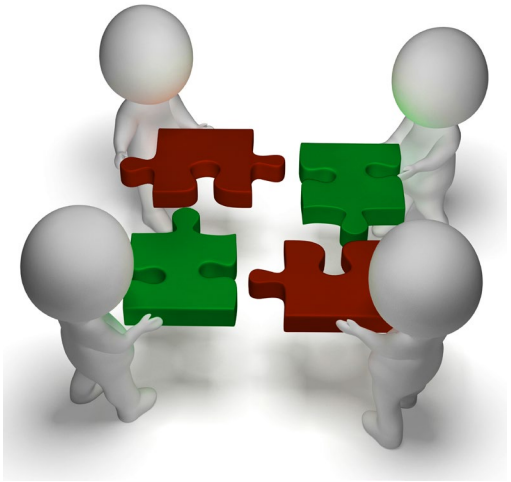
SWABATHONS

- Typically 100-300 swabs over one or two days
- Maybe during routine or for cause inspection
- Will include Zone 1
- May include finished product
- Looking for Salmonella and/or Listeria monocytogenes
- May take up to two weeks to get final results



SWABATHONS POLICY

- Taking duplicate samples
  - Pros
    - You will get an answer faster
  - Cons
    - Any positive FDA finds overrules your finding
    - If you find a positive and FDA finds a negative, you are in trouble
- Take photographs and notes of each site swabbed
- Plan for holding program for Zone 1 and finished product
- Plan for shut down/clean up post sampling



REGULATORY TOOLS

- Inspections
- Form 483
  - Companies must correct deficiencies and respond in writing
- FDA warning letter – public information
- Detention of products
- Product seizure
- Public announcements
- Mandatory recall
- Suspension of registration
- Criminal investigation

APPROPRIATE RESPONSE

- Form 483
  - Not public but available via FOIA
  - Respond in 15 business days in writing
  - Respond to all the observations with corrective actions
  - Provide time-lines of actions
  - Provide time-lines for follow up
  - Thorough response is critical
  - Prepare for repeat inspection

APPROPRIATE RESPONSE

- Warning Letter
  - Public and picked up by media
  - Significant escalation above Form 483
  - Signals lack of satisfaction in response to Form 483
  - Respond in 15 business days in writing
  - Respond to all the observations with corrective actions
  - Provide time-lines of actions
  - Provide time-lines for follow up
  - Thorough response is critical
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SUMMARY

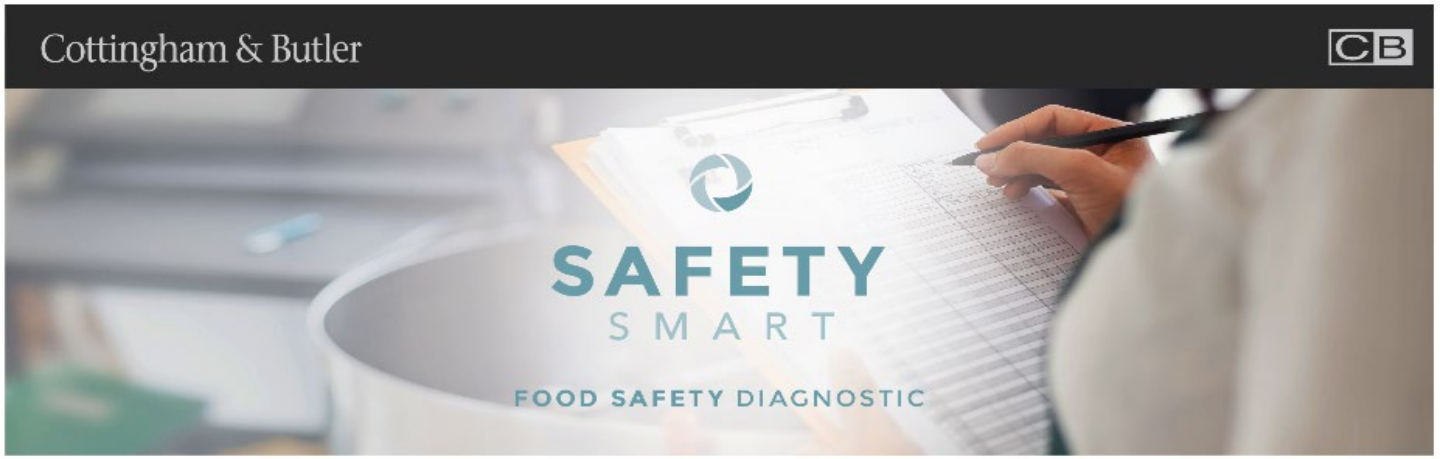
- FDA Inspection is a serious event
- Find out why the FDA is inspecting your facility
- Plan ahead and understand what the inspection is about
- Be inspection ready every day
- Know how you will respond to a Form 483
- Have outside resources available should you need them

