



Applying the Principles of Microbiological Process Control and Sanitary Design

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Data Driven Sanitary Design Improvements

Principle

- A **principle** is a fundamental truth or proposition that serves as the foundation for a system of beliefs or behavior or a chain of reasoning. That is a guide for behavior or evaluation. In [law](#), it is a [rule](#) that has to be or usually is to be followed.

-From Wikipedia

Learning Objectives

- The Value of Applying of the Principals of Sanitary Design for Microbial Process Control
- Measurement of Sanitary Design & Sanitation Effectiveness
- The Interaction of Sanitary Design and Sanitation
- How to Communicate Sanitary Design Issues
- Demonstrate Improvements of Sanitary Equipment Design



Microbiological Process Control

- **Principles**

- Identifying and Controlling Growth Niches & Harborage Sites by:
 - Sampling
 - Investigative (Seek & Destroy)
 - Process Control
 - Verification
 - Cleaning
 - Sanitization
 - Sanitary Design

The Value of Applying of the Principals of Sanitary Design

- Principles provide guidance.
- Principles educate
- “Best Practices” and Preventive Controls are deployed to address problems defined by principles



Measurement of Sanitary Design & Sanitation Effectiveness

Preventive and Predictive Measures Include:

- Seek and Destroy Investigations
- Process Control Indicator Sites

The Interaction of Sanitary Design and Sanitation

Accessibility

Thank You!

FOOD SAFETY BY DESIGN

AWARENESS

ENLIGHTENMENT

PREVENTATIVE

PREDICTIVE

Data Driven Food Safety Consulting Focused to Prevent

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Improving Hygienic Design Through Collaboration



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Introduction

- Through the Meat Institute, Marel approached Maple Leaf Foods and began a collaboration between equipment manufacturer and customer to validate the hygienic design modifications made to the 2800 peeling machine.
- Hygienic design improvements were validated through swabbing.
- Hygienic design improvements were evaluated by the effectiveness of daily sanitation and by the frequency required for non-daily sanitation tasks.



