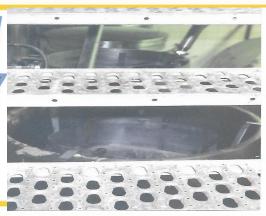
Legacy Facilities & Legacy Equipment: Impact on Achieving Food Safety











Sara Mortimore
Panelist

Larry Keener Moderator

Nick Rowley
Panelist

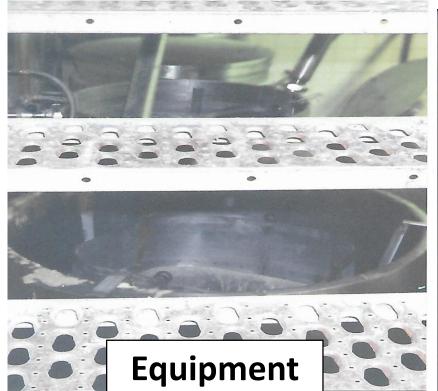
Liz Presnell, Esq.
Panelist

The Challenge: "Sweating the Assets"



"Legacy facilities and the legacy food processing equipment operating in those facilities represent the industry's greatest threat to food safety"

(L. Keener – Houston Chronicle and Austin American Statesman 2016)







Floors & Drains

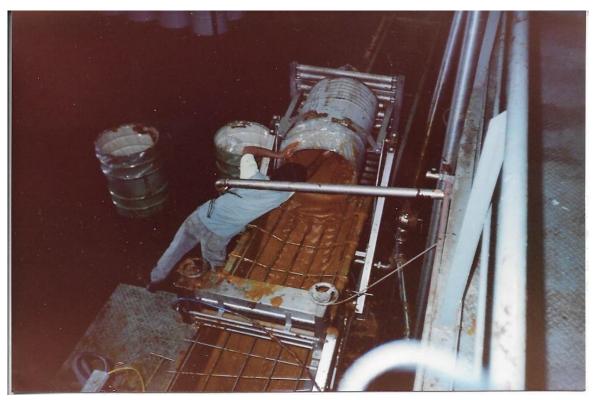
Buildings & Structures

Sweating the Assets and Accepting the increased Risk of Food Safety Failures



The <u>challenge</u> of Legacy Equipment and Facilities is far greater than the ability of the "willing worker" to overcome and the outcomes for <u>Food Safety</u> are predictable





Hygienic Design Principles for Equipment and Facilities to prevent product adulteration and promote Food Safety Assurance is comparatively new to the industry

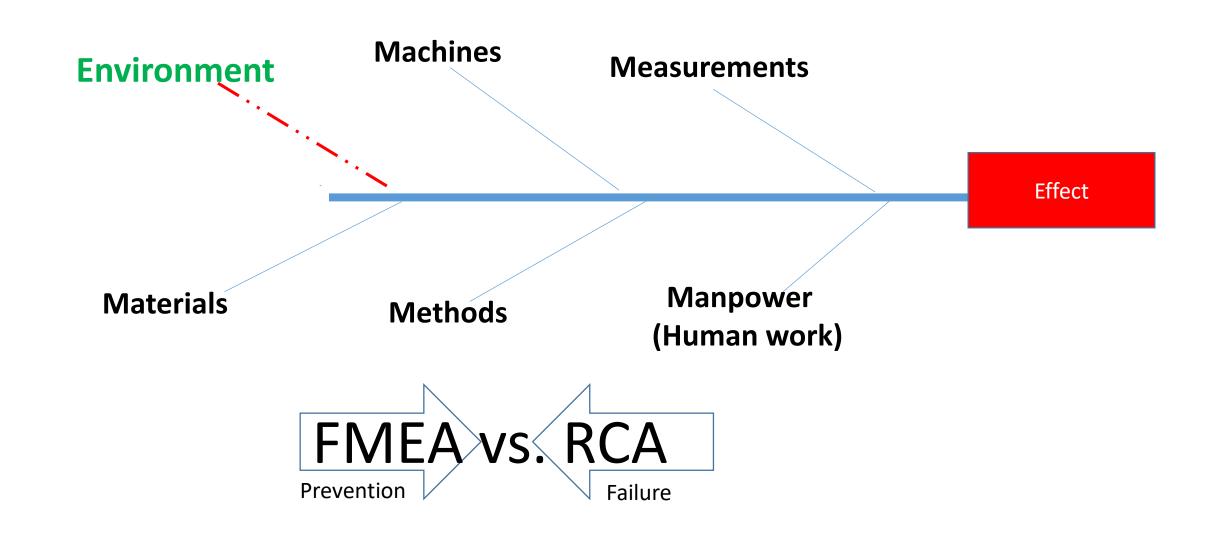
What is Hygienic Design?

