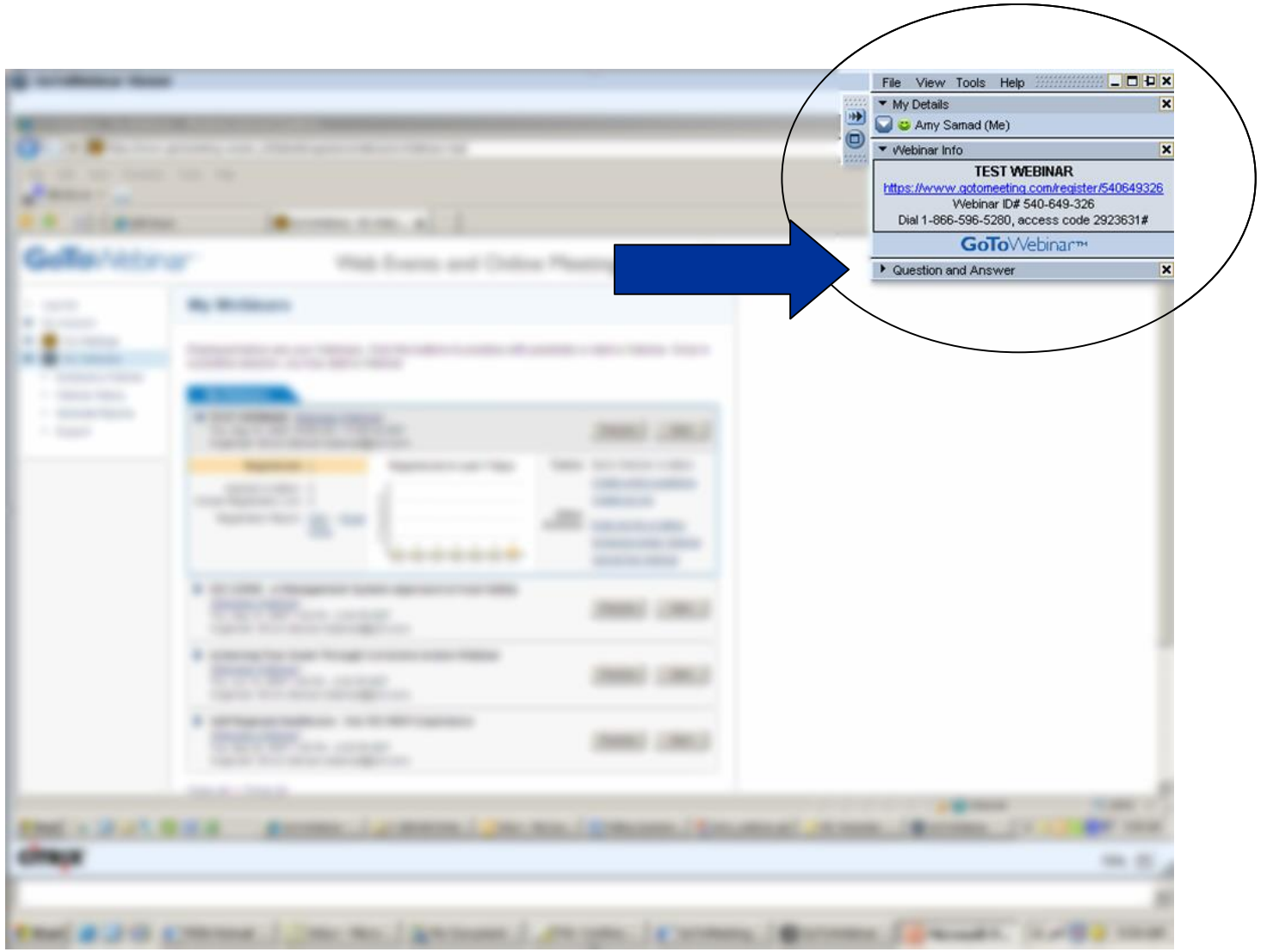
Cornell University

PJR FSI Food Safety, Inc.