Equipment Design & Operation

Infeed – Cased Joined Links



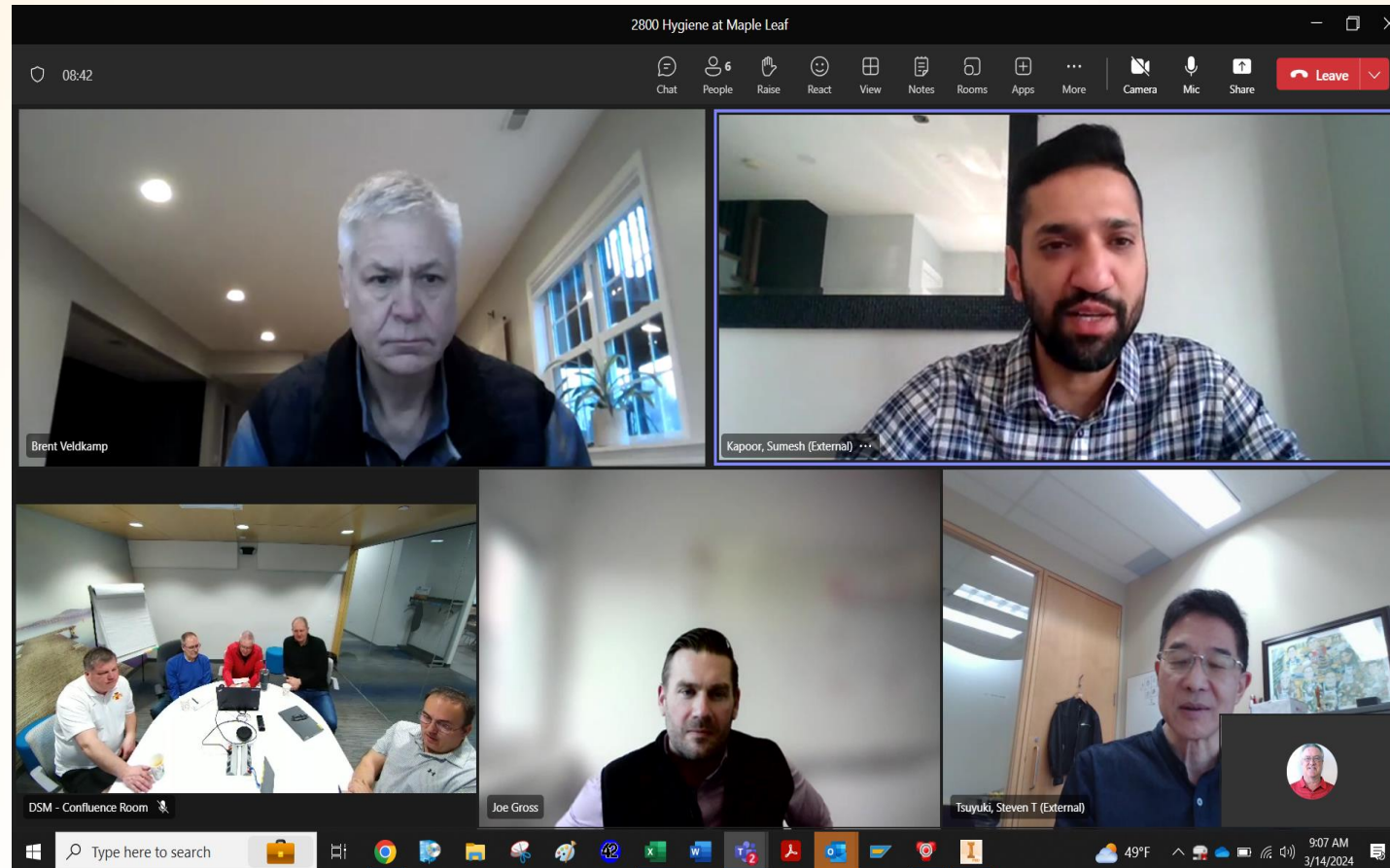
Discharge – Peeled Units



Improved Hygienic Design Changes

- 1. Housing redesigned:**
Reduced critical corners to meet AMI, NSF, USDA and EC standards.
More open to increase accessibility when cleaning.
- 2. Peeler head and tombstone construction modified:** to a single base frame to eliminates flange with gasket between the two parts.
- 3. Base plate replaced with stainless steel 316:** to avoid corrosion from steam, smoking acids, and salts carried into the housing and heated by the steam.
- 4. Door on the backside of the machine is enlarged:** to allow easier access inside the unit for cleaning.
- 5. Electrical components are mounted in the top corner of the machine and shielded:**
Cleaning inside the machine is less obstructed.

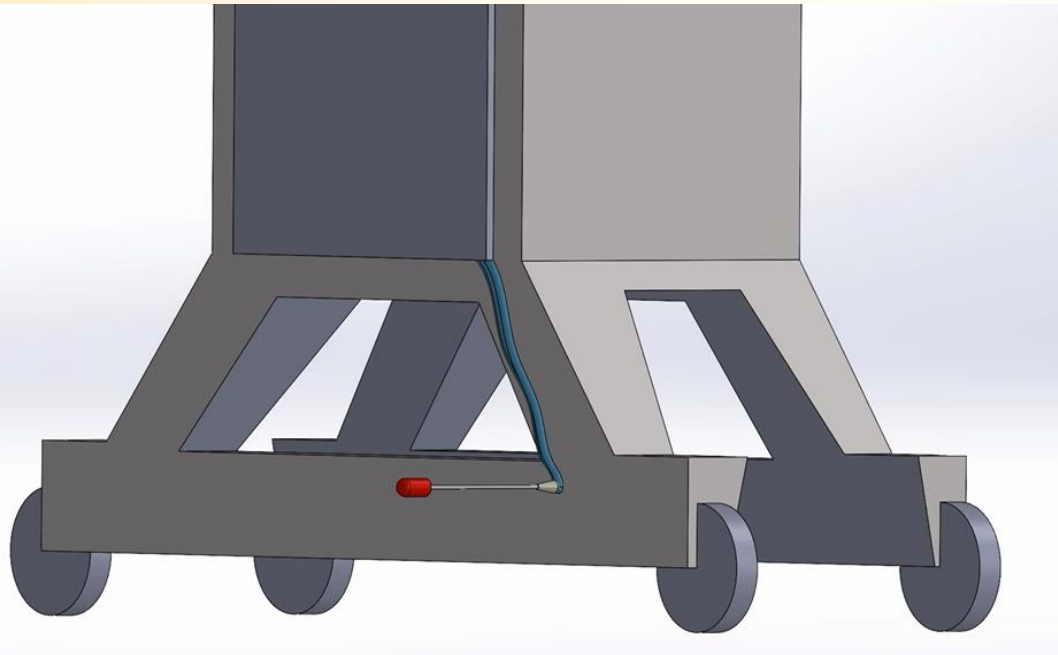
Active Collaboration



Regular biweekly meetings between Marel and Maple Leaf Foods to share results and to have an open discussion on findings.

Rinsate Swabbing – “Game Changer”

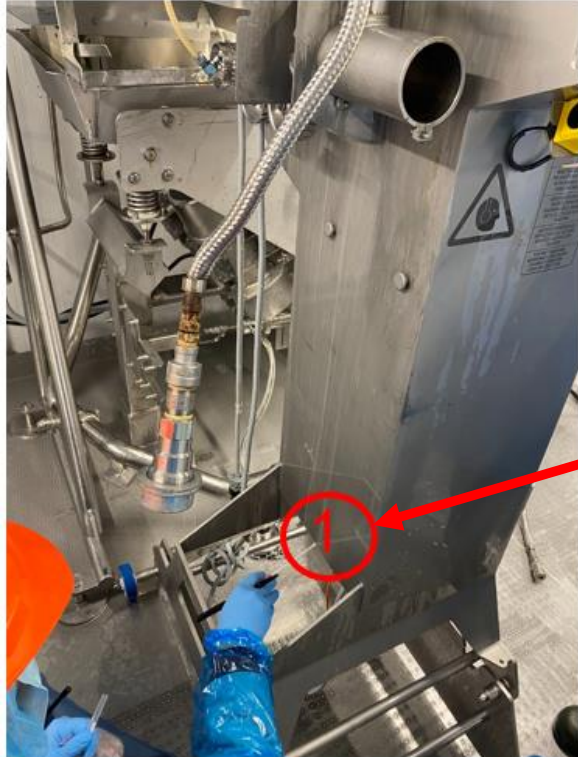
- It is a practical method that allows surveillance of those surfaces that are either inaccessible or not practical to swab directly.
- The sample collected is NOT rinse water. It is the weeping water residue that collects on the lower framework and equipment legs at the floor juncture AFTER post rinse water falls to the floor.
- Sampling is performed during sanitation, immediately after rinse steps (at the normal boosted hot water pressure and volume). It is an “indicator” site representing “many” equipment (internal and external) surfaces above and adjacent to the swab site.