Hygienic Design refers to the design, materials of construction and the installation of all components and appurtenances of food processing machinery, as well as the architectural design and construction of the food processing facility, in order to promote cleaning and to reduce the risk of contaminating food products with hazardous substances that would cause the food to become injurious to the public health (food safety).

European Hygienic Engineering and Design Group (1989)

3A Sanitary Standards (1920 US Dairy Industry)

Hygienic Design impacts every aspect of facility and production operations



"The State of Food Manufacturing"

Food Engineering Magazine Survey Aug. 2023

Survey Question - Requirements for Productivity Improvements?

- **Equipment upgrades** 80% ranked **1/20**
- Improve maintenance systems 67% ranked 4/20
- Increase *flexibility* on existing lines 56% ranked 9/20
 - Retrofit and upgrade facilities 56% ranked 10/20
- Improve overall equipment effectiveness reporting 54% ranked 12/20

Nearly 50% of survey respondents expected increased budgets for **production and processing**<u>equipment</u> in the range of about 23%

Sweating the Assets = Accepting the increased Risk of Food Safety Failures



Legacy Facilities & Legacy Equipment: Impact on Food Safety

Our Expert Panel:

Sara Mortimore - Industry Consultant
Nick Rowley - Global Director Sanitation — Kellanova Corp.
Liz Presnell, Esq. — Food Industry Counsel LLC





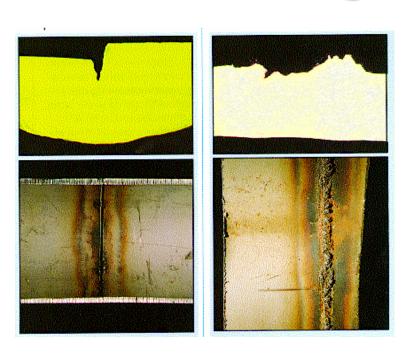


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"Sweating the Assets, accepting the Risk"



Food Safety Summit Legacy Facilities and Equipment: "Sweating the Assets, accepting the Risk"



Order of Discussion

Sara Mortimore
Nick Rowley
Liz Presnell
Q&A







Legacy Facilities and Legacy Equipment and their impact on Food Safety Assurance



Sara Mortimore May 2024



Inadequate infrastructure, inappropriate equipment and sanitation program is a common barrier to having an effective program

- Buildings Design
 - Hygienic Fabric
 - Hygienic zoning/work-flow
 - Utilities
 - Employee facilities
- Equipment
 - Appropriate for the task
 - Hygienic design
 - Process capability

Key messages

- Majority of process facilities have opportunities for improvement
 - Manufacturing, foodservice and retail
 - Legacy or new construction
- Knowledge is key to managing what you have and reducing risk





Strengthening the risk-based preventive control program

A practical hazard analysis and risk assessment process can be applied to hygienic design continuous improvement and prioritized capital planning

Understand:

- The product and its intended use
- The plant layout, the HACCP Process Flow Diagrams, and relook at the hazard analysis
- The ongoing plant hygiene profile, verified through inspection, EMP, and audit.

Evaluate:

- Sources and vectors of hazards
- Best practice preventive control measures
 short term and longer term
- What the data is telling you





Understanding what makes the product safe is important in determining a risk management strategy

- How safe is the product due to its recipe and inherent safety factors?
- e.g. formulation controls such as pH, Aw, preservatives etc.