Matrix SCIENCES

ENVIRONMENTAL MONITORING: TO SWAB OR NOT TO SWAB

PJRFSI – Your Partner for Food Safety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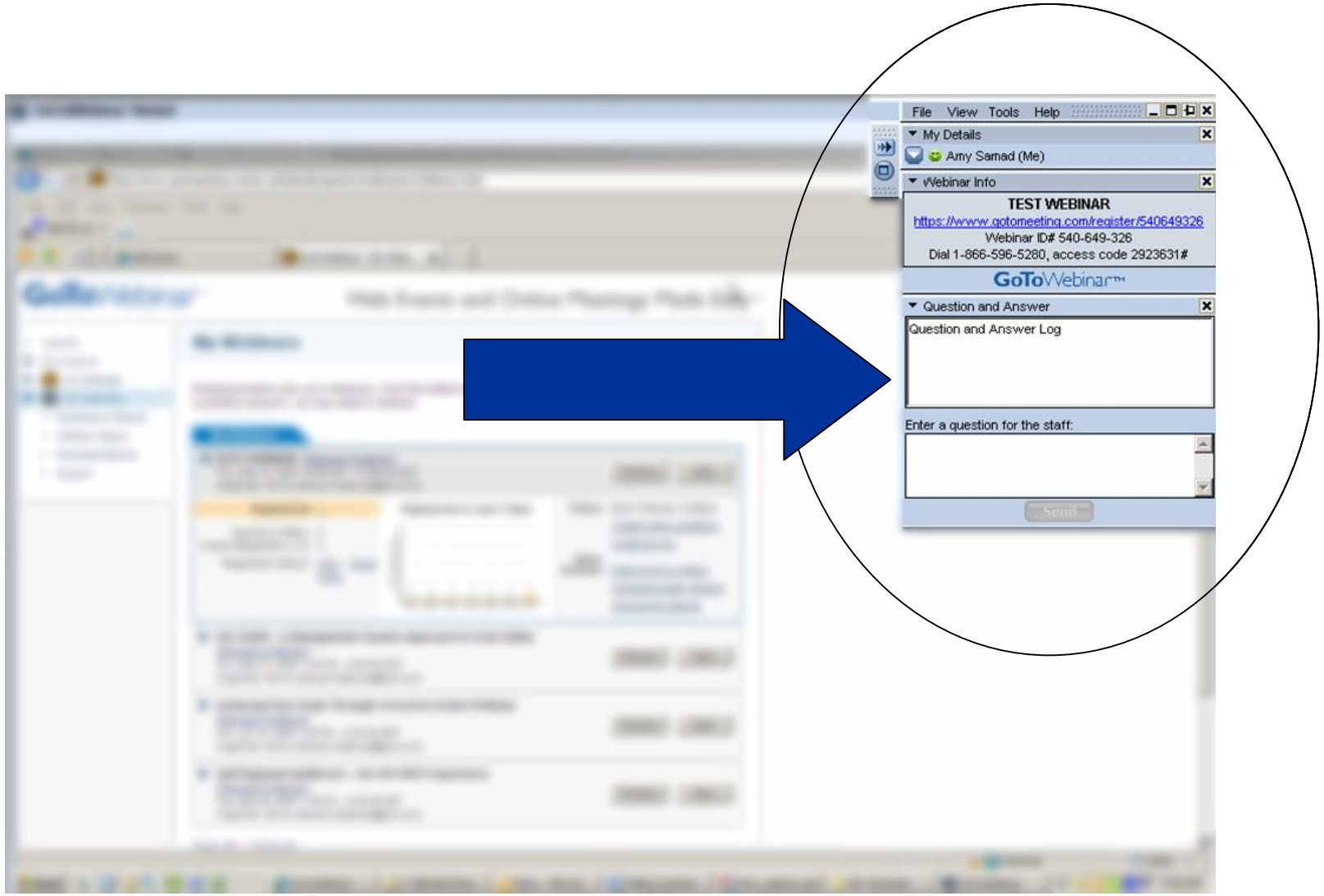
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POLLING QUESTION # 1

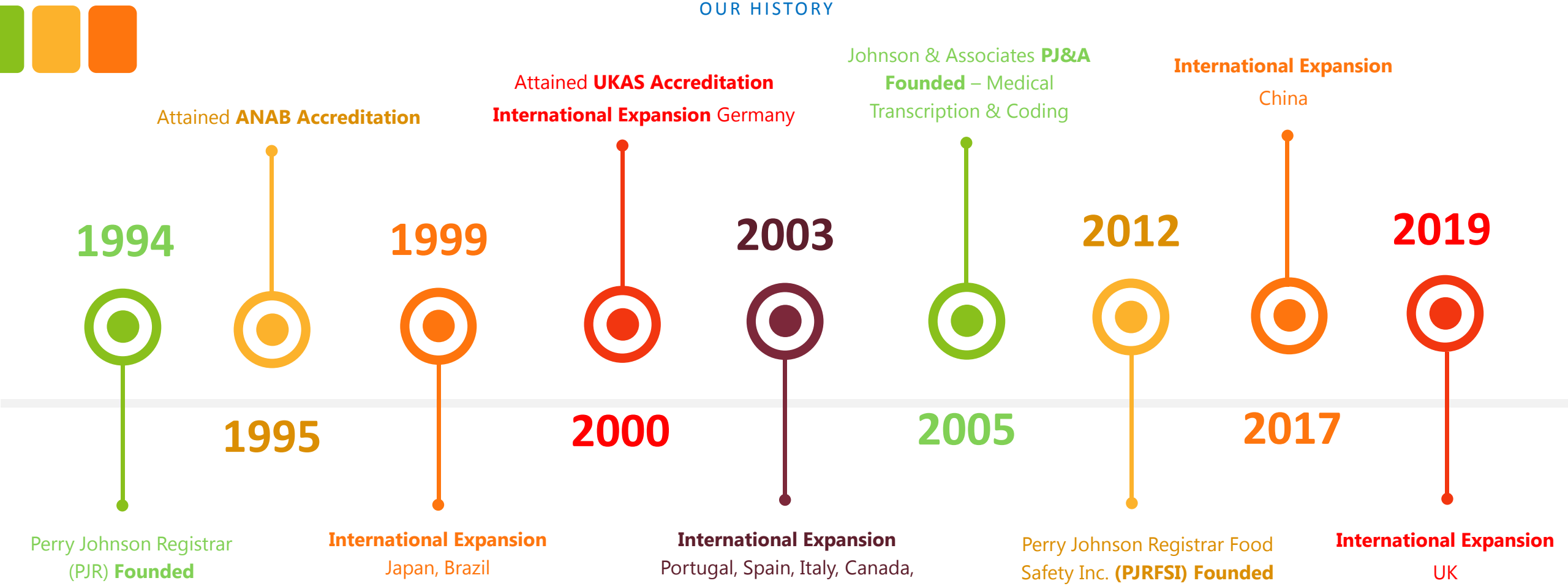
PJRFSI – Your Partner for Food Safety

Paul Damaren

Senior Vice President of Food Safety &
Supply Chain, PJRFSI

PERRY JOHNSON, FAMILY of COMPANIES

OUR HISTORY



Working with the Entire Food Supply Chain

Imports

Farm

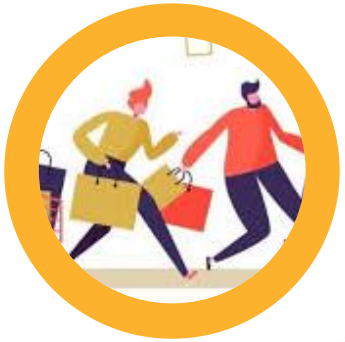
Marketer

Food Processor

Wholesaler
Distributor

Exports

Retailer



Consumer

Our Services

The Certification and Inspection industry has been deemed an essential service!
Here is a link of all Essential Services Canada
Here is a link of all Essential Services USA