Example of a Rinsate Finding



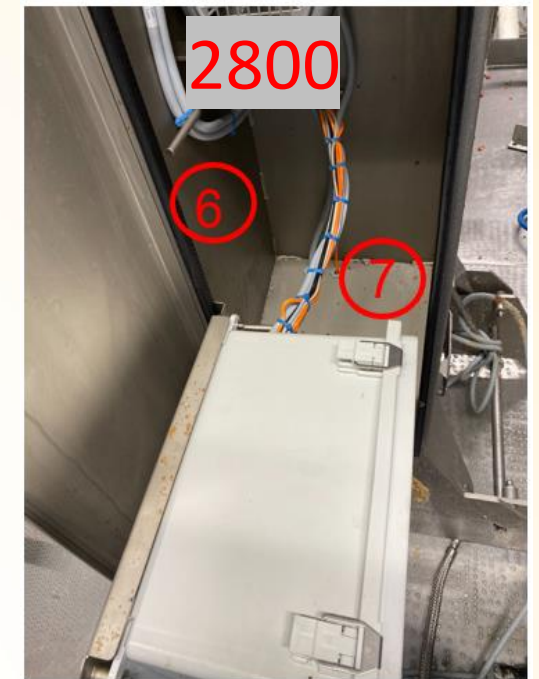
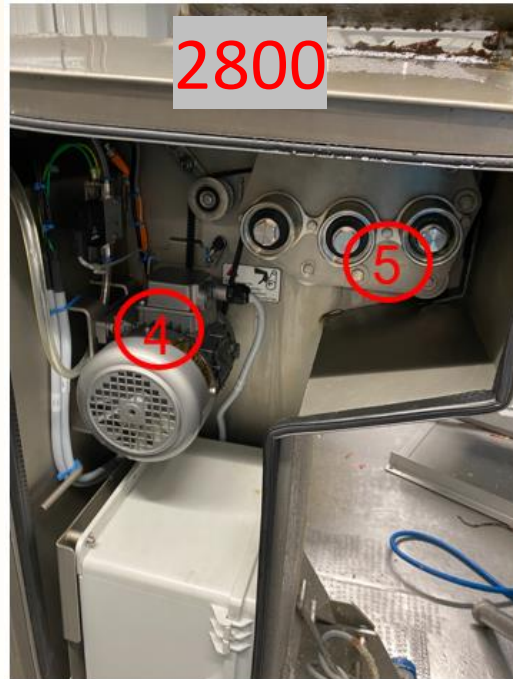
Rinsate Swab Locations



- Rinsate swabs were taken weekly (steaming and deep cleaning frequency for the 2600 was weekly).
- Location 1 (Operator side) : Captures the water from blade holder, carriage and drive wheels.
- Locations 2 and 3 (Non – Operator side) : Captures water from the gasket seals and condensation from inside the cabinet.



Interior Swab Locations



- Site 4 – Motor surface
- Site 5 – Drive wheels

- Site 6 – Lower inner cabinet wall
- Site 7 - Lower inner cabinet floor

Swab Results Confirmed Hygienic Design Improvements

Swab Site	Week 1	Week 2	Week 3	Week 4
Site 1 – Rinsate	0	0	0	0
Site 2 – Rinsate	0	0	0	0
Site 3 – Rinsate	0	0	0	0
Site 4 – Surface	0	0	0	0
Site 5 – Surface	1	0	0	0
Site 6 – Surface	0	0	0	0
Site 7 – Surface	0	0	1	0

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Future Improvement Opportunities

1. Cabinet Gasket Design



2. Inner cabinet corrosion resistance and prevention of condensation build up



Thank You!