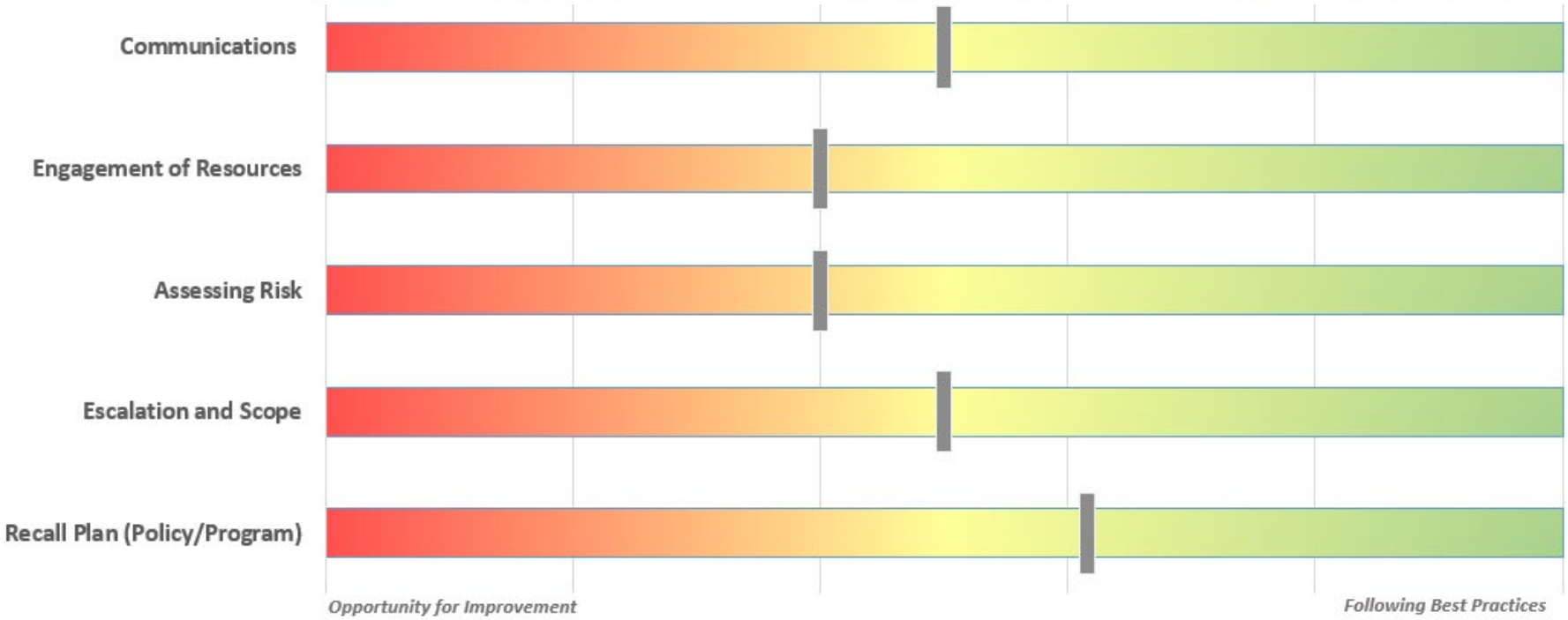
QUESTIONS?

FOOD SAFETY DIAGNOSTICS

Complete the C&B online Food SafetySMART Diagnostics to benchmark you 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

FOOD AND AG PRACTICE – FOOD SAFETY

Operational

- Program Analysis and Design:
  - Product Recall and Crisis Management
  - Internal Supply Chain Controls
  - Environmental Control and Monitoring
- Inspection and Crisis Preparedness
  - Mock Recall Simulations
  - Mock FDA Inspections
  - Hands-on Team Training

Regulatory Risk

- Compliance: FDA, USDA & CFIA Regulation, FSMA, USDA FSIS, HACCP
- Navigation and training: Managing regulatory expectations, response team to regulatory actions, HACCP and PCQI training

Reputational Risk

- 24/7 Crisis & Recall Support
- Health Hazzard Evaluations
- Social medial and executive and team communication training

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PRODUCT RECALL

INSURANCE PROGRAM

A RECALL CAN INSTANTLY SHATTER COMPANY BRAND AND PROFITABILITY

Every day, unexpected losses are costing food and agribusiness companies millions in direct cost, business interruption, brand damage and lost sales. **Can your business afford this type of loss?**

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

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PRODUCT RECALL ADVANTAGE

Cottingham & Butler's Product Recall Advantage is designed especially for food and agribusiness companies that produce goods consumed by individuals. The coverage is flexible, and tailored to each company's specific needs.

PLEASE DON'T HESITATE TO REACH OUT!

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Upcoming Webinars

May 21, 2020
Contamination of Ready to Eat Foods

August 20, 2020
Preparing for a Recall

November 19, 2020
End of Year Regulatory Update

Upcoming Events

Food & Ag Workshop| Chicago, IL
May 7, 2020

Please reach out to Molly Welu with any questions on upcoming webinars and events.

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