Intrinsic factors

Raw materials and supply chain controls

- Likely presence of microbiological, toxicological, allergen, physical hazards
- Are potential hazards controlled by the supplier or at the facility?
- Is packaging required for food safety?

Likelihood of abuse, alternative use, and consequences

Principle process steps and operating environment

- Does the process include pathogen reduction steps?
- Where in the process is the product considered "safe"?
- Is hygienic zoning required for food safety?

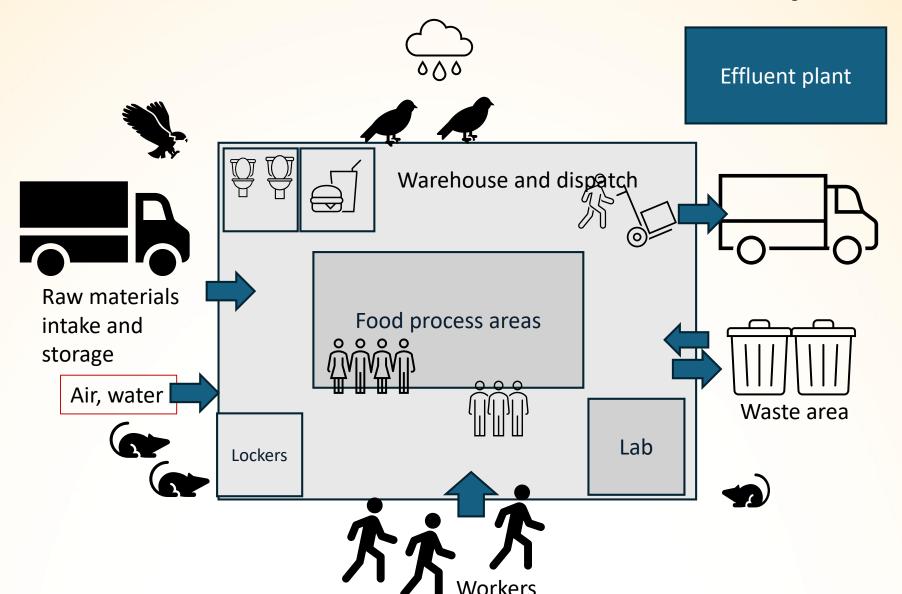


- What happens if the product is contaminated e.g. growth, survival?
- How could the consumer use it differently than designed?
- Storage/distribution makes the product more/less safe?



Main routes of contamination into a food plant







Identifying and controlling sources and vectors of contamination

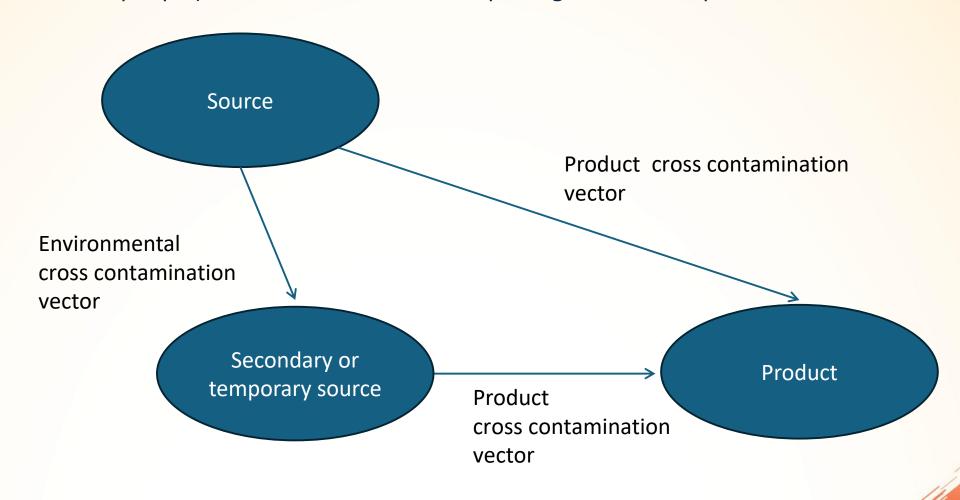
Sources of product contamination include:

- Harborage sites physical areas in which pathogens can lodge (survive) and be protected from cleaning and disinfection actions
- Growth niche a harborage site that provides an environment suitable for growth, i.e. food, water, temperature, oxygen and lack of competition from other microbial flora



Contamination: understanding sources and vectors

Vectors of contamination are anything (air, water and other liquids, physical objects, pests or people) that carries or transfers a pathogen from one place to another





Control of microorganisms in the processing environment: plant and equipment

Control **SOURCES** of contamination

Control entry

Kill or remove

Control **VECTORS** of contamination

Control transfer

Control growth

Control of microorganisms in the processing environment: plant and equipment

Control **SOURCES** of contamination

- Raw material control (supply chain preventive controls)
- Utilities (air, water)
- Pest control
- People:
 - Hygienic work wear and entry procedures,
 - Contractor, construction and visitor procedures

Kill or remove

- Hazard reduction step e.g. heat kill
- Cleaning and sanitation procedures
- Sanitary design of equipment and facility for cleanability

- Control of water
- Sanitary design of equipment and facilities (harborage and niche areas)
- Frequency of cleaning and sanitation
- Time/temp control

Control growth

Control **VECTORS** of contamination

Control transfer

- Raw material and personnel traffic patterns and hygiene junctures
- Separation of pre- and postlethality areas
- Control of product and environmental vectors



Prevent entry





Manufacturing plants:

- Most facilities and equipment have challenges – legacy or new build
- Understanding the plant and the risks through critical inspection, EMP, and 3rd party expert input can be helpful

Retail:

- Facilities/equipment capability and improvement needs must be evaluated to be understood
- Legacy and new facilities may have challenges – the implications will be related to what they are processing and selling







A practical hazard analysis can be used to prioritize the improvement needs and manage CAPEX based on risk

Process step or area of plant	Issue identified	Likely hazard associated with issue?	Vector identified?	Likelihood of occurrence H/M/L	Severity if present H/M/L	Sort term risk mitigation plan	CAPA and Verified as completed and effective Yes/No? Date:	If no then when? Date:	Longer term mitigation plan	Cost estimate	Approval	Timing: Year 1/2/3	CAPA verified as complete and effective? Date:



This will include short and longer terms improvements and may span multiple years.

Poor hygienic design alone does not always lead to unsafe food.

Rigorously applied food safety knowledge and can make the difference between

having a well managed facility with inadequate infrastructure and one that is taking unnecessary risk



Management Responsibility





Thank you

Sara Mortimore

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H. L. M. Lelieveld and J. T. Holah, *Hazards, sources and vectors of contamination* in Hygiene in food processing: Principles and Practice (Second edition). Eds. H.L.M. Lelieveld, J. Holah and D. Napper, Woodhead Publishing. 2013

J.T. Holah et al. Identifying and Controlling Microbiological Cross-Contamination, Food Safety magazine, 2012

HYGIENIC DESIGNIN PRACTICE

(May 2024)

- Nick Rowley
- > Kellanova
- Director, Global Sanitation



WHY - HYGIENIC DESIGN

- Upfront costs are miniscule compared to long-term losses / remediation
 - Ongoing Sanitation Labor, chemicals (Time & Effort)
 - Remediation from events (Pests, Pathogens)



SANITARY DESIGN





















EUROPEAN HYGIENIC ENGINEERING & DESIGN GROUP 3-A SANITARY STANDARDS

AMI formerly
NORTH
AMERICAN
MEAT
(MEAT, DAIRY
AND FRESH
CUT PRODUCE
INDUSTRY)

CBA formerly GMA INSTITUTE (LOW MOISTURE FOODS)

NATIONAL SANITATION FOUNDATION

FOOD & DRUG ADMINISTR ATION, FSMA INTERNATION
AL
ORGANIZATIO
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STANDARDIZA
TION

FSSC22000

BUILD HD CAPABILITY

- 1. Organize a HD Community / Committee
 - Cross-Functional Team
- 2. Develop Standards & Assessment Strategy
 - Personal Safety vs. Food Safety
- 3. Communicate Standards, Develop Training
- 4. Deliver Training / Capability to perform Assessments
- 5. Execute Plan to Assess & Address defects

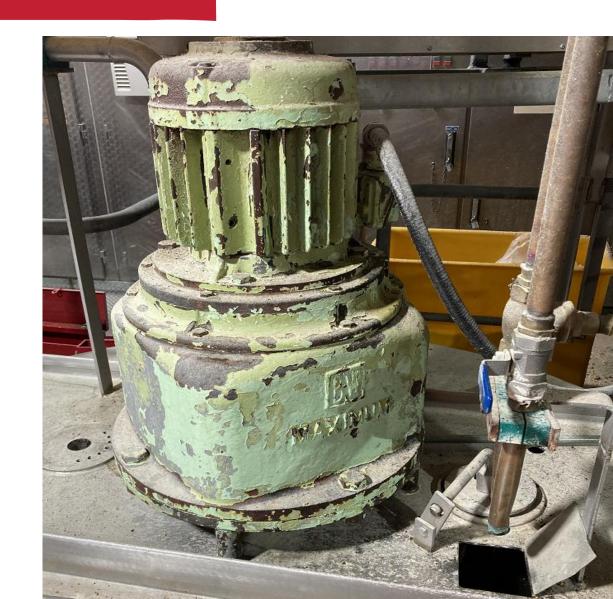
HD CHECKLIST STRATEGY

Old Equipment, Tools, Bins, Containers, Infrastructure, Utilities

New Equipment

- Factory Acceptance Testing
- Build into Engineering System

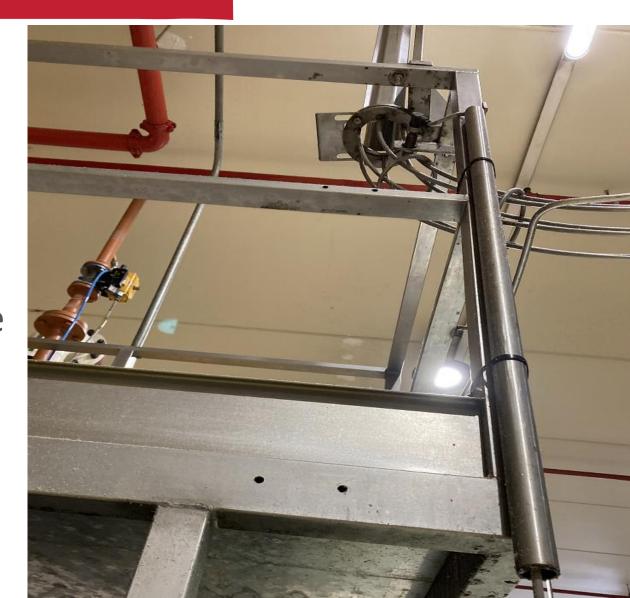




HOW DO WE ASSESS LEGACY

Strategies:

- 1. Systematic, Line by Line, Area by Area
- 2. For Cause ATP, EMP trend
- 3. Target Legacy Technologies (close or beyond amortized value)



WET VS. DRY CLEAN

Key differences in Design Standard

- BOTH need to meet standards of cleaning
 - Allergen Free, Gluten Free
 - Pathogen Free

EASILY CLEANABLE! READILY ACCESSIBLE!

- Effectiveness always first
- Efficiency is key business enabler
- MORE Difficult to Dry Clean poor HD equipment/facility



Legacy Facilities and Equipment: Diligence Required



"GOING ALL-IN FOR FOOD AND ALL-OUT FOR THOSE WHO PRODUCE IT"

Liz Presnell
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201-606-3182

What Risks Exist

- Historical Uses of the Equipment/Facility
- Resident Organisms Environmental Monitoring
- Historical Regulatory Interactions
- Design
- Suitability for Intended Use

Investigate Thoroughly

- Independent Research
 - FDA Records and State/Local Regulatory Inspection Records
 - Investigational Environmental Monitoring

Ask Questions

 Conduct a Hazard Analysis to Evaluate Risks – Take Action as Appropriate



Potential Risks

- Regulatory Action
- Foodborne Illness or Outbreak
- Brand Reputational Harm
- Civil Damages
- Criminal Charges Individual and Company



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