Auditing & Certification

Third party risk-based certification of products and systems provides a solid infrastructure for organizations to maximize business performance, increase efficiency, drive continual improvement and manage risk.

Customer Specific & Second Party Auditing

Protect your brand and minimize recalls by building a robust supplier end-to-end program which will improve supplier processes, mitigate risk. Establish confidence your product vision is protected.

Supply Chain Solutions

Your companies supply chain is very complex and the need to manage these risks globally has never been more important. Perry Johnson Food Safety Inc. can help you control and eliminate many of the risks you face today in your supply chain.

Training Solutions

Speak to us about our customized onsite training options for your company. We conduct training to countless standards globally.

PJR FSI Food Safety, Inc.

Perry Johnson Registrars Food Safety Inc.

FOOD SAFETY & SUPPLY CHAIN

FIRST PARTY Customer Specific	Supply Chain Assessments	Food Safety, Quality, Brand Protection	Social Accountability, (SMETA, WRAP, CTPAT) EHS, OHS	Recall, Regulatory
SECOND PARTY CB Owned Protocols	GMP - Good Manufacturing Practices GAP – Good Agricultural Practices	GDP/GPP - Good Distribution/Packaging Practices	Cannabis/Hemp (Retail, Manufacturing, Cultivation)	HACCP (Seafood, Laundry)
THIRD PARTY Accredited, GFSI	SQF, BRC, FSSC,	G.R.M.A. Dietary Supplements, Cosmetics, OTC's	GLOBALG.A.P, GFCP	ISO 22000, PrimusGFS
RETAILER ADDENDA	McDonald's, Costco	Whole Foods	Custom 1st, 2nd, Party programs	Product Attribute Testing
GOVERNMENT	FSMA	FSVP	VQIP	FDA/CFIA

Recognized Globally, Applied Locally

Standards, Accreditation and Scheme Owners

BRCGS

FSSC 22000

SQF

GLOBALG.A.P.

CANADAGAP

GRMA
GLOBAL RETAILER AND MANUFACTURER ALLIANCE

primusGFS

PJLA

FDA
FDA FOOD SAFETY MODERNIZATION ACT

VQIP

PJ
PJRFSI
Cannabis Safety Certification Program

NATIONAL FOUNDATION FOR CELIAC AWARENESS
CERTIFIED GLUTEN-FREE
WWW.GF-CERT.ORG

CANADIAN CELIAC ASSOCIATION
GLUTEN-FREE
SANS GLUTEN
ASSOCIATION CANADIENNE DE LA MALADIE COELIAQUE
TM/MC

IAOB
INTERNATIONAL AUTOMOTIVE OVERSIGHT BUREAU

APAC
ASIA PACIFIC ACCREDITATION COOPERATION

ISO

ANSI ANAB
ANSI National Accreditation Board
Your partner in accreditation

JAB

ENEA

ACCREDIA
L'ENTE DI ACCREDITAMENTO

UKAS
MANAGEMENT SYSTEMS

emra

IATF

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF

ilac-MRA

PJR FSI
Food Safety, Inc.

Why Perry Johnson Food Safety?

1. **PJR – A Brand To Trust**
   - Previously recognized as the #1 reporting registrar,
     - (Source: www.iaar.org) Industry Association of Accredited Registrars
   - Over 30 Years Of Auditing

2. **Value Added Partner**
   - Complimentary plaque to every client
   - Complimentary certificate
   - Free webinar training
   - Free press release & marketing tools for your business
   - Option of virtual assessments

3. PJRFSI has the resources, capability, established infrastructure and commitment to support your mission, objectives and requirements.

4. PJRFSI will become your **trusted partner** for the following reasons:

   - Our ability to align with your organization to achieve your food risk and brand protection objectives.
   - The technical expertise of field-based audit and leadership & account management teams.
   - Delivery of real time management information.
   - Delivery of a close and transparent partnership with your organization
   - Unparalleled expertise to be your partner in food safety management system assessments.

PJR FSI
Food Safety, Inc.

POLLING QUESTION # 2

To swab or not to swab

- Martin Wiedmann
- Department of Food Science
- Cornell University, Ithaca, NY
- E-mail: mw16@cornell.edu
- Phone: 607-254-2838

Take-home messages

Summary

- Food safety issues (outbreaks and recalls) are often tracked back to failures of the pre-requisite programs (and not critical control point failures)
  - The processing plant environment and other food associated environments are important sources of pathogen and spoilage organism contamination
- “Swabbing” (aka *Environmental monitoring programs*) should be set up to **validate** and **verify** prerequisite programs (e.g., sanitation)

Industry recommendations

- Review your swabbing program and make sure it has defined goals (preferably validation and verification)
- Improve integration of “swabbing programs” that are currently separately run and managed (pathogen, ATP, allergen)
- Get an external party to stress test your system

What is swabbing?

