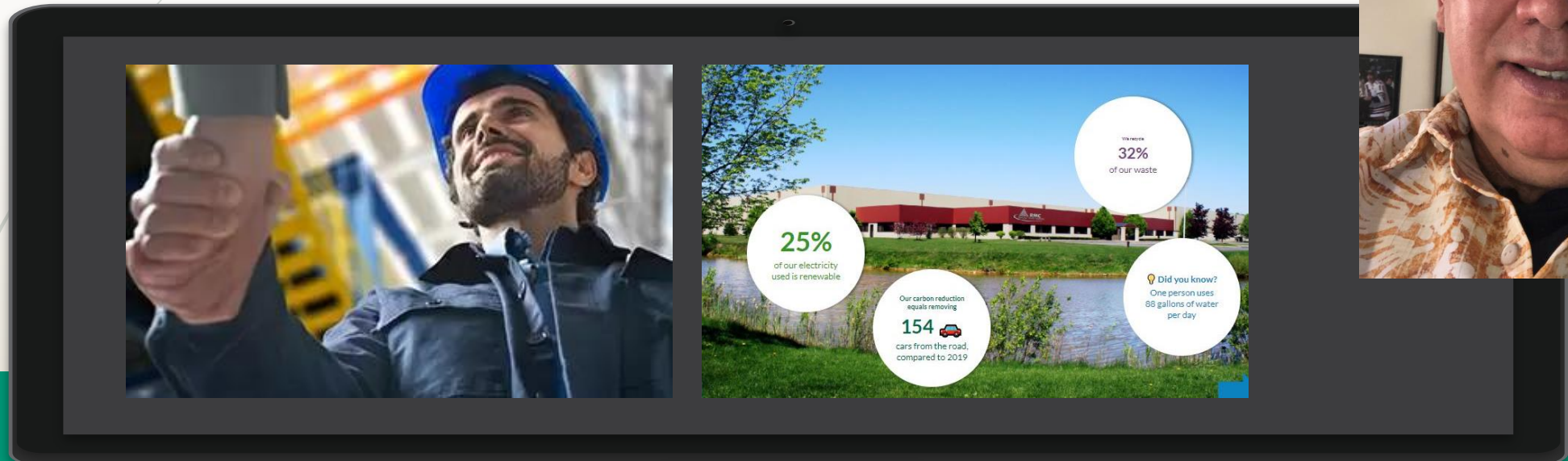


# Environmental Hygiene Monitoring

1:15pm – 2:05pm

## Rationale and Tools to Verify and Validate Your Program



Charles J. Giambrone

VP, Technical Services

Rochester Midland Corporation



Sustainable Solutions for Health,  
Productivity and the Environment.

# ***Environmental Hygiene Monitoring: Rationale & tools to verify & validate your program***



***OFPA Meeting***

***November 18, 2021***

***C. Giambrone, M.S.***

***V.P. Technical Services, Research &  
Development***

***Food Safety Division***

***Rochester Midland Corporation***

# Agenda

1. Why conduct Environmental Monitoring ?  
*the Drivers for verification & validation of EM program.*
2. Zone concept & Risk Assessment: *'It depends'*
3. Sampling Frequency strategies & scenarios.
4. Soil, Microbial & Allergen Methodologies: Air sampling, Fogging and Fungal primer
5. EM data interpretation: Remediation & Corrective actions
6. Discussion  
>Addendum: specific EM control components:  
Drain Sanitation >>

## ***Why conduct Environmental Monitoring ?***

- Fundamental need to verify and validate your sanitation program under Prerequisite program [PRP]
  - Regulatory requirements: CFIA, SFCA, FSMA, USDA , FSIS & GFSI.
  - Customer & 3<sup>rd</sup> party pressures & expectations: Silliker, AIB, Cook & Thurber [NSF], YUM Brands, etc.
- Provides a food quality & safety program with invaluable information on contamination sources
  - Much more revealing than in-process or finished product testing.
  - EM testing reveals microbial & chemical contaminants traits, sources
- The EM data developed & accrued will allow trend analysis:
  - Key component of solving the contamination source problem.



## Environmental Monitoring: Canadian Regulatory Perspectives

### National Microbiological Monitoring Program and Food Safety Oversight Program Annual Report 2019-2020 - Canadian Food Inspection Agency (canada.ca)

- *National Microbiological Monitoring Program (NMMP) is a food surveillance program managed by the CFIA to verify industry compliance with microbial standards, facilitate access of Canadian food products to international markets, provide information on the effectiveness of food safety control measures and interventions, and maintain consumer confidence in the safety of the food supply.*
- Food Safety Oversight (FSO) Program is another food surveillance program that was introduced to complement the NMMP by increasing CFIA's oversight over fresh fruit and vegetables, fish and seafood and manufactured foods
- *Under NMMP / FSO programs, environmental sampling was also performed at federal licence holding establishments to verify the producer's ability to control the presence of pathogens within the processing environment >> confirm that food products are produced under sanitary conditions.*
  - environmental samples collected under the NMMP and FSO programs were tested at CFIA laboratories to verify industry compliance with food microbiological safety and quality standards.
  - *there were 1941 tests performed on 1,608 environmental samples, which were assessed as 97.4% satisfactory.*

### Food inspection guidance: sample collection - Canadian Food Inspection Agency (canada.ca).

- **General sampling principles**

## Environmental Monitoring: SFCA Regulatory Perspectives

### Safe Food for Canadians Act ([justice.gc.ca](http://justice.gc.ca))

- **SUBDIVISION B Sanitation, Pest Control and Non-food Agents**
  - **Marginal note: Clean and sanitary condition**
    - **50 (1)** An establishment, and any conveyance or equipment in it that is used in connection with an activity that is regulated under the Act, must be clean and in a sanitary condition.
  - **Marginal note: Cleaning and sanitation**
    - **(2)** The cleaning and sanitation of the establishment and of any conveyance or equipment in it that is used in connection with an activity that is regulated under the Act must be conducted in a manner that does not present a risk of contamination of a food

## Environmental Monitoring: SFCA Regulatory SUBDIVISION D Conditions Respecting Establishments

### Safe Food for Canadians Act (justice.gc.ca) *Interior of facility or conveyance :*

**57** The interior of any facility or conveyance where a food is manufactured, prepared, stored, packaged or labelled or where a food animal is slaughtered must be

- (a)** designed to prevent the accumulation of substances that present a risk of contamination of the food, including dust, dirt, micro-organisms and food particles, and to permit effective maintenance, cleaning and sanitizing;
- (b)** designed, constructed and maintained in such a manner that
  - (i)** the size and layout is adequate to accommodate the activity being conducted and the equipment used in the activity,
  - (ii)** the entry of insects, rodents and other vermin is prevented,
  - (iii)** any floors, walls, ceilings, windows and doors are smooth, non-absorbent and impervious to moisture, except if those floors, walls, ceilings, windows or doors do not present a risk of the contamination of the food, and
  - (iv)** any floors provide or permit good drainage, except if there is no risk of liquid accumulation;
- (c)** constructed of, and maintained using, materials that are
  - (i)** suitable for their intended use, **(ii)** appropriate for the food or the food animal, as the case may be, and for the activity being conducted, **(iii)** durable, **(iv)** capable of withstanding repeated cleaning and, if necessary to prevent contamination of the food, repeated sanitizing,
  - (v)** free of any noxious constituent;
- (d)** of sound construction and in good repair.

## SFCA Regulatory Perspectives on EM related to Design, construction and maintenance — movement

**59 (1)** A facility or conveyance where a food is manufactured, prepared >>>> must be designed, constructed and maintained in such a manner that the movement of persons and things within, into and out of it **is controlled**.

- **Marginal note: Movement — no risk of contamination**

- **(2)** The movement must not present a risk of contamination of the food.

- **Marginal note: Incompatible activities**

- **60** Physical or other effective means must be used **to separate incompatible activities** in order to prevent contamination of a food.

**Ventilation system: 64** A facility or conveyance where a food is manufactured, prepared, stored, packaged or labelled or where a food animal is slaughtered must be equipped with a ventilation system that **(a)** provides natural or mechanical ventilation with sufficient air exchange to provide clean air and to remove unclean air and odours that might affect the food; **(b)** is accessible and, if necessary for its cleaning, maintenance or inspection, is able to be disassembled; **(c)** is capable of withstanding repeated cleaning; **(d)** functions as intended.

**Temperature and humidity 65 (1)** The temperature and humidity level in a facility or conveyance >>>> must be maintained at levels that are appropriate for the food or the food animal, as the case may be, and for the activity being conducted. **Heating, cooling or humidity-control system**

- **(2)** If the facility or conveyance is equipped with a heating, cooling or humidity-control system, the system must

- **(a)** if necessary to prevent contamination of a food, be equipped with instruments to control, indicate and record the temperature and humidity levels;

- **(b)** be accessible and, if necessary for its cleaning, maintenance or inspection, is able to be disassembled; **(c)** be capable of withstanding repeated cleaning; and **(d)** function as intended.



## Environmental Monitoring: *US & GFSI* *Regulatory Perspectives*

- Food Safety Modernization Act [FSMA]: food market sectors have mandated validations using hygiene monitoring methods & FSIS model. [Public Law 111-353 An Act to amend the FFDCA ]
  - Sec 418 4C: “*an EM program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant.*”
- USDA Food Safety Inspection Service [FSIS]: Verification Testing Program 9 CFR Part 430: Alternative A, B & C tracks.
  - Alternative B : Lethality Intervention/Ingredient inhibitor & Sanitation
  - Alternative C: Sanitation alone >>> most EM samples.
- FSIS March 2006 Directives 10.240.4 & 10,240.5 :
  - LM risk based Verification program
  - EIAO assessment of compliance with LM regulations: both Food Contact & Environmental sources.
- ***G.F.S.I program [SQF & BRC] have updated versions that emphasize EM Validation-Verification programs:***
  - **SQF Ed. 9.0 Modules 11.2.13 & 11.3: Mandatory elements.**
  - **BRC Issue Standard 8: Enforcement on Validation-Verification in Clause 4.11 EMP: 4.11.8.1 : Fundamental Clause**  
**& 4.9.1: Chemical & Physical Contamination Control.**

## ***What does an EM program tell you?***

- Data on contamination sources
  - Has to include both environmental & food contact surfaces
  - Has to include the following parameters:
    - Soil indicators
    - Surface Microbial indicators
    - Surface Pathogen testing
    - Protein tests specific for Allergens. [Chemical contaminants]
  - Air Monitoring for TPC, Fungi, Coliforms.
  - All sampling and monitoring must be temporal and 3 Dimensional.
- EM data test sites have to be prioritized and categorized both for environmental & food contact surfaces :
  - Only a properly designed site sampling plan will provide data that gives you realistic, actionable trend analysis
  - EM data provides you with insights into your plant, your processes, as well as your products.
    - This includes Plant Hygienic Design & Equipment Hygienic Design
      - GMA Facility Design & Equipment Design Checklists [2010] are excellent resource tools

## Zones or Strata Concept:

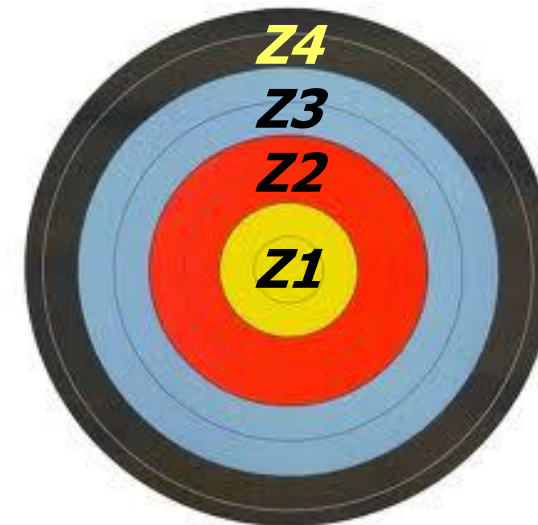
- Under Dynamic conditions: you establish monitoring locations by **mapping or gridding**
- Establish baselines for each zone in each area or room of the plant.
- Risk assessment of each area, each line and their design based upon product type and criteria
  - Is it a raw or RTE area of the plant?

### CRITICAL AREAS:

- ZONE 1: DIRECT product contact surface
- ZONE 2: Indirect or non product contact
  - Areas adjacent to direct product surfaces

### CONTROLLED AREAS:

- ZONE 3: Environmental/non product contact in a processing area are removed from but could result in product cross contamination.
- Zone 4: farthest environmental areas outside the room [hallway floors, walls, ceilings.]



## Zone sampling plans

- OBJECTIVE of zone sampling:
  - Maintain Microbial control [indicator & pathogen] outward from zone 2. By controlling the outer Controlled areas you have a better statistical chance of preventing cross contamination into Zones 2 & 1
- 4 questions you need to answer to justify your Sampling plans:
  - Why are you sampling?
  - What are you sampling for?
  - What are the technical limits or capabilities of the sampling method?
  - How is the data going to be utilized ?
- Two types of sampling plans for all zones
  - Quantitative: Indicator microbes [TPC, Coliform, Enterobacteriaceae, Yeast Mold]
  - Qualitative: Pathogens [Lm, Salmonella spp, STECs,]
  - BOTH are needed!
- Sampling Plans are either
  - “Statistical” or “Risk Based”
  - Monitoring or Investigative [Proactive vs. Reactive] : both are important.

## Zone sampling plans

- Where do you sample??
  - Mapping of all zone 1 > 4 sites needs to be done based upon the specific processing room's risk assessment based on sampling studies during processing or cleaning [dynamic ] conditions.
  - Must establish BASELINE !
  - Determine most significant sites or worst case sites using Gridding or Mapping study.
- When do you sample each segment of the plant's operation
  - Pre-op?
    - Verification or validation tool of actual SSOPs for equipment or area.
  - Refresh or shift sanitation?
    - Verification or validation tool OR assessing impact on cross contamination assessments.
  - Operational?
    - Vital tool to assess GMP performance standards, risk assessment of operations and frequency of sanitation for all Zones in your area.



## ***Insights on sample sites & frequency***

- Plant layout & Design: GMA Facility Design Checklist.
- Overhead and wall structural niches.
- Processing equipment, where its located, how its located
  - Permanent structures vs. mobile [to clean in a washroom]
- Product Flow:
  - From receiving to raw
  - From raw to post lethality
  - Post lethality to packaging.
- All zone sample sites must be **randomly selected**
  - *Critical sites need to be sampled on a regular basis*
- Sample size dependent on:
  - Nature and type of equipment /environmental surfaces
  - Indicator microbe or direct pathogen testing

## ***Environmental Monitoring Program [EMP] plan & frequencies***

- EMP Plan:
  - Use a facility grid/map to ID sampling sites:
  - High risk sites: routine selective
  - In a grid/map >> random rotation.
  - Must *justify* frequency, procedures, number, & procedures
  - Detailed Corrective action plan.
- Zone sampling frequencies & examples:
  - Z 1 > Weekly: tables, conveyor belts, buckets/hoppers, fillers, utensils, hands/gloves, surfaces directly over/adjacent to [lights, pipes, air lines.]
    - Z1 validation both for indicators & pathogens of concern
  - Z 2 > Weekly: framing, drip shields & pans, control panels, overhead fixtures not near Z 1, tools used on equipment.
  - Z3 > Weekly: drains, floors, coving, walls, ceilings, hoses, HVAC units & drip pans, carts, pallets, forklift wheels, floorscrubber blades & brushes, foot baths, hand sinks
  - Z 4 > Monthly: Bathrooms & Locker rooms, hallways, warehouses, docks, cafeterias & break rooms [sinks], Maintenance shops.

## ***How are the results going to be utilized?***

- All properly designed Sampling plans must clearly describe sequential progressive action plan and remediative steps.
  - *More on this later*
- We sample to TREND the results: *Follow the data !!*
- Create for each zone and site type:
  - Appropriate alert and action levels/limits [Pass> Caution > Alert]
- Track the trends via evaluation & investigation
- Why a site/sites are periodically / consistently hitting alert/ action limits ?
- Trend Analysis: >> Data Interpretation
- Corrective action plans [Remediation procedures] in place to confront an alert /action limit at sites.

# GMA Design Checklist

## GMA Facility Design Checklist

Version 1.0 - June 2010

For detailed directions on the use of the checklist, please click on the tab marked "Directions."

Date:

Completed By:

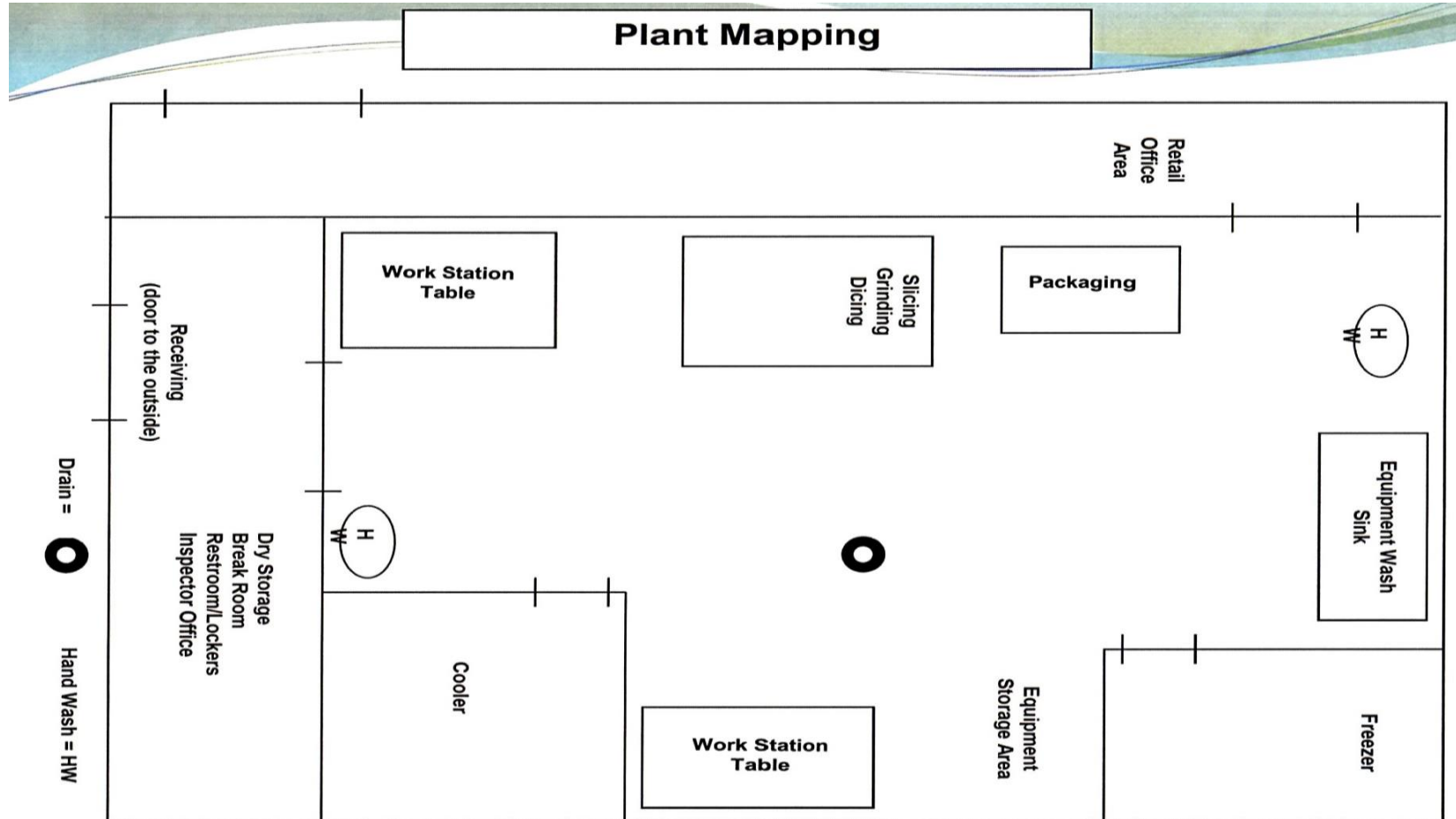
Location:

Facility purpose:

**Facilities, equipment and machinery must meet all federal, state and local food safety regulations as well as personnel safety requirements during operation, cleaning and sanitizing. Any modifications must not affect compliance with these requirements.**

#	Description	S	M	U	NA	Comments
<b>PRINCIPLE #1 - Distinct Hygienic Zones Established In The Facility</b>						
1.01	Facility drawings show hygienic zones, (Ready-to-eat vs. raw, high care vs. low care, etc.) where applicable. Hygienic zones should be clearly demarcated on the plant schematics with colors or other markings to facilitate easy identification					
1.02	Separate locker rooms and lunch rooms should exist for RTE/high risk and non-RTE/lower risk personnel, or provisions to separate high risk and low risk employees exist					
1.03	Restroom facilities are not located in RTE/high risk zones (see point 10.08)					
1.04	Separate storage areas for tools and spare parts exist to minimize contamination from non-RTE/lower risk zones to RTE/high risk zones					
1.05	Separate quality labs should exist for RTE/high risk and non-RTE/lower risk zones					
1.06	Separate storage areas for sanitation crews exist for RTE/high risk and non-RTE/lower risk zones (e.g., vacuums, mops, brooms etc. are segregated)					
<b>TOTAL POINTS FOR THIS SECTION</b>						
<b>PRINCIPLE #2 - Personnel and Material Flows are Controlled to Reduce Hazards</b>						
2.01	Facility is designed such that movement of employees and visitors throughout the facility is controlled in a manner that does not contribute to potential cross contamination (e.g., employees working with raw product travel separate paths from those working with RTE product)					
2.02	Facility is designed such that movement of contractors and maintenance					

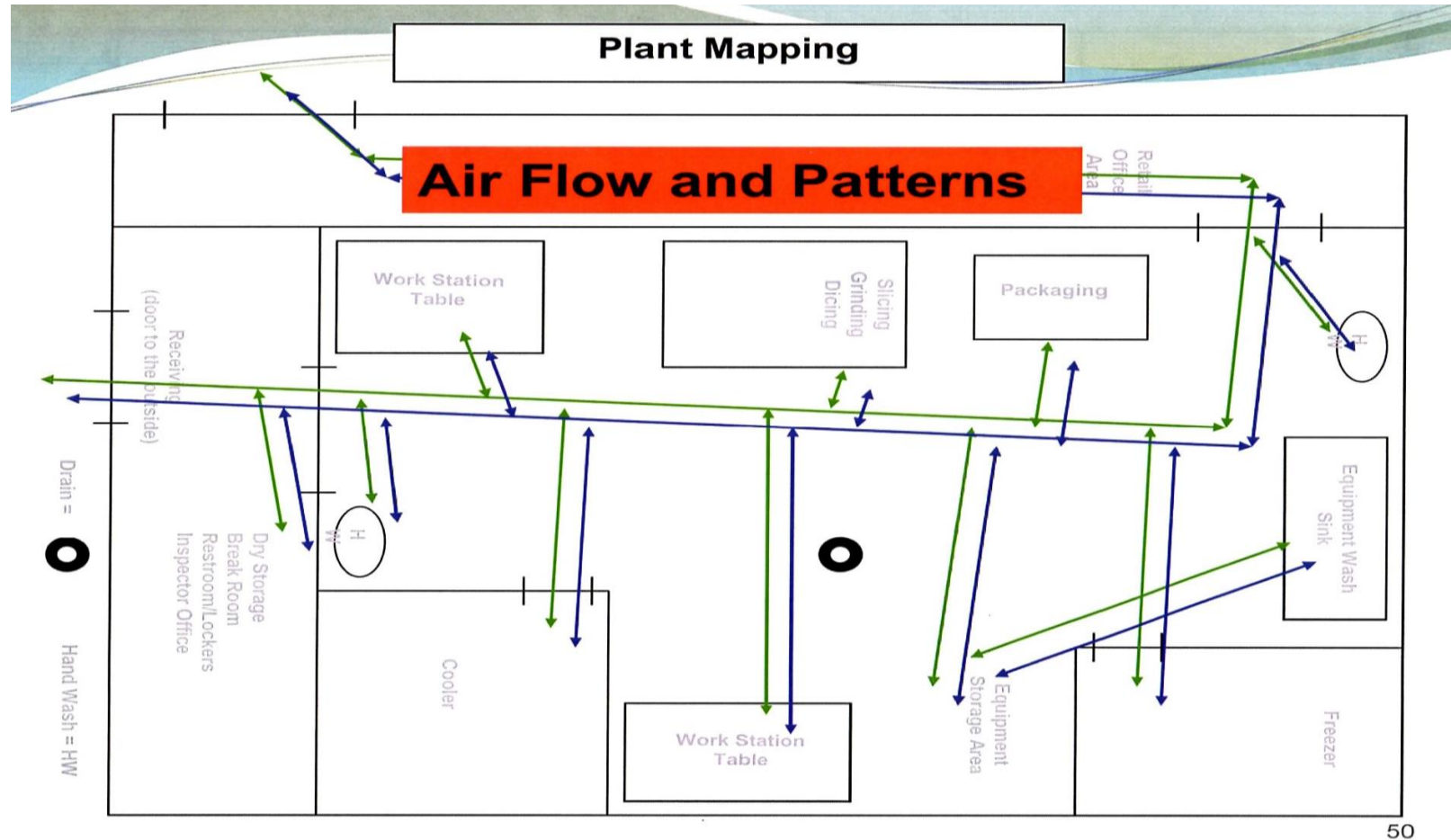
# Plant Mapping example



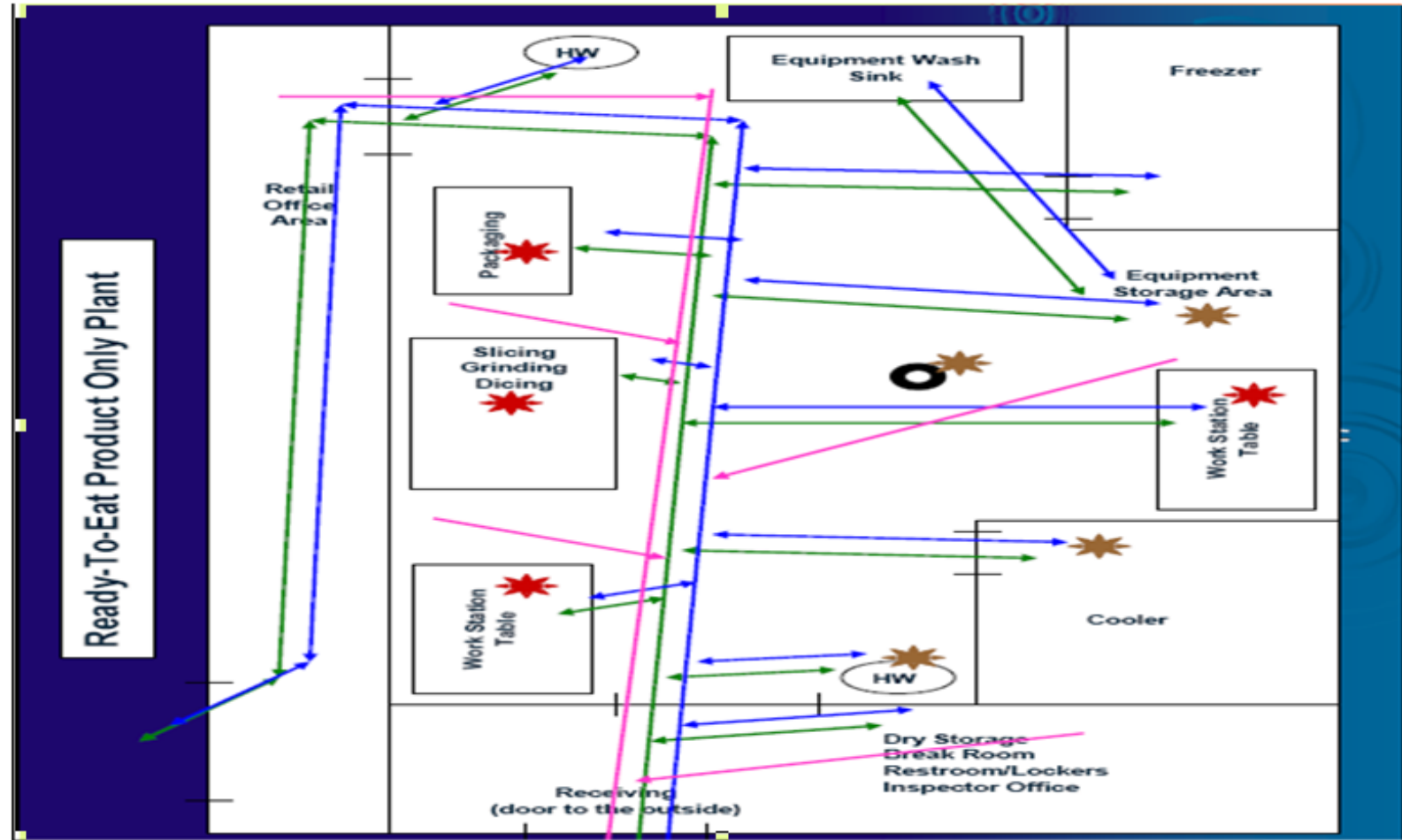
49



# Plant Mapping with Air flow & Traffic patterns



## Mapping a RTE Plant with multiple crossovers



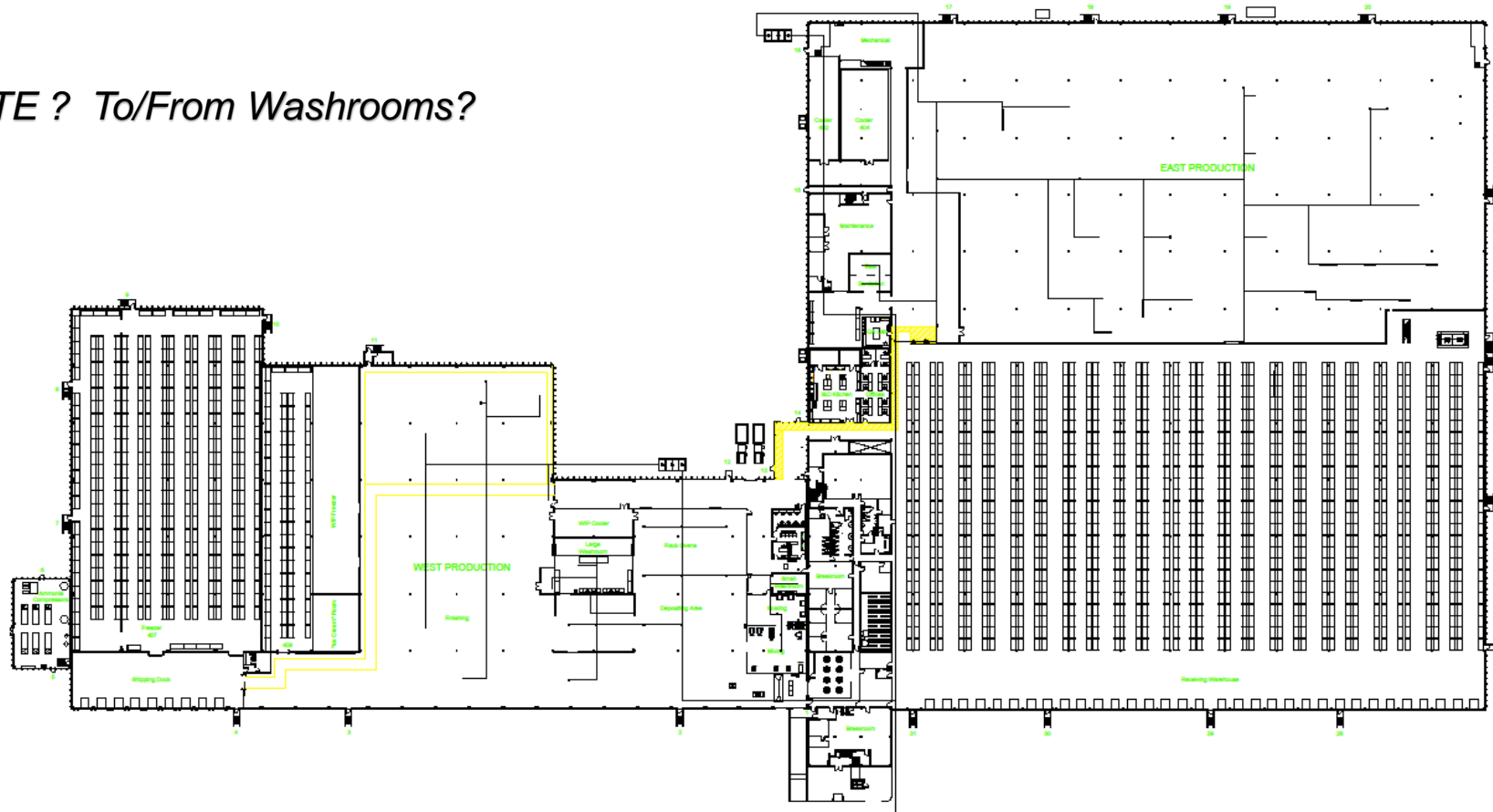
**LEGEND:** Green: Traffic patterns,  
Blue: RTE Product. Orange: Raw  
Product  
Pink: Inedible/Trash, Red: Food  
contact site, Tan: Environmental  
sites

## Facility Design Challenges

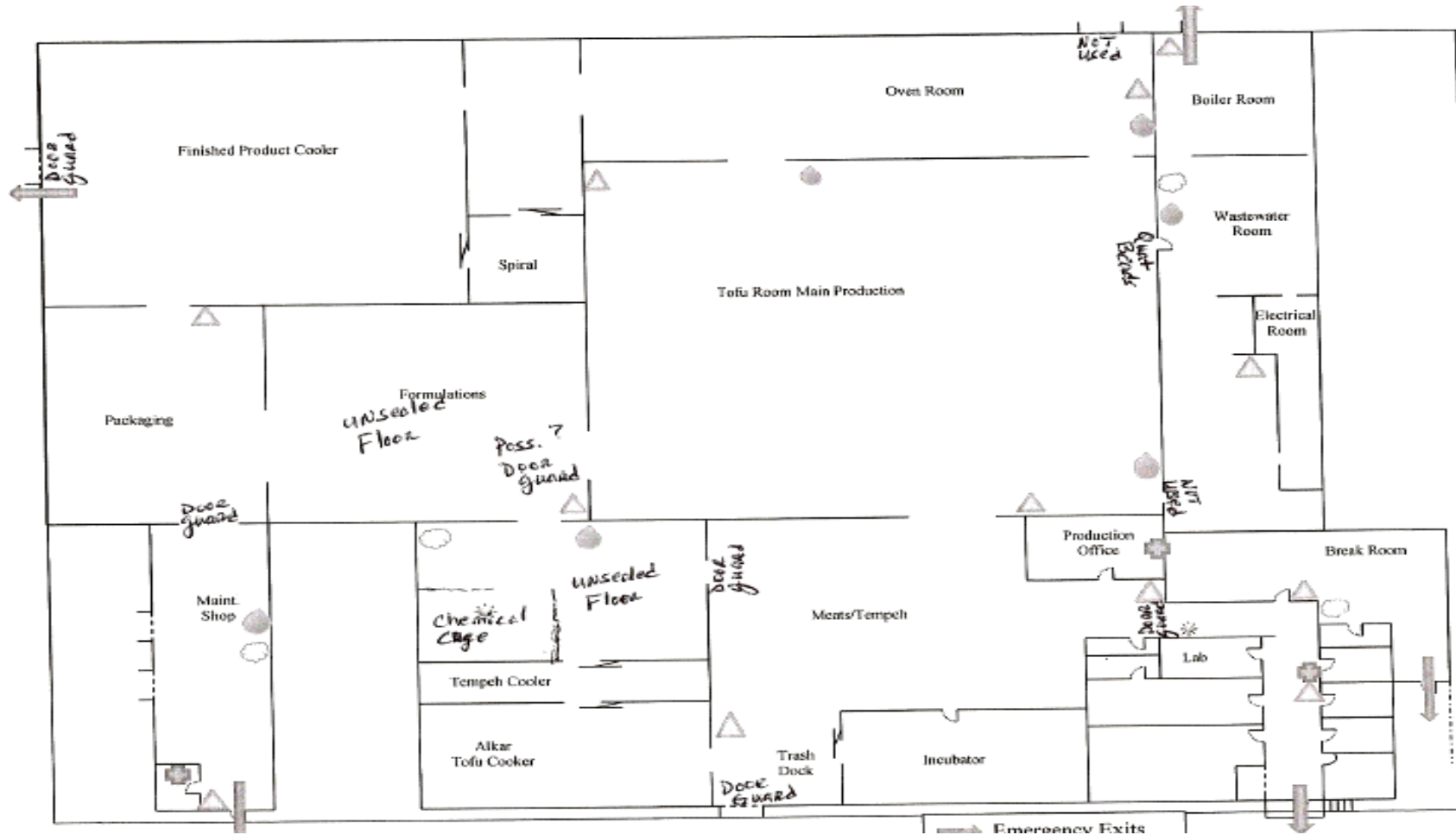
- What are the Traffic Pattern issues of concern?
- Cross traffic issues
- Wall, Coving, and Drain issues
- Air dynamics
- Equipment Footings

## Examples of plant design challenges: a Warehouse converted to a processing plant?

- *Drains? Sloped flooring?*
- *Proper materials for walls, coving.*
- *Ceilings*
- *Product flows:*
  - *Raw to RTE ? To/From Washrooms?*

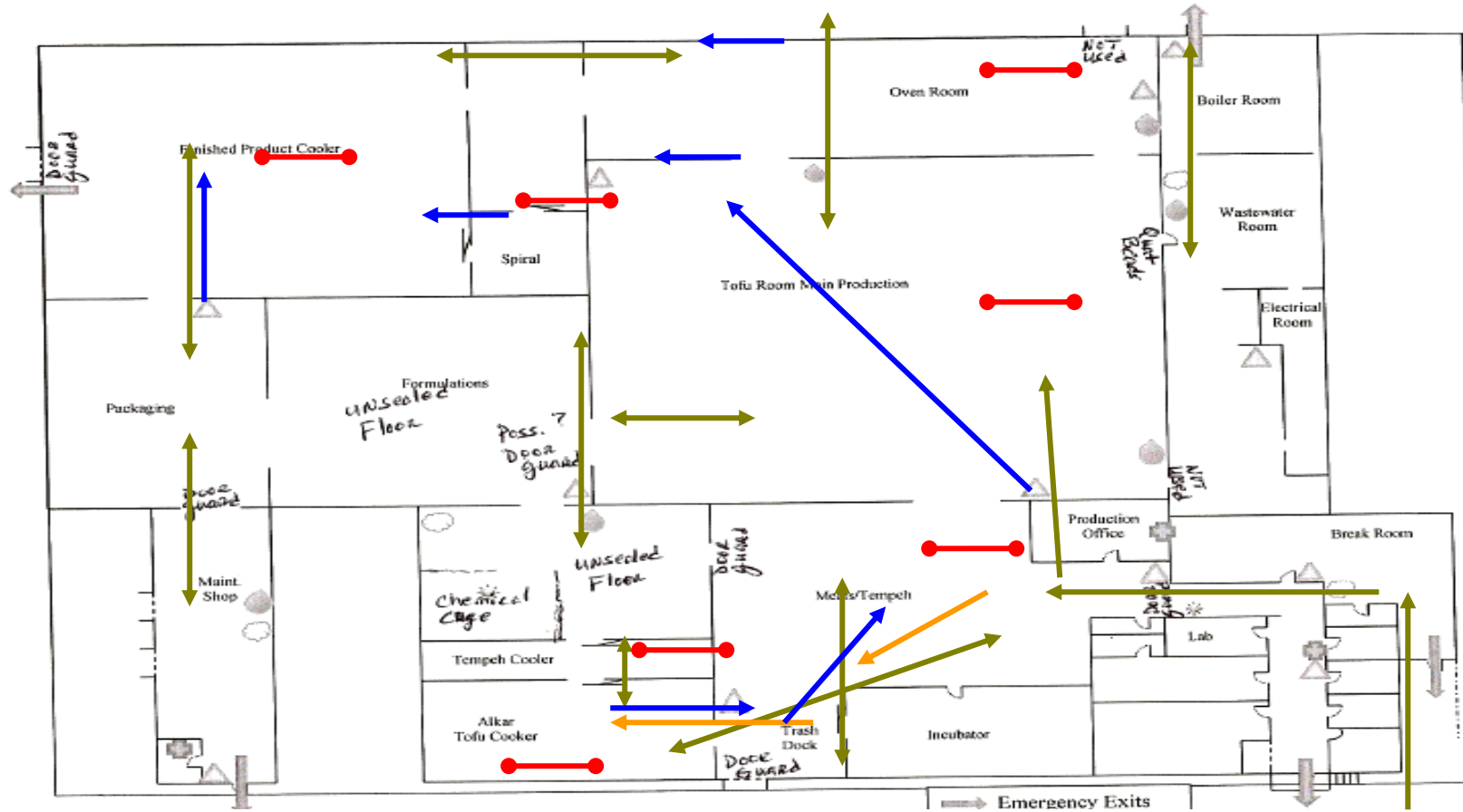


# Soy-Tofu-Tempeh plant Case Study Exercise





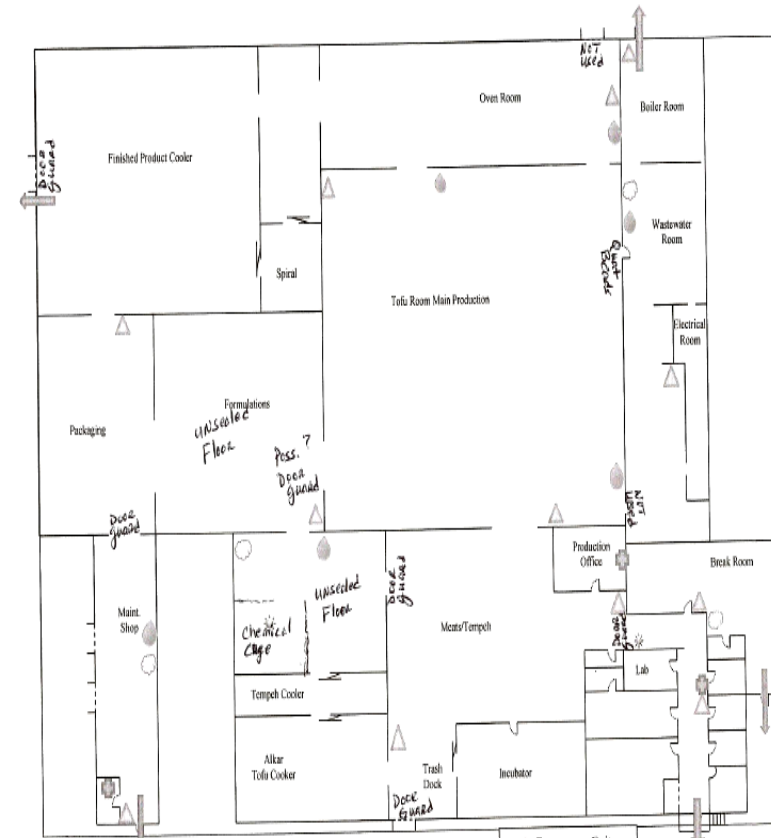
# Soy-Tofu – Tempeh Plant Traffic pattern issues



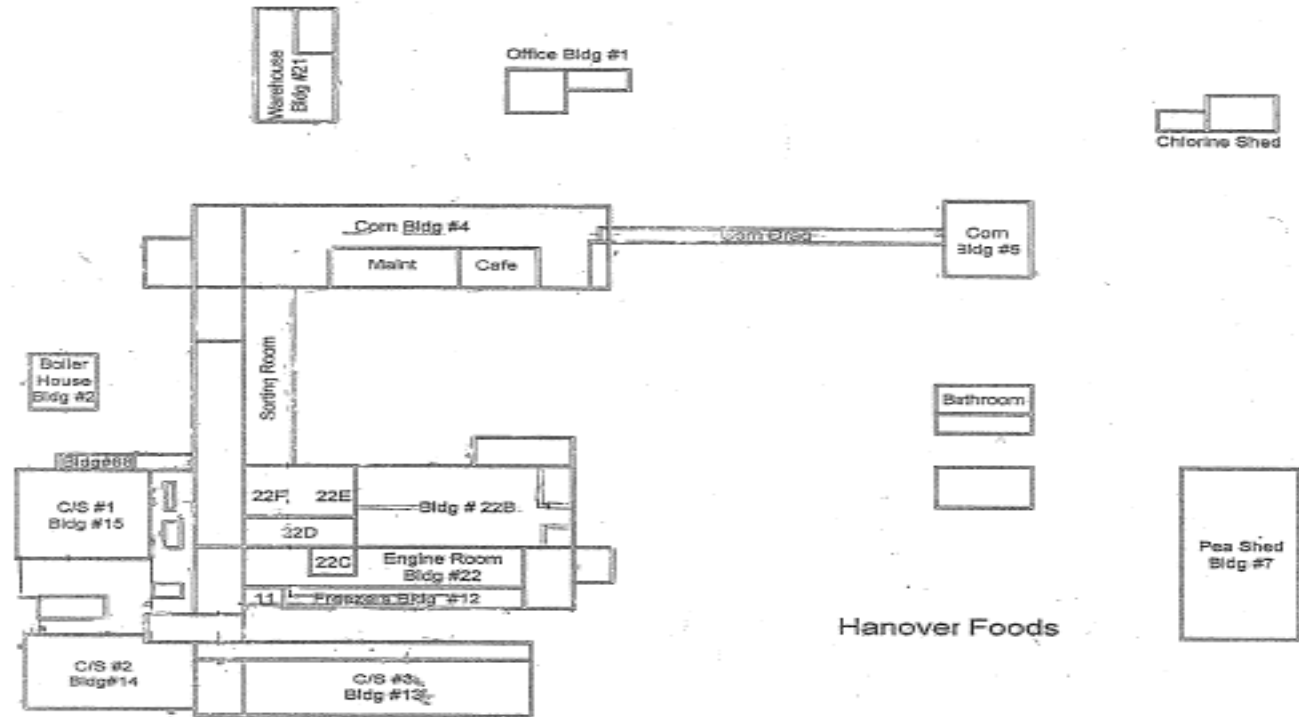
**LEGEND:** Green: Traffic patterns, Blue: RTE Product. Orange: Raw Product  
Red: Food contact site, 

## Site Observations & Recommendations

- Employee Entrance Way:
  - DoorGuard unit & Captive Shoe program
- Trash Dock: utilize dry QAC/Peroxide in this area
- Meats-Tempeh to/from Trash dock some crossovers issues.
- Tempeh Oven room: too many crossover traffic patterns !
- Tofu room: flooring has been fully resurfaced with epoxy.
- Baked Tofu room: 3 doorways need 3 DoorGuard units.
- Refrigerated Receiving Dock: flooring marginal hygienically & structurally
  - Use of high pressure floor rinsing practiced here needs to stop. Why?
  - Utilize floor scrubber with proper PM program to maintain.
  - Dry biocide beads at trucker & maintenance shop entrance.
- Formulation room: environmental structural issues including drains and flooring.



## Produce Plant Design Diagram



BRG 4.1.1 Facility Mapping  
Hanover Foods Corp  
Cayton, DE Facility

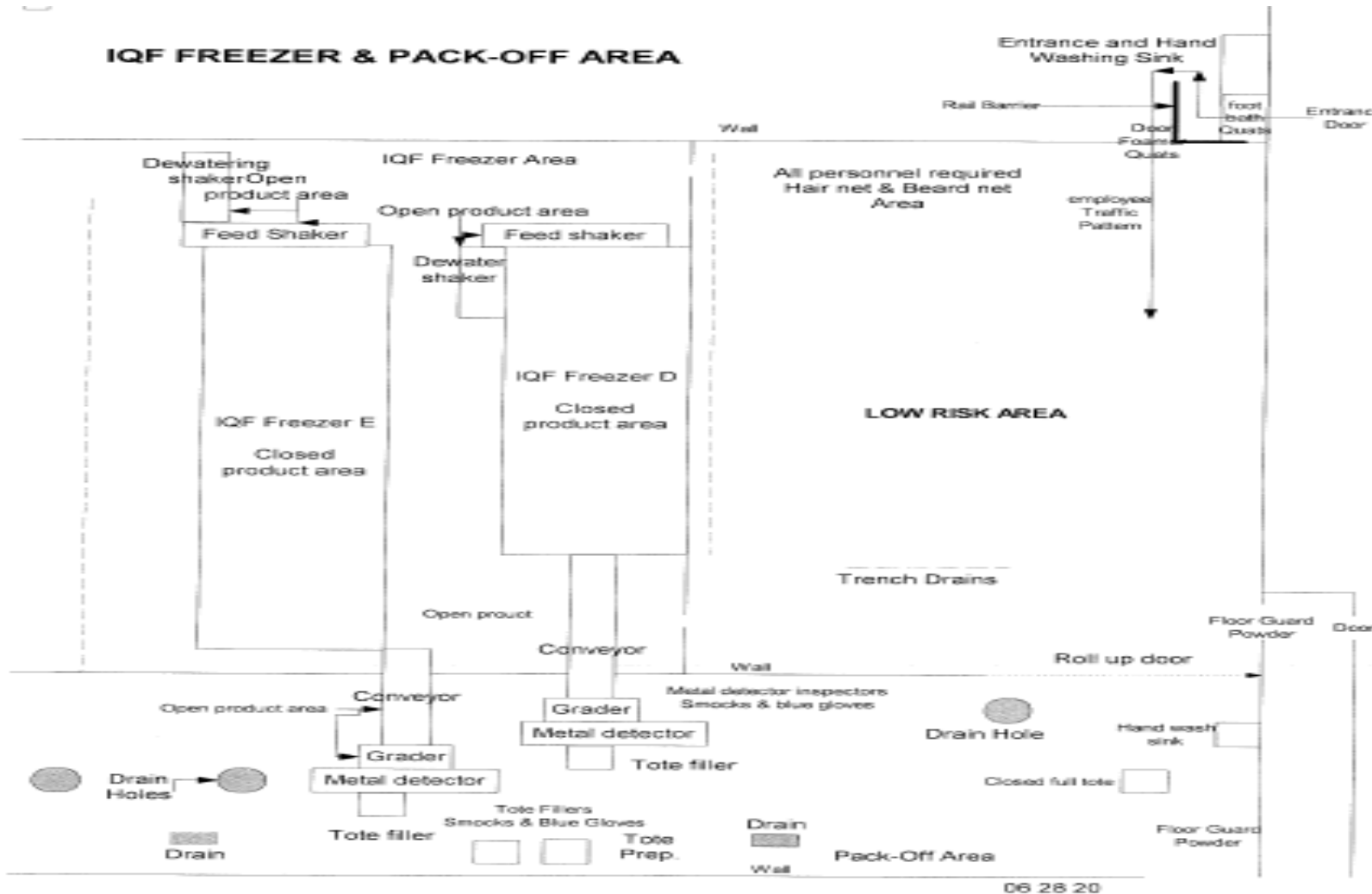
Updated 6.21.20 18

*What are the key concerns with a multi building Design Layout??*

*How do we control & monitor the access points into each building??*

*Which modifications and improvements can occur ?*

**IQF FREEZER & PACK-OFF AREA**

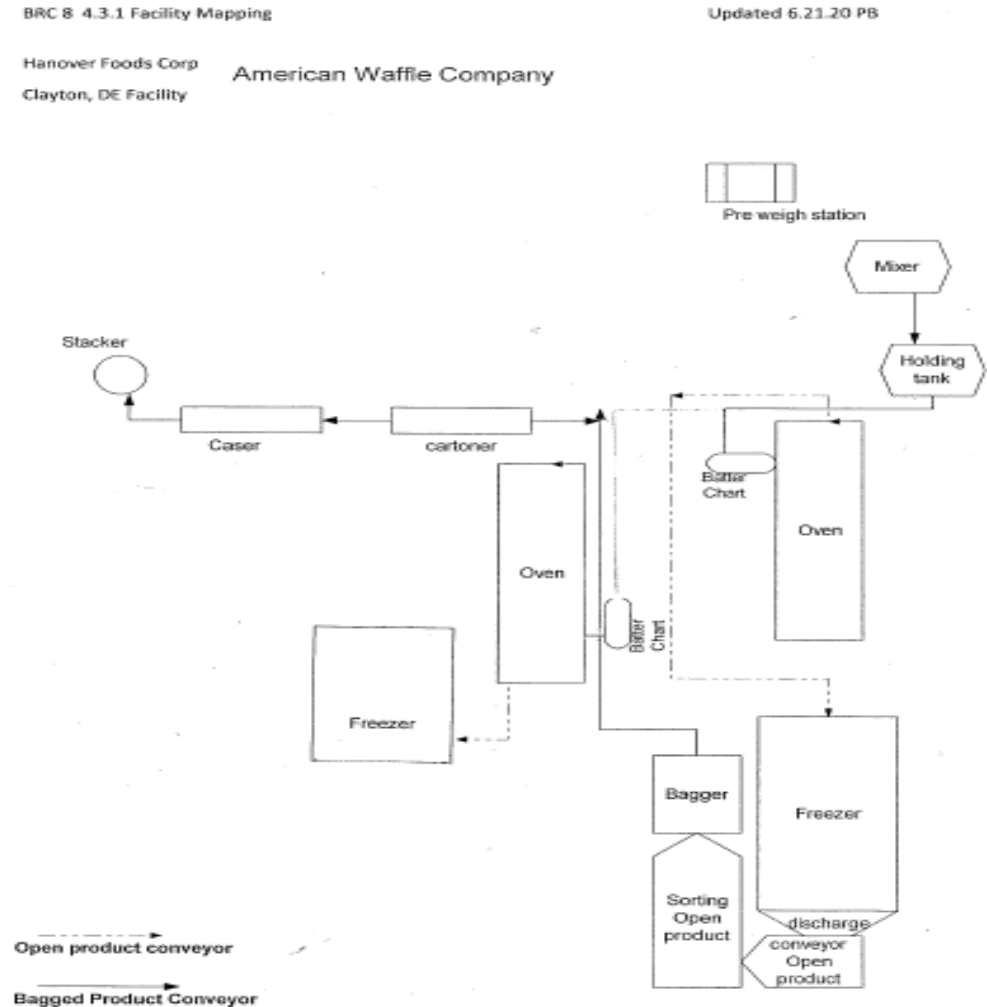


**Produce IQF Freezer-  
Packoff Design:  
Traffic Pattern & Drain  
Issues & Concerns**

- Where are the cross contamination vulnerability sites?
- Drain location and risk assessments?

## Waffle Room Design: Traffic Pattern Issues & Concerns

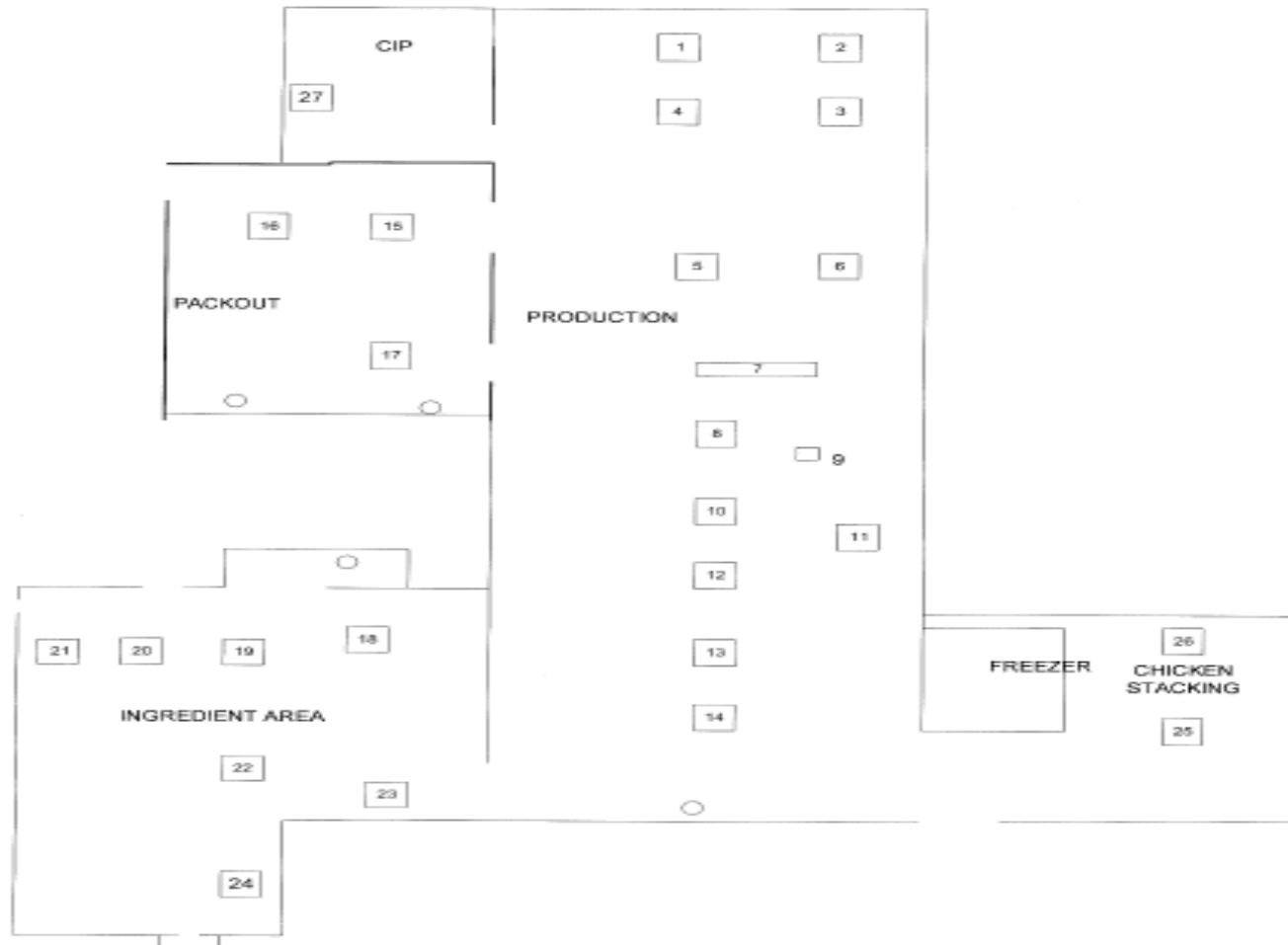
- What are the weak links that contribute to microbial niches?
  - That create a higher risk??
- How does the operation currently reduce cross contamination risks?
- What are the hygienic design issues that can be improved?





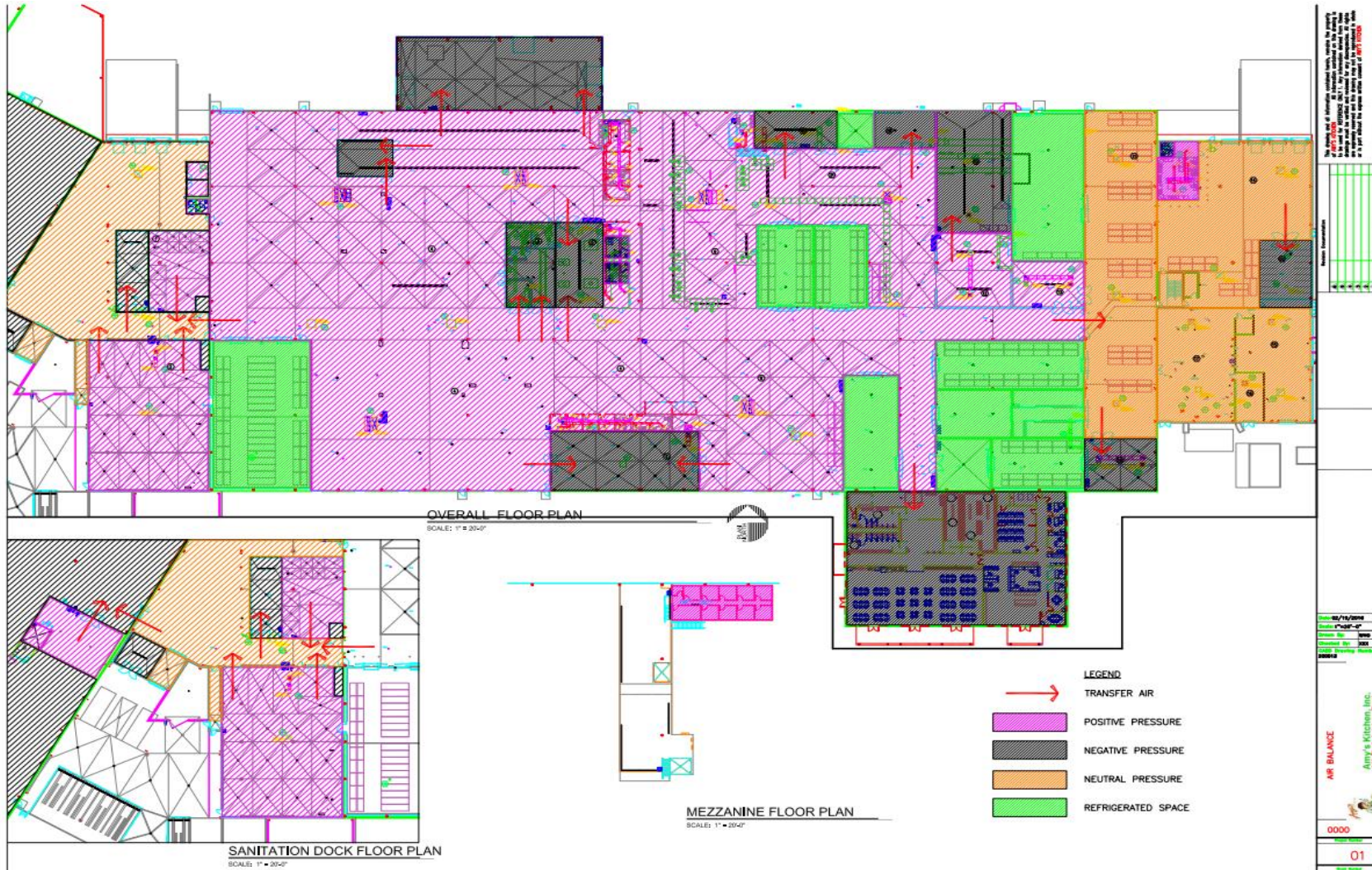
WAFFLE ROOM  
DRAINS

Updated 1/13/18



## Waffle Room Drain Layout Design:

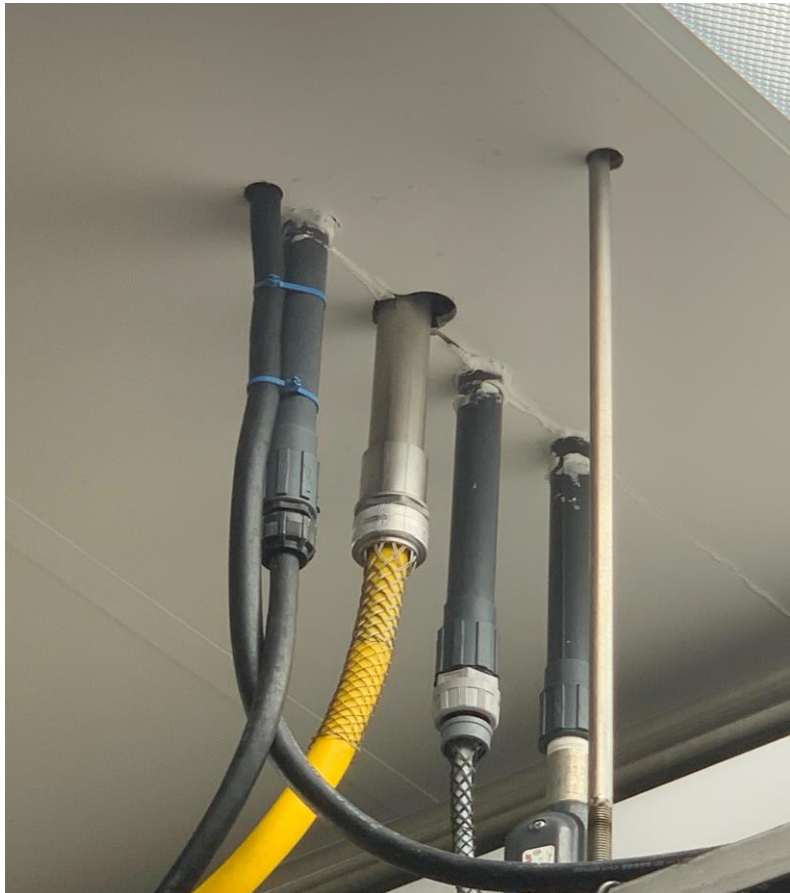
- Drain Priority??
  - Risk Assessments



**Large multi room &  
process plants pose  
numerous traffic  
pattern challenges !**



***Vertical Utility & Underside of  
Housing Frame examples:  
Why are they niches??***

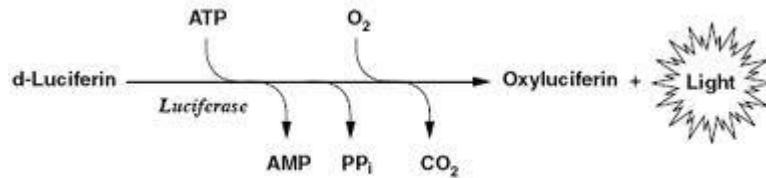


## ***Good practices***





# EM Soil Detection methods: ATP



- ATP [Adenosine Tri Phosphate] handheld devices:
  - Celsis, Charm, 3M, Lightning, Hygiene, Neogen.
  - All OEMs have a variety of Relative Light Unit scales
- Measure organic soil via the firefly enzymatic reaction,
  - will NOT measure inorganic soils !
  - Not an accurate measurement of microbial load
- ATP relies on enzymes, so ATP soil measurement has certain specs:
  - Active sanitizer residues can result in false positives [QACs] or false negatives [oxidizing sanitizers]
  - Should be utilized after post rinse of cleaner to quantify/validate cleaning effectiveness





## EM Soil detection assays: Proteins & Sugars

- Enzymatic & colorimetric:
  - utilize after rinse step , sanitization step
- Qualitative
- Give you a full profile of cleaning efficacy
- Qualitative protein tests can assist in allergen verification test programs
  - Also for allergens with no specific test kits
- Qualitative sugar tests can assist in detecting microbial decomposition of carbohydrates & biofilms.

not



# Hygiene Soil detection methods: Protein & Sugars



Demonstrate due diligence with Spotcheck

**SPOTCHECK**



### Key features

- Results in 60 seconds
- No instrument required
- All-in-one device
- Easy to use and interpret
- Detects all major food types
- Robust
- Demonstrate due diligence

### Products Detected

- Dairy products
- Raw meats
- Fruits
- Root vegetables
- Salad vegetables
- Food dressings and sauces
- Beverages:
  - cola, milk shake
- Cooked products:
  - chicken, egg, french fries
- Bakery products:
  - bread bun, apple pie



No Need to Contract Out - Do it Yourself!

Distributed by

## PRO-Clean™

### Rapid Protein Food Residue Test

PRO-Clean is a quick and easy way to accurately monitor the cleanliness of food equipment surfaces to help ensure food safety and product quality. PRO-Clean detects protein residues left on a surface after cleaning. Simply swab a surface, release the reagent and if food residue is present the reagent will turn purple. The color change provides a semiquantitative measure of the surface cleanliness. The more contamination present, the quicker the color change to purple and the darker the color. PRO-Clean quickly validates the hygiene of a surface, allowing immediate corrective action to be taken if necessary.

#### Key Features and Benefits


- Results in under 10 minutes
- All-in-one device — No instrumentation
- 12 month shelf life
- Easy to interpret
- Affordable
- Excellent for employee training and feedback
- Provides HACCP/SSOP verification

#### Ideal for

- Meat Processors
- Food Processors
- Restaurants and Food Service
- Grocery Stores

#### How to Use

- 1 Swab
- 2 Snap & Squeeze
- 3 Results

Order #PRO-100 / 100 per case!

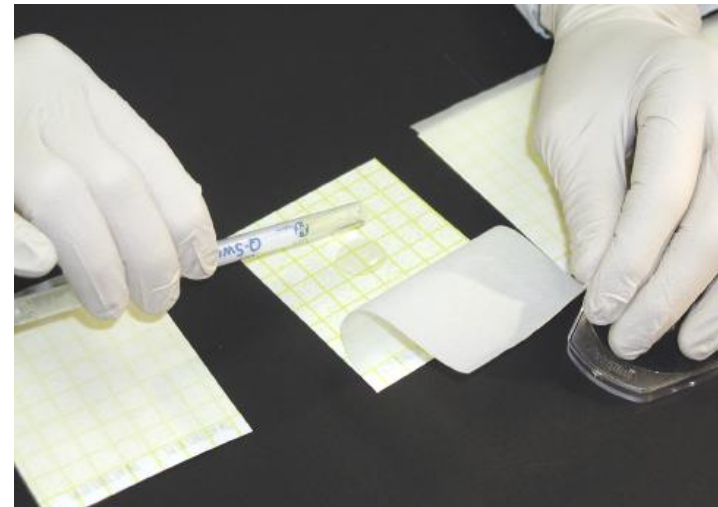




## ***Utilizing a Hygiene Swab Extension Stick***

## Indicator Microbial swab detection systems

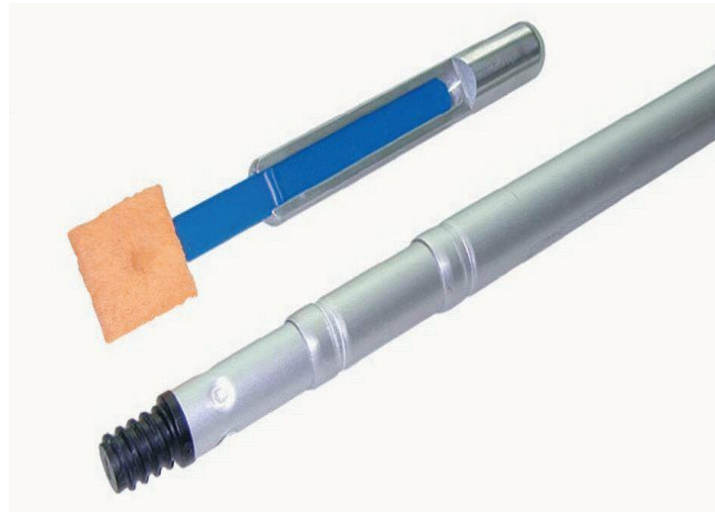
- Utilize a recovery swab system [eg Hygiena Q swab] containing Lethen broth [neutralizes residual sanitizer]
- Plate direct/serial dilute onto 3 M Petrifilms, Direct Plating or Membrane filtration.



- RODACs good tool for flat, smooth sample sites
- Sponges are excellent for larger flat surfaces
- Sponges good for pathogen detection.
- *Which is best : swab/sponge/wipe??*



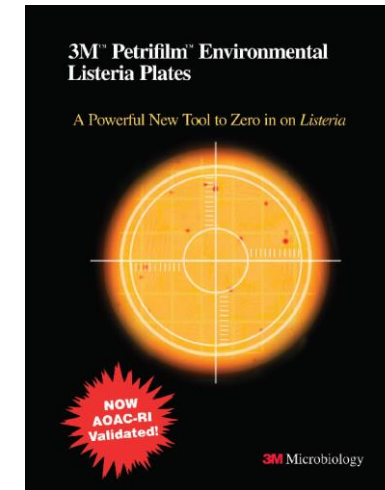
## Indicator Microbial detection systems: RODACs & Sponges





## EM Pathogen Detection kits

- Variety of Qualitative and some Quantitative field kits for EM programs
- Environmental Listeria:
  - Hygiena has a colorimetric test InSite,
  - Neogen has a lateral flow Ag:Ab test kit.
  - 3M has an Environmental Petrifilm
- Salmonella: Neogen [Reveal] a lateral flow Ag:Ab



- *Biotest's RCS Air sampler*
  - Relies on centrifugal air flow
  - Impingement of bacteria on agar strip.
  - APC, Coliform & Yeast-Mold Strips
  - *Part of AuditGuard program as well*



**Microbial detection methods  
for your Baking plant: AIR  
MONITORING Program**

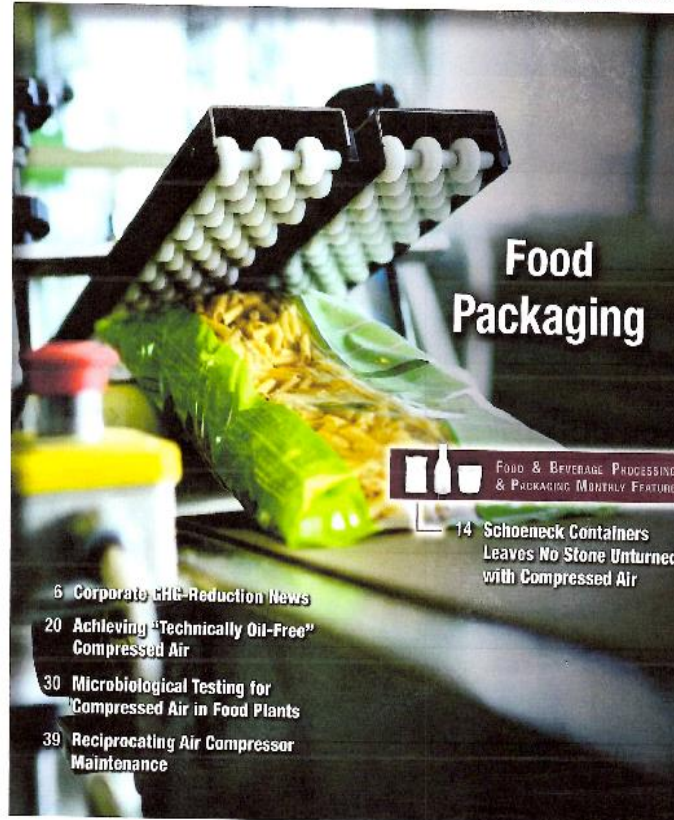






# COMPRESSED AIR BEST PRACTICES

airbestpractices.com



## Compressed & High Risk Ambient Air testing required by SQF

## SAS Air Samplers

- Pinocchio Adapter:
  - *Designed for Compressed Air Testing*

**SAS-SUPER100**

**Your partner in environmental microbiology**  
The familiar bright yellow SAS, an established international standard in portable air sampling, brings a new shape to the 21st century. The SAS Super 100 offers over a dozen enhancements gained from its users in the space program, leading food companies and the top five pharmaceutical companies in the world.

**THE BASIC IDEA**

- To use a simple and inexpensive "Contact Plate" for air sampling and surface sampling.
- To have the flexibility to choose between 55 mm Contact Plates, 84 mm Maxi Contact Plates or 90 mm Standard Petri dishes.
- To introduce active air sampling in conjunction with the use of settle plates.
- To apply cGMP and cGMP to air sampling operations.

• To produce quantifiable results in connection with the sampled air volume.  
• To allow the operator to use either general or specific agar types of their choice to lower running cost.  
• To establish data on the microbial levels in selected environments.  
• To improve hygiene standards through regular monitoring and recording of results.  
• To organize sequential sampling to obtain a more representative sample under actual operating conditions.

**Life-size**

• **Maxi screen:** Large, easy-to-read backlit input screen  
• Day, month, year, time, site and operator's name in compliance with SOP

**Food** **Pharma** **Hospital** **Biotechnology**

**55 mm Contact Plate standard version** **84 mm Maxi Contact System: adaptor and head for Maxi Contact Plates**

**Petri System** **Maxi Contact System**

head  
55 mm Contact Plate standard version  
head  
90 mm Petri dishes adaptor  
head  
84 mm Maxi Contact adaptor

The SAS (Surface Air System) is used by NASA and in the joint American-Russian space program on board the MIR orbiting station.

- ✓ **FLEXIBLE** - No need to purchase special strips or films; Contact Plates or Standard Petri dishes can be used.
- ✓ **LOW RUNNING COST** - Contact Plates or Standard Petri dishes can be poured in house.
- ✓ **INTERNAL SAMPLING** - Programmable time between aspirations, volume of air for each aspiration, and total air volume to be sampled.
- ✓ **START DELAY** - Programmable delayed start option.
- ✓ **7 HOURS OPERATION** - Clear 40,000 litres sampled on one power pack charge.
- ✓ **LED** - Active operator status confirmed by flashing red led
- ✓ **INFRARED REMOTE CONTROL**
- ✓ **DATA TRANSFER ACCORDING TO GLP-GMP** - RS232 output for PC printer connection.
- ✓ **BATTERY CHARGING** - Overnight standard charger or optional 2.5 hour fast charger.
- ✓ **MICROBIOLOGICAL VALIDATION** - NIST traceable validation system.
- ✓ **CERTIFIED ASPIRATING HEAD** - Each aspirating head is certified and laser engraved with a serial number.
- ✓ **STAINLESS STEEL HEAD** - SS head particle emission free for clean rooms.
- ✓ **100% SAMPLING EFFICIENCY** - Optional head allows 100% sampling efficiency for particles down to 1 micron.
- ✓ **MULTIPLE LANGUAGE CHOICE** - Programming selection available in several languages, including English, Spanish and French.
- ✓ **DURABLE CONSTRUCTION** - Polyurethane resin housing for added strength and operational life.
- ✓ **SAMPLING TIME** - Reduced to ten minutes (SAS Super 100) or to less than six minutes (SAS Super 100i) for 1000 litres of air.






DESIRED UNITS	CALCULATION	CONVERSION FACTOR
CFU per Liter	$\frac{\text{CFU on Agar Strip}}{\text{Liters of Air Samples}}$	Liters of Air Sampled
CFU per Cubic Meter [m <sup>3</sup> ]	$\frac{1000 \text{ L} \times \text{CFU on Agar Strip}}{\text{Liters of Air Sampled}}$	1000 Liters Per Cubic Meter
CFU per Cubic Foot [ft <sup>3</sup> ]	$\frac{28.3 \times \text{CFU on Agar Strip}}{\text{Liters of Air Sampled}}$	28.3 Liters Per Cubic Foot

## AIR MONITORING Program: Examples of Calculations & Baking plant Sampling sites.

- #1: Roll Production, Near Ribbon Mixer
- #2: Roll Production, Center of Room
- #3 : Roll Production, Near Fire Exits & leading to Donut Prod
- #4: Donut Production
- #5: Pita Bread Production
- #6: Sweet Goods Production
- #7: Freezer Production
- #8: Cooler
- #9: Cookie Production



## Fogging Programs for Environmental Control Programs utilize variety of RMC systems

- Fogging relies on small dispensed droplet size to provide for proper coverage & penetration into crevices/cracks.
  - 80% of droplets *should be less than 20 microns*
- Oxidant products to fog *are effective vs. Yeasts & Molds:*
  - *Stabilized Chlorine dioxide Oxine/Pro Oxine [activated] & PAA*



## What distinguishing features do Fungi have cont'd??

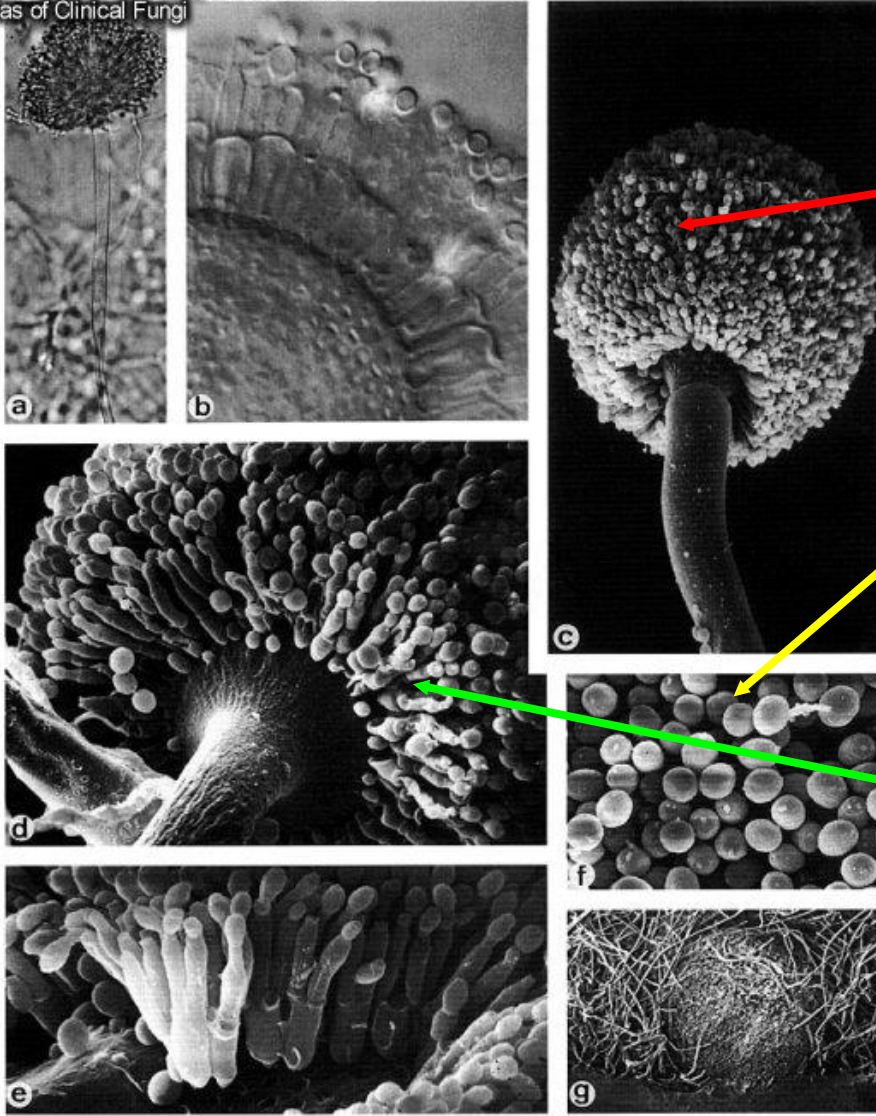


- *Fungi's basic cell units are*
  - *Hyphae have all the same subcellular parts that higher life forms have*
    - *Cell Wall contains Chitin*
  - *Hyphae branch >>> Network or mass of hyphae are called Mycelium*
  - *Many create Septate Hyphae*
  - *Lower fungi have autonomous septae*
  - *Higher fungi have perforated septae*
    - *These septae communicate with each other biochemically*
  - *Growth happens at the tip of the hyphae*



## Fungi also have “Fruiting Bodies”

Courtesy G. S. de Hoog and J. Guarro  
Atlas of Clinical Fungi



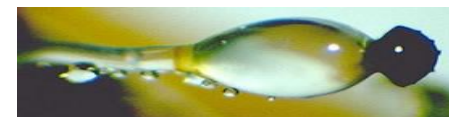
• *Phialides* produce the spores in Fungi in Asexual Reproduction.

• The *Asci* are the modified hyphae form various types of clumped spores

• In Ascomycete fungi these are called *Conidiospores*

• Zygomycete fungi form *Sporangiums*

• More complex fungi embed their spores in structures called *Sporodochium*.



## Data Interpretation: Trend Analysis

- Site Data [Soil / Microbial /Allergenic Protein] must be grouped by:
  - Raw Material sources
    - leafy greens, tubers {ground} or red meat]
  - Product type at Site
    - Raw, Inprocess, Par-Cooked, Fully Cooked, Chilled, Frozen??
  - Time sampled at Site:
    - Should be rotated, variable
    - Pre-op: Day? Stage of process?
    - Shift: Clean-up? Operational?
- Data then should be analyzed on a category/group basis
- Statistical Process Control : use software packages here.
- Upper Control limits: Mean + 2 / 3 standard deviations



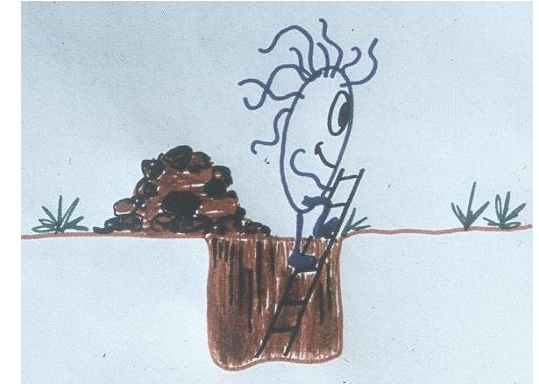
## ***Corrective actions need a Response team & plan !***

- Response team members: QA/QC, Sanitation, Production & Maintenance >> includes both management & staff.
- Corrective actions include:
  - Equipment breakdown & inspection.
  - Re-clean & sanitize equipment, surfaces, tools , then re-swab
  - Hot site should be monitored to detect patterns, trends for sources
  - Re do sanitation process and re assay as required.
  - Need 3 consecutive negative results at site.
- Response plan guidelines:
  - Zone 1 pathogen >>> report to authorities, product is adulterated.
  - Team needs to decide on product disposition if pathogen found in Z2 / Z3 areas
    - Test & Hold, Repeat kill step [if utilized]. Destroy or Divert.
    - In/around contamination site increase monitoring to find and destroy sources
- Reportable Food Registry [FDA] Salmonella 38%, L m: 14% & Allergens: 35%

## ***Listeria monocytogenes:* Characteristics & sources**

- *L. monocytogenes* is from a genera of soil bacteria comprising a handful of species, most of which are non-pathogenic.
  - Ubiquitous in soil and vegetation Water & silage.
  - Domestic & wild animals, fowl & humans.
- Microbial Characteristics of LM
  - Nonsporeforming, gram positive rod that is “facultative anaerobe”
    - Can grow both in presence or absence of air.
  - Withstands freeze-thaw cycles & dessication quite well.
  - Psychrotrophic, can and does at refrigeration/cooler temperatures
  - Documented studies have shown good growth @ 37 deg F / 3 C.
- Human transmission via Ingestion of live, vegetative bacteria
  - via contaminated animal, produce or dairy products
  - Infectious dose varies depending on host’s health
    - Susceptible hosts : as few as 100 cells per gram
    - Healthy Hosts: 10 million cells per gram.





## ***Locations of LM in a plant [NICHES]***

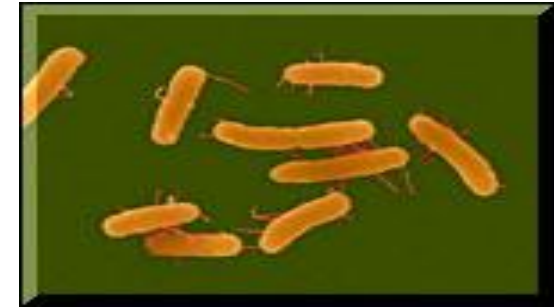
- | • Plant Location        | & | LM Percentage Positive |
|-------------------------|---|------------------------|
| – Floors                |   | 37                     |
| – Drains                |   | 37                     |
| – Cleaning aids         |   | 24                     |
| – Wash areas            |   | 24                     |
| – Sausage Peelers       |   | 22                     |
| – Food Contact Surfaces |   | 20                     |
| – Condensate            |   | 7                      |

## ***LM control strategies***

- Floor & Drain program adhered to using mechanical action as well as C & S.
- Biocide drain program: automated foamed or drain plug/ring.
- Clean all environmental equipment exteriors, light fixtures,
  - including piping & vents, cooling & heating units, ducts weekly.
- Insure there are no cracks in walls, flooring, ceilings of equipment & environmental surfaces.
- Raw material areas need to be scrubbed & cleaned
- Segregate traffic patterns & personnel for Raw, Processing & Packaging
- Closely controlled GMP program to prevent cross contamination
- Effective Environmental monitoring program to validate, verify Listeria control .



## ***Salmonella species: Characteristics & Sources***



- Enteric microbe with *many Serotypes* derived from *Intestinal Tract* of domestic & wild animals, humans.
- Microbial characteristics include:
  - Enteric class of Gram negative microbes
  - Nonsporeforming
  - Also a “facultative” : grows under aerobic/anaerobic conditions
  - Must be ingested in an infectious dose usually 100-1000 /gram
  - Will multiply at above refrigeration temps 40-118 F [35-37 C], but optimum is 95-100 [35-37]
  - For a Gram negative does well in dessicated state [makes it more heat resistant], and also in a frozen state.
  - Over 2,000 Serotypes of Salmonellae species are known.

**Salmonella outbreaks**  
<http://www.cdc.gov/salmonella/outbreaks.html>

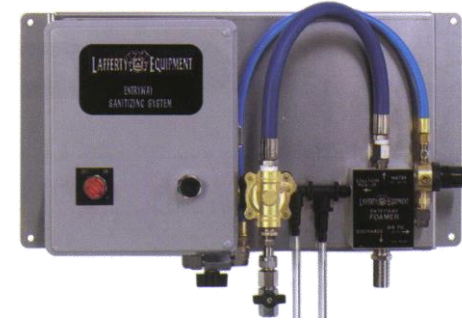
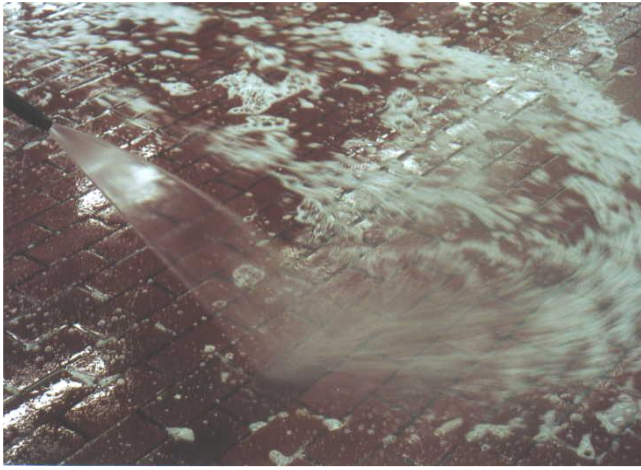
DATE	CASES	SOURCES	LOCATION
<b>2014</b>	<b>6</b>	<b>Peanut &amp; Almond butter [nSpired]</b>	<b>Conn, IA , NM , TN, TX</b>
<b>2013</b>	<b>16</b>	<b>Tahini Sesame Paste</b>	<b>CA , GA , IA , LA , MN , N Y ,</b>
<b>2012</b>	<b>42</b>	<b>Peanut Butter</b>	<b>N D , TX , WI</b>
<b>2009</b>	<b>714</b>	<b>Peanut Butter [King Nut]</b>	<b>20 states</b>
<b>2007</b>	<b>425</b>	<b>Peanut Butter [Peter Pan]</b>	<b>46 states</b>
			<b>47 states</b>
2001	225	Deli sandwiches	VA
1999	200	Orange Juice	WA, CA
1998-99	14	Mamey fruit	FL
1997	54	Raw milk, cheese	WA
1997	24	Cantaloupe	CA
1996	44	Chile relleno	GA
1995	62	Orange juice, raw	FL
1995	241	Alfalfa sprouts	6 states,
1994	158	Raw Gnd Beef	WI
1993	19	Egg Rolls	TX
1990	690	Bread Pudding	IL
1989	164	Shredded Mozzar.	MN, WI, NY



***Program Assessments consist of a  
HACCP based visual audit with  
recommendations plus:***

- A diagnostic program assessment with a variety of our rapid hygiene tests.
  - Microbial Surface Swabs
  - Microbial AIR Monitoring
- Can focus on a variety of issues or topics:
  - Pre-Op
  - Pre GFSI Recertification
  - Operational
  - Allergen Validation or verification



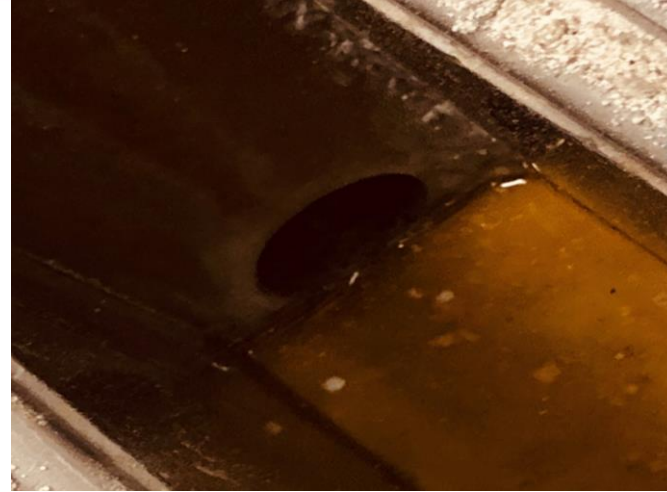


**FLOOR SANITIZATION CAN CONTROL CROSS CONTAMINATION**





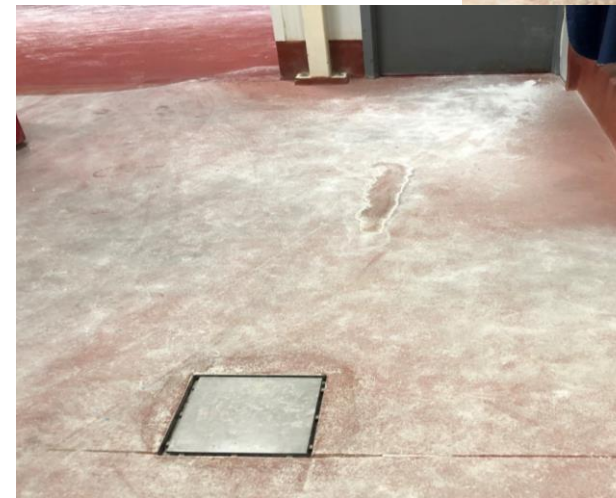
## ***DRAIN Hygienic Design Issues***



- ***Improper slope & drainage creates Biofilm zones & niches.***



## ***Floor Slope To Drain Creates ISSUES!***



- Note the water trail etched in the Devere SFT



***Three Compartment Sink Drain  
Sanitation program is essential***



# Examples of S.S.O.P.s: Drain Cleaning

## SSOP for Floor Drain & Flooring with foamed PAA

<b>GENERAL CLEANING PROCEDURE: &amp; Disinfection OR Sanitization:</b>  <b>Floor Drains &amp; Flooring using Powerfoam ALS and foamed Peracetic acid.</b>		Date of Development <b>June 7, 2007</b>	Revision No: Procedure No. 2	Supersedes: _____ Date
<b>PRODUCTS</b> Powerfoam ES/ALS & Foamed PAA	<b>CONC.</b> See directions on right.	<p align="center"><b>Cleaning Procedures:</b></p> <ol style="list-style-type: none"> <li>Pre-Rinse affected area using warm water with low pressure [Flooding], then remove Drain cover.</li> <li>Utilizing installed chemical dispensing unit, apply Powerfoam ALS™ or F-364 at 3-5 OZ Per Gallon water using designated tagged portable foamer ensuring perimeter covered overlaps actual spill region. Do same to drain cover. Use MF drain cleaning attachment or Innovative Equipment drain cleaning system.</li> <li>Upon completion of actual foaming, allow 5 min of contact and then apply mechanical agitation utilizing color coded [black] brushes to all affected floor regions and a 3 foot perimeter beyond.</li> <li>Squeegee all extraneous foam into drain.</li> <li>Flood Rinse [low pressure only] thoroughly using warm [130-150 deg water] till rinse water is clear.</li> </ol> <p align="center"><b>Disinfection &amp; Sanitization Procedures:</b></p> <ol style="list-style-type: none"> <li>Using the designated, labeled portable foamer for the foamed Peracetic product. Use PAA [Enviroguard sanitizer] fill unit with a 0.5 OZ per gallon [200 ppm av. PAA] &amp; 14% PAA foam additive either as HRS for Perafoam for Enviroguard sanitizer .[32 ozs per 25 gallons solution]</li> <li>Foam sanitize same affected areas that were Wet Vac'd, and Foam cleaned applying a dense foam layer. Allow the foamed Peracetic Acid, to remain on floor and drain areas for 30 minutes. This includes drain cover.</li> <li>Optionally can apply FloorGuard Quaternary beads as a single layer over whole affected area.</li> </ol> <p><b>NOTE:</b> All floor drain sanitation equipment [Squeegees, Brooms &amp; Drain Cleaning attachments used for floor drain must be designated for such use.</p> <p>All such floor / drain equipment must be kept on separate cart, cleaned after using then immersed in 1,000 ppm clean F-25 sanitizer.</p> <p>Re Wet Vac, filters need to be placed on PM program, and interior receptacle must also be foamed cleaned and sanitized.</p>		
<b>SAFETY EQUIPMENT</b> Protective Suits X Rubber Boots X Rubber Gloves X Safety Goggles X Face Shields X				
<b>TEST KITS</b> EMD Peracetic Acid Test Strips & or LaMotte PAA Titration Kit. Quat test strips from Hydron or EMD.				
<b>CLEANING FREQUENCY</b> "Wet" areas in facility : WEEKLY "Dry" areas in facility: MONTHLY				
<b>CLEANED BY</b> See Master List in Sanitation Office				
<b>SPECIAL PRECAUTIONS</b> <i>Always wear proper protective clothing. Never add water to chemical. