Why is it important and what are we trying to prevent?

- On May 7, 2015, the U.S. Food and Drug Administration released the findings from recent inspections at the Blue Bell production facilities in Brenham, Texas (CDC).

- CDC estimates that approximately 1600 illnesses and 260 deaths due to listeriosis occur annually in the United States\(^1\). (CDC)

![Listeria Monocytogenes](CDC)

![Escherichia Coli (E. coli)](CDC)

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\(^1\) CDC estimates that approximately 1600 illnesses and 260 deaths due to listeriosis occur annually in the United States.
Regulatory is holding business accountable for what they know and when they know it.
Some construction techniques are problematic

Harborage points create areas in the plant that are impossible to clean, and detect failures. are serious issues waiting to happen.

Examples include Dairy Tile, Block walls Fiberglass dairy board
How do Pathogens move through a facility?

- Hands

- Wheels

- Feet

(Duncan)

(Unknown2)
Build to the standards and document the process

- What is Global Food Safety Initiative?
- SQF
- BRC
- International Featured Standard
- FSSC 22000
- GLOBAL Good Agriculture Practices
- Best Aquaculture Practices (BAP)
- Global Markets Programme
- Canada GAP

Pick a appropriate standard
EMMI Project objectives

- Product: Gruyere
- Open curing rooms
- Design- regulatory outcome
  - Quality First
  - Building controls behavior
  - Standardize and simplify
  - Food Safety and Food defense
First document your HAACP flow process
You know your process best!

What is your process flow and the steps involved in manufacturing your process?

Document any critical information

Temperatures
Flow rates
Volumes
Run rates etc.
Based up your process flow start your HACCP flow chart

Outline your HAACP analysis and perform your initial risk analysis.

How will you control each of the risks in the process?

What risks can you design out, or significantly reduce?

<table>
<thead>
<tr>
<th>Process stage Number on flow sheet</th>
<th>Definition of risk</th>
<th>Risk to CCP/ PRP / LR</th>
<th>Tolerance/ limit values +/-</th>
<th>Monitoring (continuous monitoring criteria)</th>
<th>Corrective measures and responsibility</th>
<th>Method of verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Provided products</td>
<td>No Risk</td>
<td>LR</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>Order</td>
<td>No Risk</td>
<td>LR</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>3 Raw milk control</td>
<td>F5</td>
<td>Errors controlled further in process</td>
<td>LR</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>F5</td>
<td>Addressed in Step 7</td>
<td>LR</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>B1</td>
<td>Raw milk can be contaminated with Listeria, Salmonella or other pathogenic bacteria.</td>
<td>LR</td>
<td>None, present after Step 17</td>
<td>Is controlled by step 17 (Pasteurization)</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>F5</td>
<td>Addressed in Step 4 to 7 Step 7</td>
<td>LR</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

1) Definition of risk according to checklist / HACCP-relevant risk in food
2) Risk = according to CL HACCP - decision tree / CCP = Critical control point / oPRP = operational Prerequisite Program / LR = low risk
Map your process flow on plan

Map your people, product and trash flows.

Change paths to minimize or eliminate Cross Contact Potentials.

Use Lean principles
Review your standards, and document how you are going to comply.

Use the standards to define expectations and control the resulting outcome.

Establish design criteria early with the stakeholders.

Make sure the building will match your critical process and regulatory needs.

This living document will explain the concept and execution of the project, and provide the necessary information when the plant Quality Personnel are responding in an audit.

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**Food Defense Self-Assessment Checklist for Slaughter and Processing Plants**

**Outside Security**

1. What food defense measures does your Plant have in place for the exterior of the building?
   - Are the plant’s grounds secured to prevent entry by unauthorized persons (e.g., by locked fence, gate or entry/exit doors)?
     - Yes. All plant doors are electronically secured with company controlled key fobs.
     - Both Employee and Visitor entrances have multi door entry system (two doors must unlock to gain access).
     - Main Plant Building Plant level (A-2.39)
     - Door and window Schedule (A-2.32)
   - Is there enough lighting outside the building to properly monitor the plant at night/early morning?
     - Yes. Parking lot lighting, building parameter lighting and outside surveillance cameras are installed.
     - Building drawing Site layout (E-3.02)
   - Do emergency exits have self-locking doors and/or alarms?
     - Yes. All exterior doors self-lock with controlled access or alarms.
     - Building drawing Site layout (E-3.02)
   - Exterior of the facility is marked with signs stating it is under video surveillance and doors are alarmed. Exterior of plant also is marked with UnAUTHORIZED Personnel prohibited signs warning

2. Are the following secured with locks, seals, or sensors when unattended (after hours/weekends) to prevent entry by unauthorized persons?
   - Outside doors
Use Zoning Control and protect your facility—EMMI Example

In this example

Green - Zero Risk
Yellow – low Risk
Red – High Risk
Have the Building Control Employee Behavior and reinforce your Food Safety Program

In this example

68 Surveillance cameras

28 security doors controlled by job description

Visible air pressurization indication

Reduce the amount of required ongoing training by standardization and restricting behavior
Build in Hygiene Transition Zones into your traffic flow map

In this example

Green - Zero Risk
Yellow – low Risk
Red – High Risk

Remember:
Hands
Feet and Wheels
Recommend using color where ever possible

In this example
Green - Zero Risk
Yellow – low Risk
Red – High Risk
Use visuals with meaning
Standardize chemical usage, and water temperatures

Pre-diluted chemicals are delivered to the factory floor.

Water Hose drops have temperatures preset from a circulation loop.

Simplify your SOP’s in each step possible.
Use Proper Insulation and HVAC controls to Prevent Condensation.

Pay attention to foundations, Types of insulation and heat transfer spaces between occupied spaces.

Avoid condensation in High Risk areas.

Only use non moisture absorbing materials to avoid mold creation.
Eliminate harborage points and long term maintenance

Review all finishes for current and future harborage points

Require Permanent seamless construction where ever possible

- No Caulk in product areas
- Pay close attention to the following:
  - Door Frame to wall, and floor junctions
  - Equipment supports
  - Window frames
  - Electrical and mechanical penetrations
  - Process and sprinkler piping penetrations

Process piping should be floor supported not building supported
(buildings move)
Control the construction process by documenting expectations early in the project

- Most opportunities have very little to no cost impact
- Details established prior to the bidding process controls project costs.
  - You are in your most powerful position of negotiation
  - Forces the sub contractors to be efficient.
  - Significant reduction in post contract change orders (expensive)
Make sure your quality process is in place prior to entering contracts.

Find the right person, internal or external that has enough knowledge to protect the owner and ensure a good regulatory outcome.

Change the contracts to have that champion have the power of final decision.
United Vaccines Greenfield Project

United Vaccines

Mike Green
Project Development Manager

Project Controls

GFA

Construction Contractor (Voges)

Process Engineering

Validation Contractor

Land Acquisition

Building Design

Arch/Mechanical
Electrical structure
fire Civil
Recommendations during the project construction phase

▪ Watch closely as foundations, exterior walls construction for compliance with your final objectives. (Cracks, gaps, insulation etc).

▪ Start your Pathogen monitoring program early. No later than when the shell of the building is enclosed.
  ▪ Know if you have a problem on the site don’t be complacent.

▪ Your presence will show you are vested in the outcome.

▪ As the interior walls start being constructed, walk your traffic patterns (people, product and trash)

▪ Nearing completion the monitoring of the finishes will take more time. Be picky about the details.
EMMI Regulatory Results

Implemented FSSC22000

Results of the first pass Audit.

- 0 Majors
- 8 minors (all predicted)

All minors SOP related and none procedural
EMMI facility Results

Emmi project completion:
- $46 Million dollar  80,000 sq. ft.
- “State of the Art” GFSI food manufacturing facility for EMMI (FSSC22000)
- 2.3% Change orders
Speaker Background --- Mike Green

- 26 years project management
- 8 years Operations Director experience
- Mechanical Engineering training
- Food and Pharma experience
- Certified Six Sigma Black belt
- Certified Quality Auditor

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Works Cited
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