- It is a vague term, better terms are
  - Pathogen Environmental monitoring (PEM) Program
  - Environmental monitoring program
    - Emphasizes that a comprehensive program includes testing for pathogens, indicator and index organisms (e.g., Enterobacteriaceae, Aerobic Plate count, ATP, allergens)
- PEM actually use sponges, not swabs

Why "swab"

- Goal of an environmental monitoring programs program is to (i) assure hygienic conditions of the processing environment and (ii) prevent contamination of foods from the processing plant environment
  - Robust environmental monitoring programs are particularly important for processing facilities where RTE products are exposed to the processing environment after the "kill step"
- Key hazards that are managed with environmental monitoring programs are:
  - Environmentally transmitted pathogens: *Listeria monocytogenes*, *Salmonella* and *Cronobacter* (the latter one only in facilities that process infant formula or infant formula ingredients
  - Allergens
- Environmental monitoring programs also are used to manage spoilage risks
  - Processing plant environment is the source of many spoilage organisms

Journal of Food Protection, Vol. 61, No. 10, 1998, Pages 1336–1340

Bacterial Tracking in a Dairy Production System Using Phenotypic and Ribotyping Methods

ROBERT D. RALYEA, MARTIN WIEDMANN, AND KATHRYN J. BOOR*

Food Safety Laboratory, Department of Food Science, Cornell University, Ithaca, New York 14853, USA

MS 98-2: Received 15 January 1998/Accepted 4 May 1998

ABSTRACT

Fluid milk shelf life dropped from 17 days to < 10 days

J. Dairy Sci. 94:3176–3183
doi:10.3168/jds.2011-4312

When cheese gets the blues: *Pseudomonas fluorescens* as the causative agent of cheese spoilage

N. H. Martin, S. C. Murphy, R. D. Ralyea, M. Wiedmann, and K. J. Boor[1]
Milk Quality Improvement Program, Department of Food Science, Cornell University, Ithaca, NY 14853

Why swab – let's dig deeper

- Many facilities have "organically grown" environmentally monitoring programs that serve broad goals ("control Listeria"; "verify sanitation"), but lack coordinated programs with clear goals and metrics linked to risk management
  - Need to better integrate and coordinate environmental monitoring programs
- One strategy to focus and re-organize and re-invigorate environmental monitoring programs is to focus on their use for "validation" and "verification"

Validation and Verification Procedures

Determines the validity of the Food Safety/HACCP plan and verify that the system is operating according to the plan.

Verification

Validation

Validation and Verification Example: Pasteurization

Verification

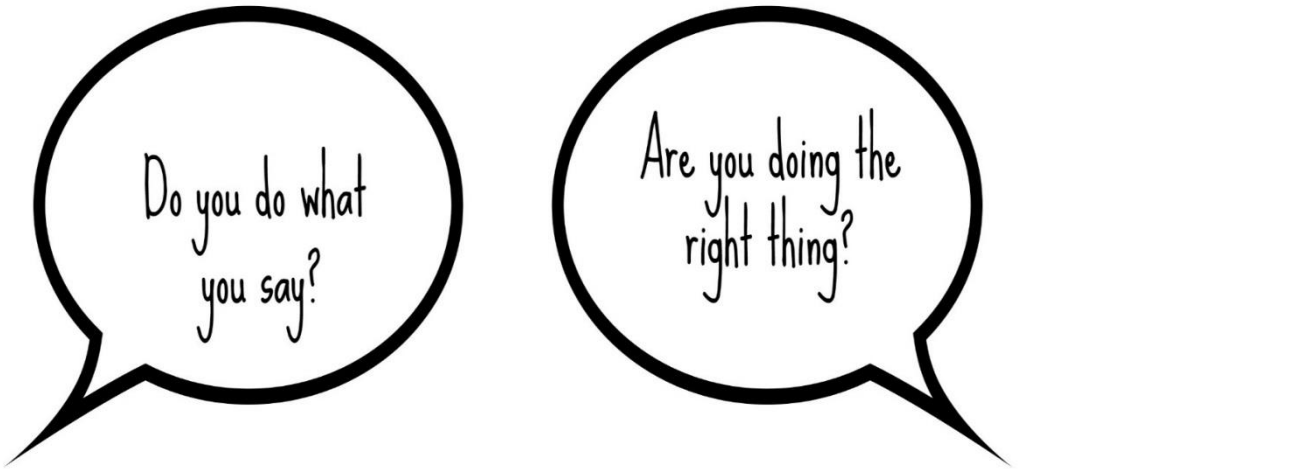
Continuous temperature recording

Validation

Scientific data that 72 C for 15 sec provides a >5 log reduction of vegetative pathogens of concern