Hygienic Design on Produce Harvesters

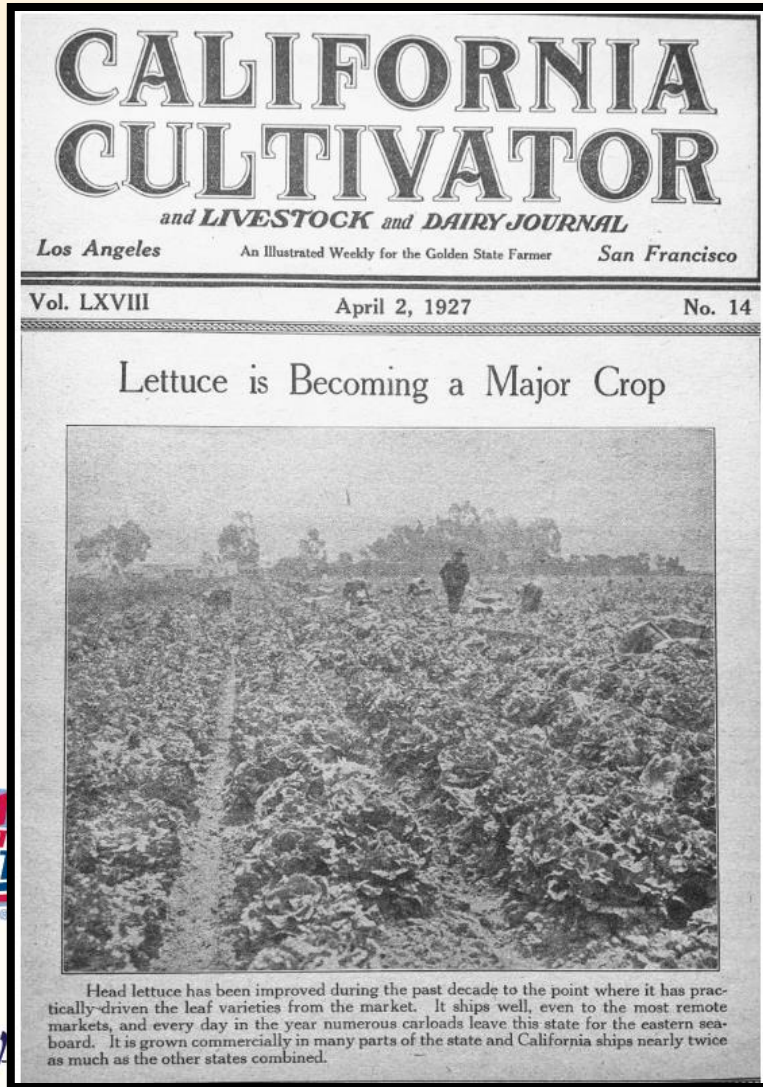
Outbreak and Recalls: Lessons from the front line

Felice Arboisiere

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Historical Perspectives on Farming

Harvest equipment developed out of necessity as demand grew



Notable events driving growth of produce production:

- **Mid to late 1800s: Southern Pacific Railroad expands south into Monterey County**
- **1922: Production for shipping to the East Coast (iceberg)**
- **1930: Industry shift to corporate or large-scale farming**
- **1960s: modified atmosphere rail cars**
- **1989: first nationwide distribution of packaged salads**

“Necessity is the mother of invention”



Courtesy of Monterey Historical Society

But the more things change...

The more they stay the same



Courtesy of Monterey Historical Society



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It all started with a phone call...

December 21, 2021 at 4:30 pm



2021 Outbreak

Unique and unprecedented situation

Two states tested two different iceberg containing products produced seven weeks apart at two different processing facilities on different sides of the country made with raw materials from different growing regions and found the same strain of *Listeria monocytogenes*

How is this possible?



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Root Cause Investigation

Assessing routes of possible contamination

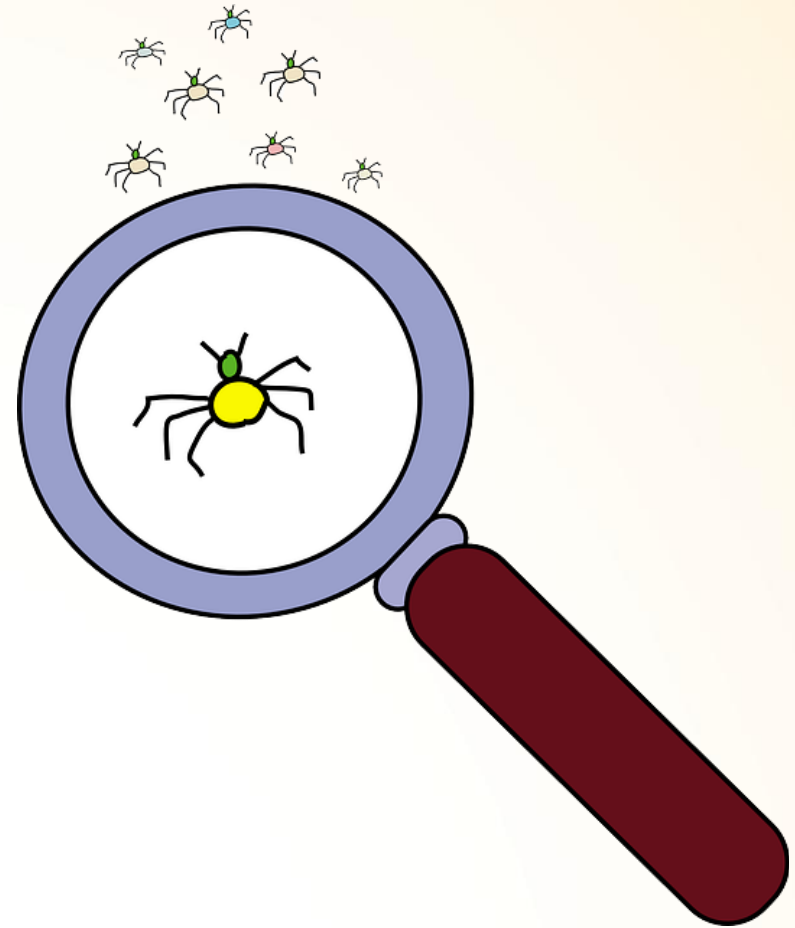
- **Option 1 - Was contamination introduced from the facility?**
- **Option 2 - Was contamination introduced in the supply chain?**
 - **Is there a common source of raw material used in both plants?**
 - **Did recycled pallets or raw corrugate introduce contamination to the plants from the field?**
 - **Is there a common piece of iceberg harvest equipment used in raw material lots used in both plants?**



Investigative Findings

Finding the source

- **Common piece of iceberg harvest equipment identified**
- **Investigative swabbing found *Listeria monocytogenes***
- **WGS of *Listeria monocytogenes* isolates matched outbreak strain**



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The Equipment

Getting to the root cause



Deeper Dive into Harvest Sanitation

“*Industry Involvement* No one can whistle a symphony. It takes a whole orchestra to play it”



- **February 2022-2024 in-person industry meetings**
 - Shippers
 - Harvesting companies
 - FDA
 - Sanitation companies
 - Academia
- **Formed worked groups**
 1. Micro Verification
 2. Training
 3. Sanitation
 4. Hygienic Design
- **Monthly calls to update on progress**
- **Current Events:**
 - 2023-2024 FDA assignment swabbing harvest equipment
 - CPS-funded project on “What is clean?”
 - LGMA reviewing metrics on harvest sanitation
 - Harvest Forward Coalition continues

Where did we start?

We borrowed from other industries who were more advanced

Machine Sanitary Design Principles	
Principle #1:	Cleanable to a microbiological level
Principle #2:	Made of compatible materials
Principle #3:	Accessible for inspection, maintenance & cleaning/sanitation
Principle #4:	No liquid collection
Principle #5:	Hollow areas hermetically sealed
Principle #6:	No niches
Principle #7:	Sanitary operational performance
Principle #8:	Hygienic design of maintenance enclosures
Principle #9:	Hygienic compatibility with other systems
Principle #10:	Validated cleaning & sanitizing protocols

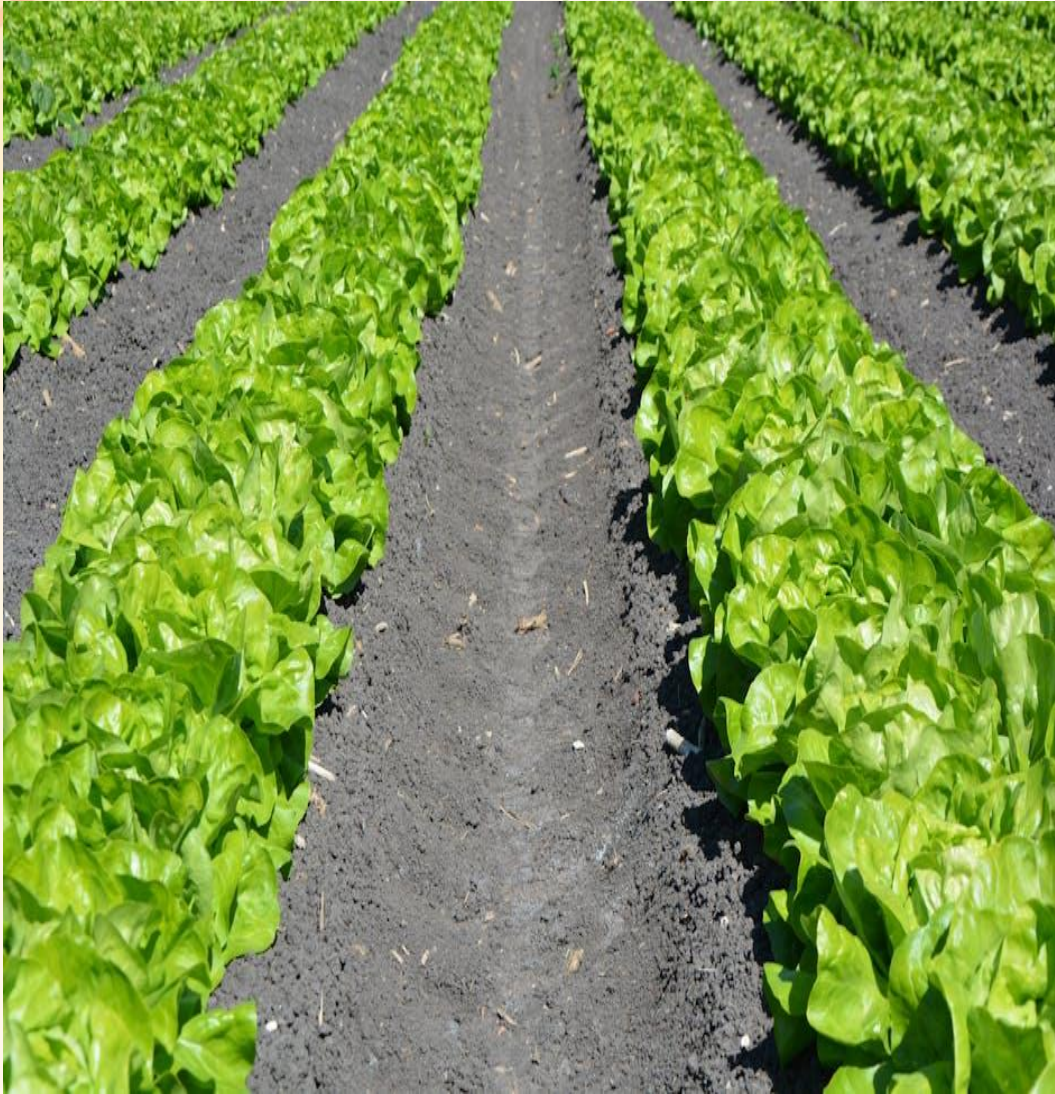
- **Designed a commission program based on work previously done by other industries**
- **Created a digital hygienic design checklist using the sanitary design principles**
- **Added questions about harvest equipment**
- **Using this checklist was able to identify problem areas**
- **Used micro-verification to identify repeat problem areas and either redesigned or created PECs**
- **Used this HD design checklist during transitions from regions and helped build out programs**
- **Used these same concepts in other areas of the produce world like cooling operations.**
- **Overall Seek and Destroy Mentality**