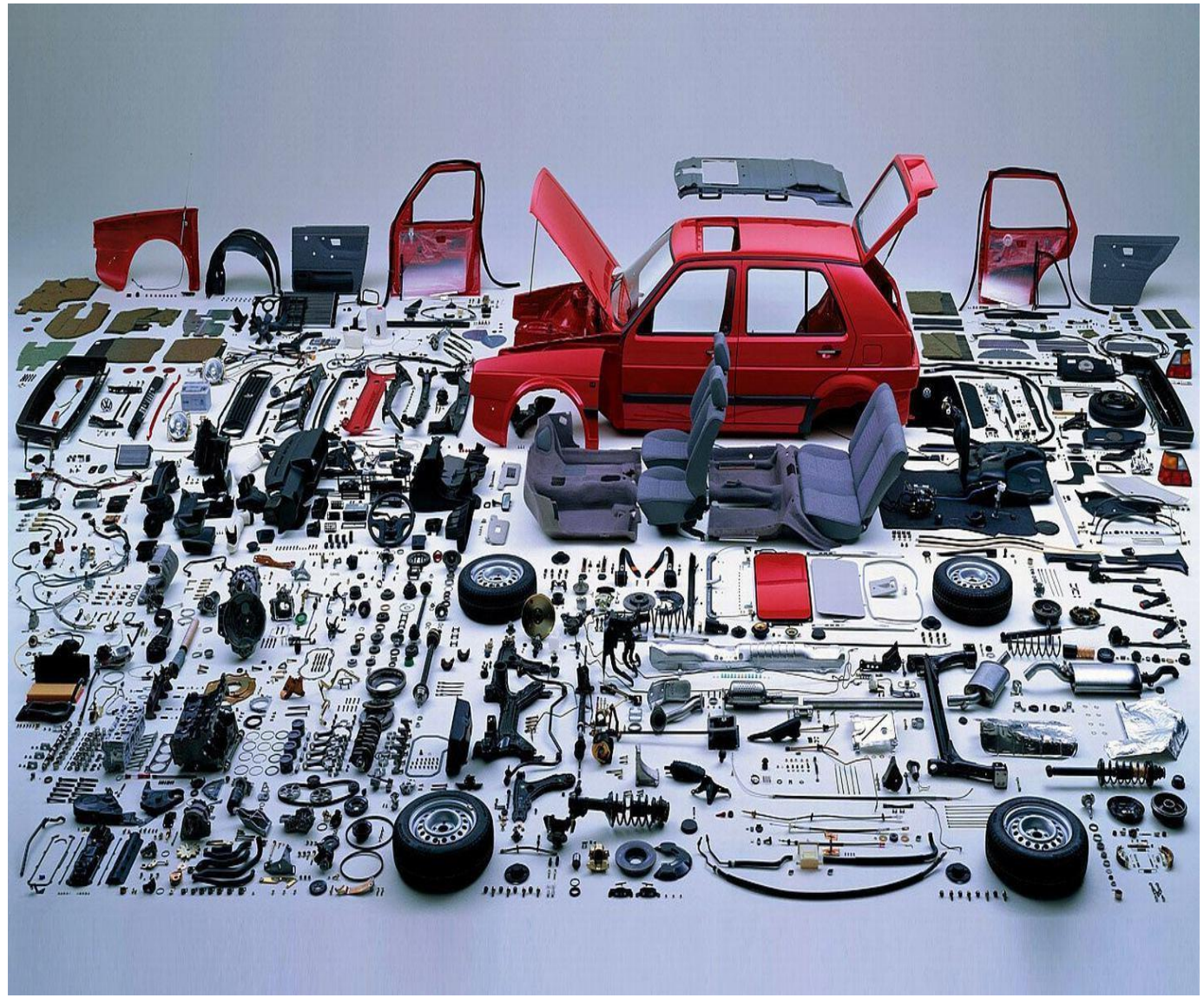
Validation and Verification: Sanitation

Lab data that a given sanitizer provides a 5 log reduction of a pathogen in a 2 x 2 inch metal chip is <u>not</u> a good validation



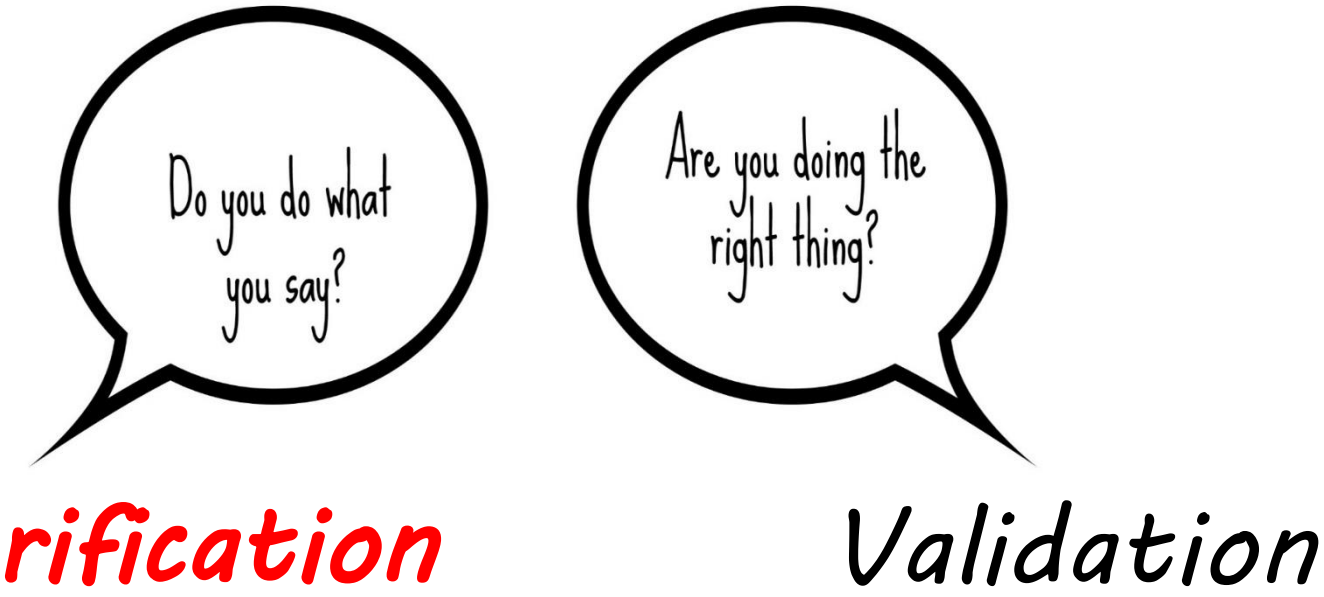
How do we develop a validated SSOP for a (new) piece of equipment

- Perform regular standardized cleaning and sanitation
- Assemble equipment and do normal start-up
- Stop before product is put onto equipment
- Disassemble to normal daily level and test with ATP, total plate count (TPC)/aerobic plate count (APC) and pathogen test
- Disassemble to the extent possible and test with ATP, total plate count (TPC)/aerobic plate count (APC) and pathogen test
- If all samples are negative/below threshold that indicates that SSOP assures effective cleaning and sanitation.



Validation and Verification: Sanitation

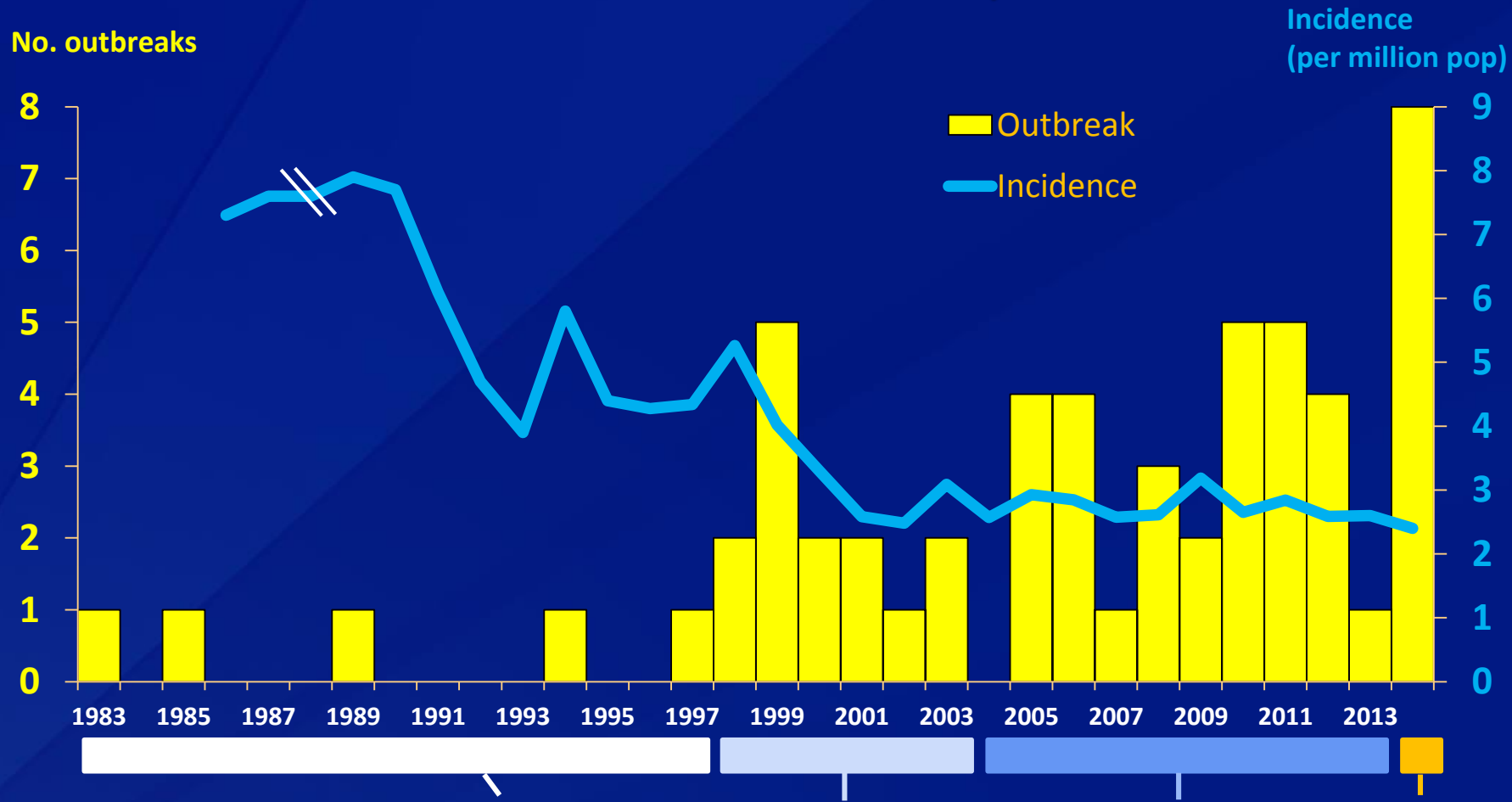
Verification sampling is your typical mandated program that focuses on swabbing during operation, but also includes other activities (sanitation logs, ATP swabbing etc.)



Why swab – we have not had an issue forever

- Whole genome sequencing
  - Detects more outbreaks and identifies pathogen persistence
- Social media

Listeria Outbreaks and Incidence, 1983-2014



Era	Pre-PulseNet	Early PulseNet	*Listeria* Initiative	WGS
Outbreaks per year	0.3	2.3	2.9	8
Median cases per outbreak	69	11	5.5	4.5

Data are preliminary and subject to change

Rachel Phillips
WARNING TO ALL PARENTS: my friend Jennifer gave her son a caprisun Saturday and he told her it tasted funny. She took a sip and said it tasted like straight alcohol. Cut it open and it was nothing but mold inside. Evidently, this happens a lot. They say the lack of preservatives [illegible] susceptible to fermentation. I will never let Delo drink another. FYI: this pouch expires April 2013 and we don't own a delorian to go "back to the future" so it wasn't expired. 🙂 God bless, have a great day! — with Rachelle Lenise Bennett, Melissa Jones Stevens, Kate Watson and 39 others.

February 4, 2013 near Dexter, MO

Karen Dean Keega, Clotiel Young, Soraya Kay and 27,142 others like this.

407,794 shares

27,145 likes
407,794 shares

https://www.facebook.com/photo.php?fbid=3665369692466&set=a.1561209289771.62897.1821484578&type=1

Does swabbing really find issues?

Plant ID	Listeria Prevalence (1 year routine program)
A	**5.1%** (34/664)
E	**11%** (88/795)
F	**<0.3%** (0/334)
G	**9.1%** (19/209)
H	**23%** (24/106)
I	**0.4%** (1/222)
J	**0.9%** (1/106)

Independent PEM program check-up (non-regulatory "swabathon")

Plant ID	Listeria Prevalence (1 year routine program)	Prevalence from non-regulatory swabathon
A	**5.1%** (34/664)	**1.3%** (2/150)
E	**11%** (88/795)	**10%** (6/60)
F	**<0.3%** (0/334)	**6.0%** (3/50)
G	**9.1%** (19/209)	**2.4%** (2/85)
H	**23%** (24/106)	**4%** (2/50)
I	**0.4%** (1/222)	**<2.0%** (0/50)
J	**0.9%** (1/106)	**14%** (7/50)

Take-home messages

Summary

- Food safety issues (outbreaks and recalls) are often tracked back to failures of the pre-requisite programs (and not critical control point failures)
  - The processing plant environment and other food associated environments are important sources of pathogen and spoilage organism contamination
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- Get an external party to stress test your system

POLLING QUESTION # 3

Environmental Monitoring- to Swab or Not to Swab

BECAUSE CONFIDENCE MATTERS

Expertise
Integrity
Communication

Melanie Neumann, J.D., M.S.
EVP and General Counsel, Matrix Sciences International, Inc.
mneumann@matrixsciences.com
www.matrixsciences.com

Key Takeaways

- Use EMP to Inform Enterprise Risk Management (ERM) process
- Translate Hazard to Risk Leveraging EMP data
- Quantify Risk in $$
- Verify Your Current Metrics
- Be Wary of Risk Landmines

Why Should I Have a Robust EMP Program?

EMP = ERM

FDA FSMA Preventive Controls Rule: Environmental Monitoring As A Verification Activity

- 117.165 (a)(3)

  Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples;

Kill step, post processing + exposed, no further kill step

USDA: Testing Requirements *Listeria*

Table 3.1 Minimum Routine Sampling Frequencies for Testing of Food Contact Surfaces (FCS) for Alternatives 1, 2, and 3.

Alternative	Daily Production Volume Ranges (lbs)**	Food Contact Surface (FCS) Testing
		Minimum Frequency*
Alternative 1		2 times/year/line (every 6 months)
Alternative 2a and 2b		4 times/year/line (quarterly)
Alternative 3 Non-deli, non-hotdogs		1 time/month/line (monthly)
Alternative 3 Deli, hotdogs HACCP Size:		
Very small	1-6,000	1 times/month/line (monthly)
Small	6,001 – 50,000	2 times/month/line (every 2 weeks)
Large	50,001->600,000	4 times/month/line (weekly)

*At least **3-5 samples** per production line should be sampled each time (every 6 months, quarterly, monthly, biweekly or weekly).
**Establishments producing deli or hotdogs under Alt. 3 may decide to collect samples based on HACCP size or production volume.

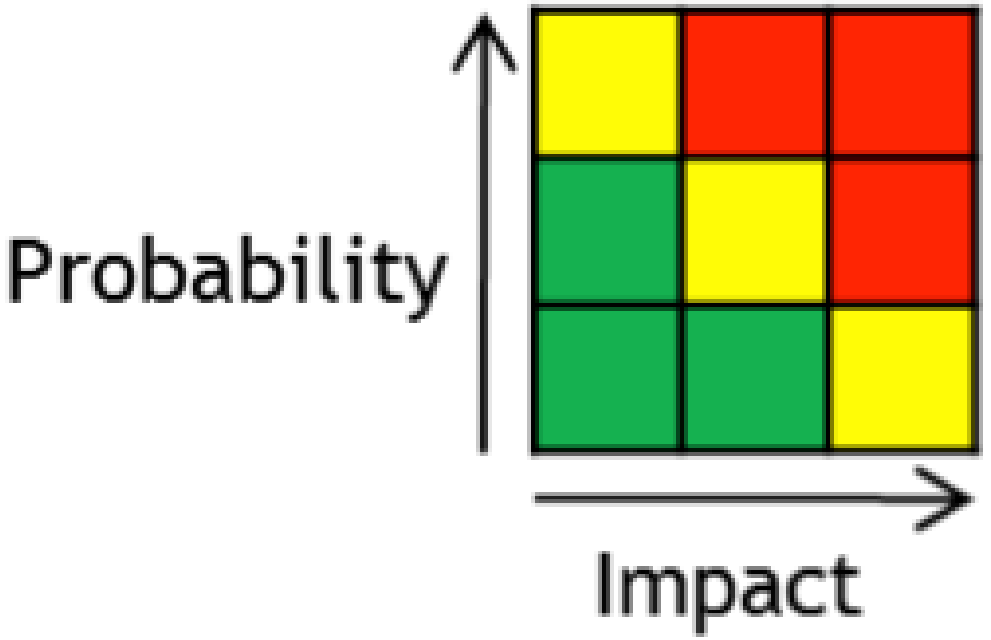
What is Enterprise Risk Management?

- Several definitions
  - A process to assist resource allocation decision making designed to
    - identify potential events (risks) that may affect the enterprise;
    - manage risk to fall within the identified risk tolerance/risk appetite; and
    - provide reasonable assurances that such risk management is being achieved (metrics)
- ERM is an enterprise-wide correlation of the risk to all other portfolio risks
- In short=A Material Balance Sheet Risk
- Sparked by financial crises of early 2000's

ERM is the discipline, culture, and control structure an organization has in place to continuously improve its risk management capabilities in a changing business and risk environment.

Examples of Enterprise Risk

- Food Safety
- IT; Cyber-Security
- Exchange Rates
- Commodity Prices
- Labor / Union
- Epidemics/Pandemics
- Workforce Injuries
- Retention of critical employees



Example of How One Company Applies ERM

2017 Sustainability Report

Table of Contents

Governance & Management

- Materiality Analysis
- Ethics & Compliance
- Sustainability Management +
- Enterprise Risk Management
- Supply Chain Management
- Sustainability Goals & Targets
- Stakeholder Engagement +
- Public Policy

Enterprise Risk Management

Risk management continues to be an important concept for [redacted]. We continue to enhance our Enterprise Risk Management (ERM) program as part of an effort to promote an aligned, integrated ERM framework across the entire company.

Our ERM program is based on the Committee of Sponsoring Organizations of the Treadway Commission (COSO)[1] ERM Integrated Framework. The objective of our ERM program is to have a sustainable process in place that can identify complex and emerging risks (both internal and external) that, if not addressed, might prohibit us from achieving our strategic, financial, and compliance objectives.

Through our parent company's [redacted] listing on the Hong Kong Exchange (HKE), [redacted] is required to demonstrate that an effective ERM program is in place. This HKE requirement took effect for fiscal years ending as of Dec. 31, 2016. The [redacted], must demonstrate that we have a formalized ERM program that includes, but is not limited to, risk identification and annual risk assessment, mitigation processes and controls, management and monitoring of key risks areas, and timely and effective reporting.

How EMP Data Helps Translate "Hazard" into "Risk" –"Back of Napkin" Calculation

Matrix SCIENCES

Hazard/Issue	Operational Risk(O) Impact (Low $/High$)	Regulatory Risk(R) Impact (Low$/High$)	Reputation Risk (R) Impact (Low$/High$)	Metrics
Environmental pathogens (Listeria)	One line-one day($10,000) Entire plant-multiple days ($500,000) -Downtime	One line-one day ($50,000); Entire plant-multiple days ($10M) Downtime + recall	Temporary customer/consumer confidence loss (e.g., 3 mo. X 30% sales loss); permanent loss of customers(s)/loss of product from the market (e.g., annual /future sales of product)	Environmental monitoring program Listeria <2% Sanitation program >98% passing

Add ORR Risk $ Low X Low Likelihood %
Add ORR Risk $ High X High Likelihood %
Determine Risk Mean

Risk Landmines :

- Swab-a-thons/Duplicate Swabs
- Starting testing for microbes not in existing EMP plan
- Handling of results/documentation
- Consider risk assessment under attorney client privilege
- Adopt a “Test yet Protect” approach

Key Points to Remember

- *EMP programs are critical to Enterprise Risk Management*
- Leverage EMP data to translate and communicate risk
- Confirm current metrics are effective
- Look out for Landmines

ERM is the discipline, culture, and control structure an organization has in place to continuously improve its risk management capabilities in a changing business and risk environment.

POLLING QUESTION # 4

UPCOMING WEBINARS


Date: Tuesday February 16th, 2021 – 2pm est.
Webinar Title - Ethical Trade & Responsible Sourcing in 2021
Webinar Description - BRCGS, an introduction to version 2 of Ethical Trade and Responsible Sourcing. Why is ethical trade and responsible sourcing important to
your brand and how can it be used in North America to grow your business.
Speakers:

- Jessica Burke, Delivery Partner Relationship Manager, BRCGS
- Paula Parejo, Marketing Strategist, BRCGS


Date: Thursday February 18th, 2021 – 2pm est.
Webinar Title - Enterprise Risk Management - Volume 1 - Effectively Communicating Risks from the Shop Floor to the Boardroom
Webinar Description - Join Neil Marshall, Managing Director of Guv Consulting International LLC, former GFSI Board member and former Global Director Quality & Food Safety at The Coca-Cola Company along with Giannis Stoitsis, Co-Founder and Chief Information Officer of Agroknow as they discuss the keys to risk and prevention, Horizon Scanning and using technology to actually "predict" risk in your business. You will hear about tools you can use to support your company's objectives.
Speakers:

- Neil Marshall, Managing Partner, Guv Consulting International LLC, former GFSI Board member and former Global Director Quality & Food Safety at The Coca-Cola Company
- Giannis Stoitsis, Co-Founder and Chief Information Officer of Agroknow

Date: Tuesday February 23rd, 2021 – 2pm est.
Webinar Title: FSVP & FSMA, A Detailed Overview, 2020 Recap & 2021 Expectations
Webinar Description - Revisit the legislative history, the requirements of FSVP, 2020 FSVP inspection report and the potential outlook for FSVP in 2021.
Speakers:

- Jennifer Crandall, CEO & Co-Founder

https://www.pjrfsi.com/webinars/

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