Table 1: NAMI guidelines table of continence *referenced from Fact Sheet,
Sanitary Equipment Design, American Meat Institute, 2012

Dole's Journey

Continuous Journey of Improvement

All growers were cleaning and sanitizing their equipment daily



- **Hygienic design of equipment-cross functional team**
- **Digital hygienic design assessments**
- **What is clean on a harvester?**
- **Verification swabs for equipment**
- **Research projects to understand the transference of pathogens**
- **Complete dismantling during region transitions**
 - **Agriculture follows the sun so region changes are a must**
 - **Equipment moves across regions**
 - **Hygienic design assessments and redesigns**
 - **Addition of D7 chemical to eliminate biofilms**
 - **Listeria spp. swabbing**
- **Enhanced protocols after weather Events**
- **Investigative risk assessments**
- **Project Charters for every new piece of equipment**
 - **Multiple teams involved**
- **Unannounced audits for sanitation teams**
- **Complete redesign of six harvesters Dole owned**
 - **Redesign of third-party harvesters 10+**

Key Hygienic Design Changes

Reimagining harvest equipment from a food safety perspective

- **Open channel frame (where possible)**
- **Stainless steel open belt vs solid belt (fabric-backed)**
- **Redesign of “lift rungs” on elevator belt**
- **Modify UHMW fasteners**
- **Sanitary welds**
- **Niche or catch points**
- **Eliminate unnecessary parts or attachments**
- **Catwalks for high areas or ability to lower those areas**
- **Identify hard-to-clean areas and redesign or make them PECS**



Challenges and Considerations

Reducing the potential for future events

- **Harvest is the beginning of the production process, *but doesn't take place in a controlled environment***
- **Need a hybrid mindset**
- **Not stationary like in a plant**
- **Structural design considerations**
 - **Hollow tubing provides structural integrity and flexibility**
 - **Limit exposure to zone 1 surfaces**
- **DOT weight restrictions-can't sink equipment**
- **Establish an appropriate definition of "clean"**
- **Develop baseline and data-driven metrics**
- **Validation and verification**



Examples of key modifications

Belts and frame

Before



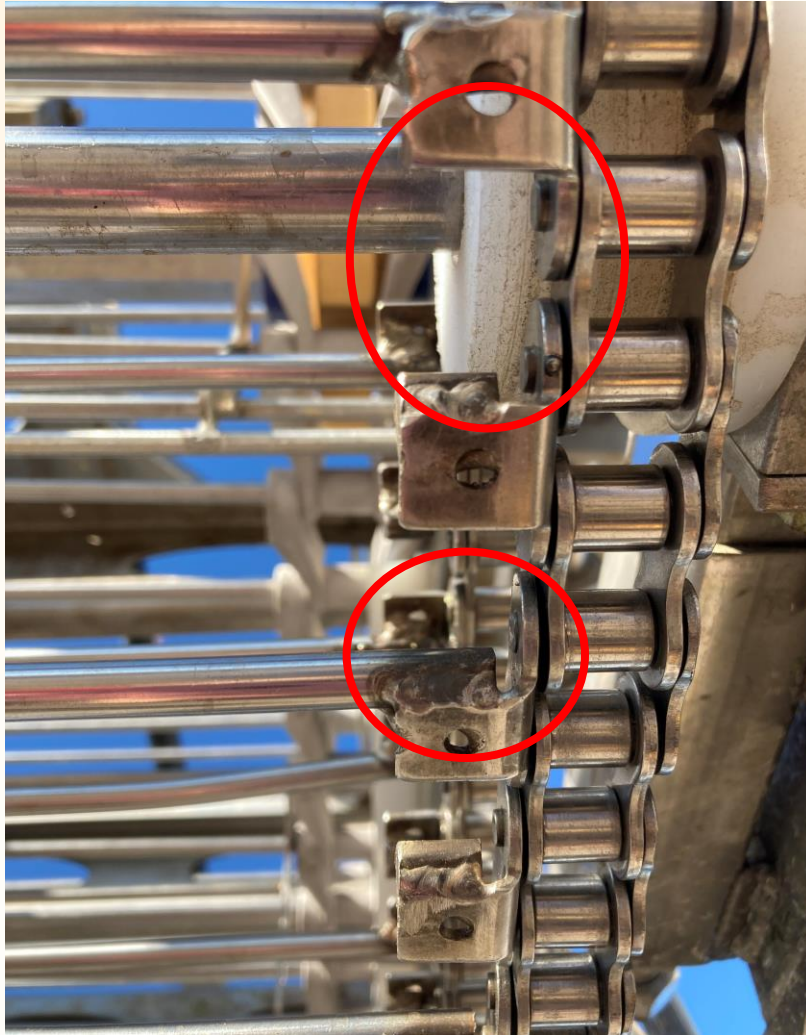
After



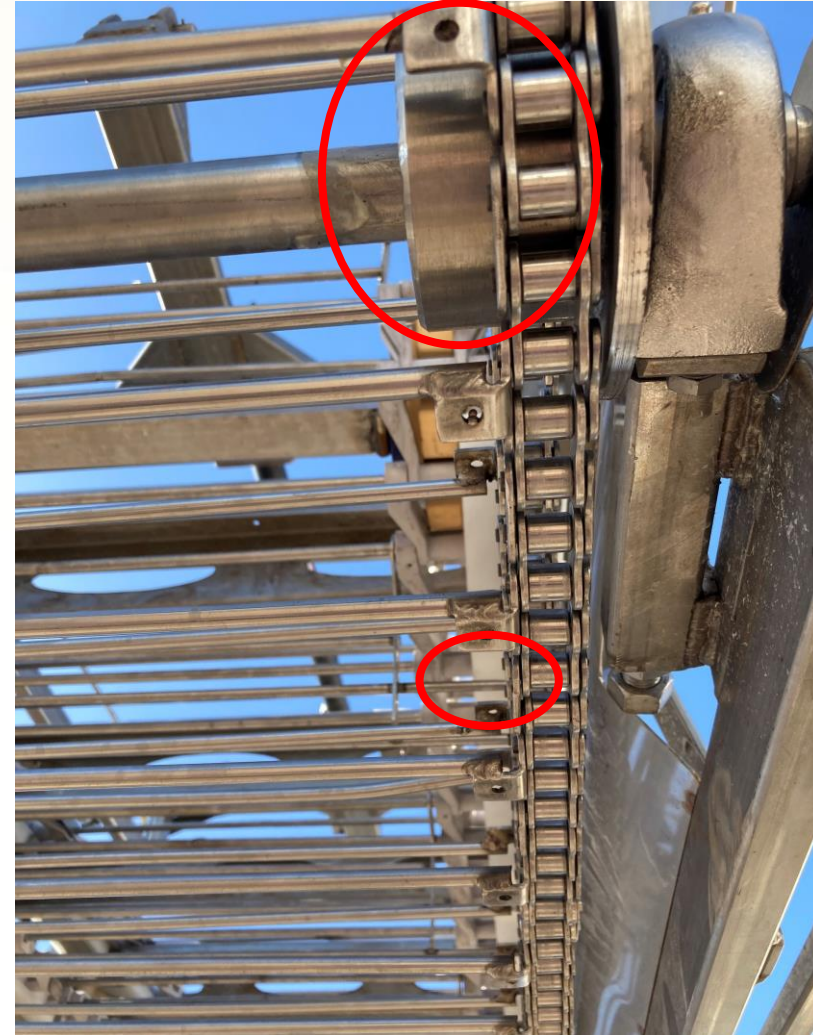
Examples of key modifications

Belts

Before



After



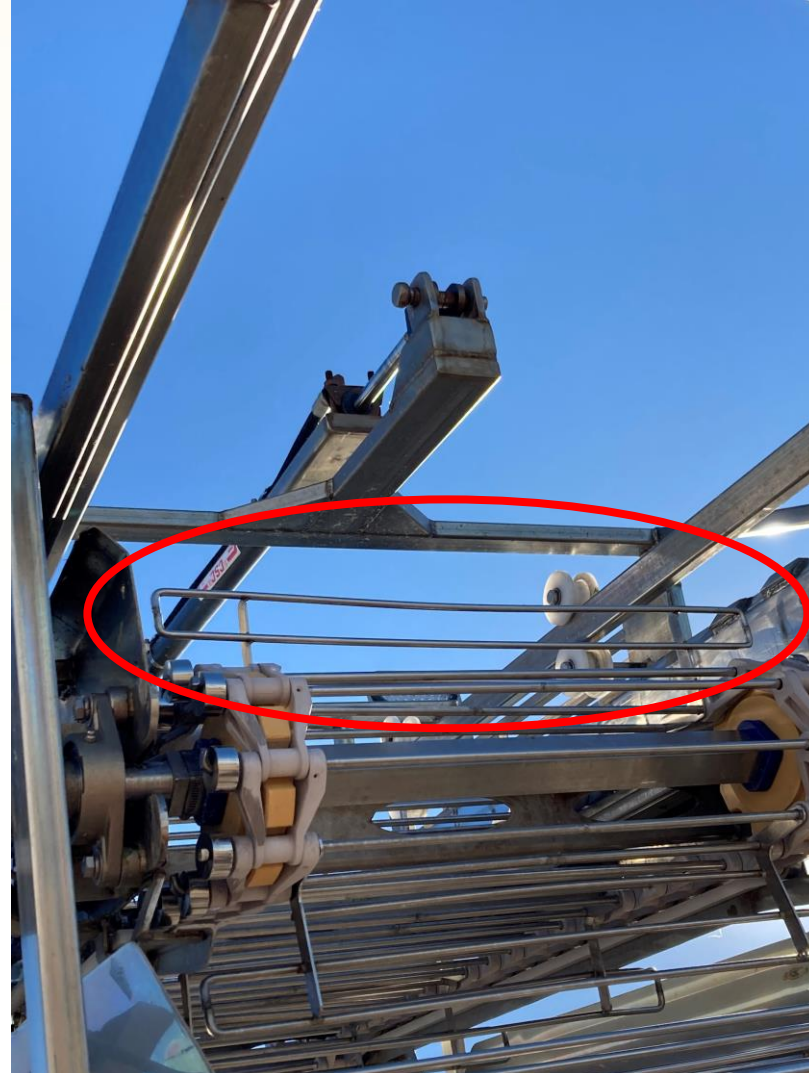
Examples of key modifications

Elevator Belts

Before



After



Examples of key modifications

Hollow Rollers

Before



After



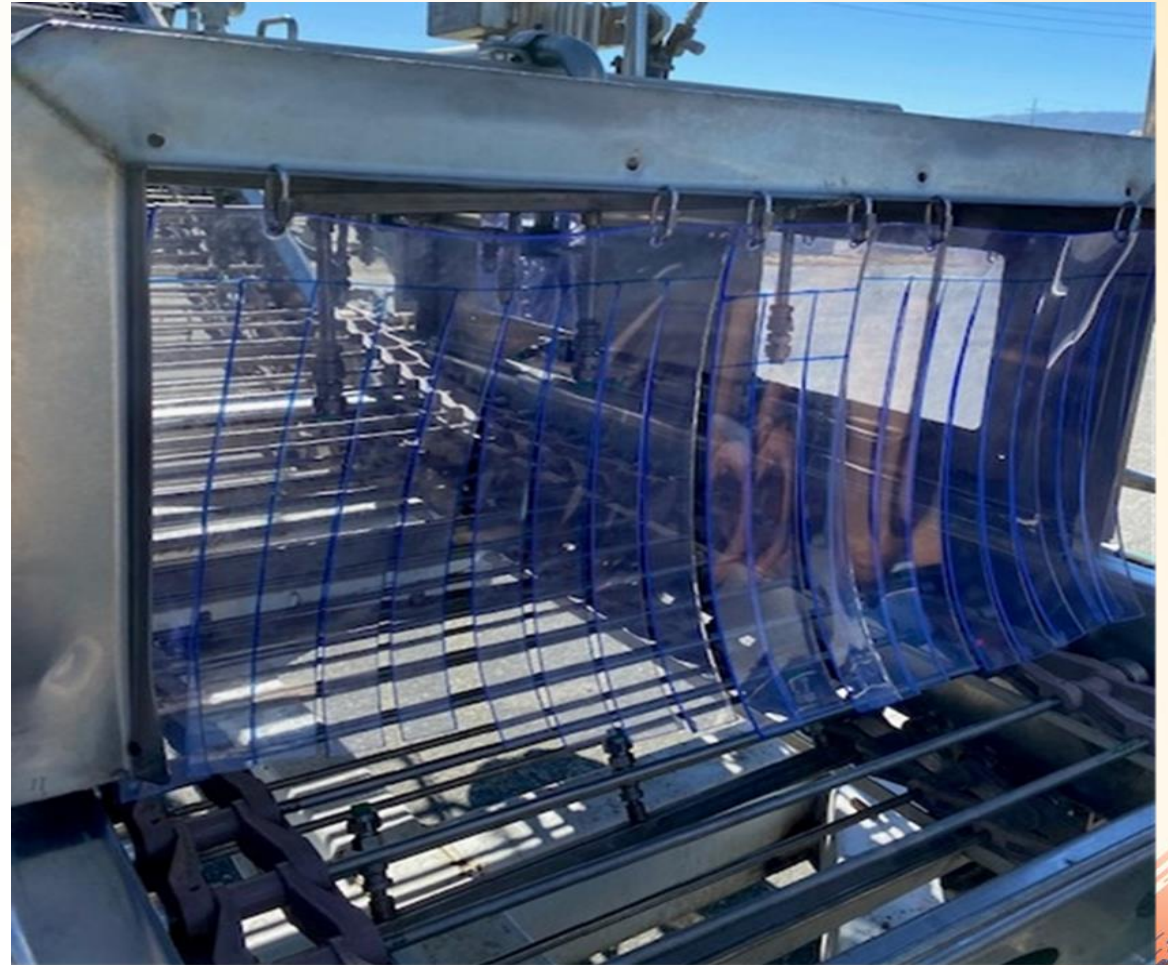
Examples of key modifications

Curtains

Before



After





Hard to clean area

- **Very High**
- **How do you get up there?**
- **What tools do you use?**
- **Can our foam tanks reach?**
- **Is it safe?**

Redesigned hard-to-clean areas: UHMW Glides





THANK YOU!

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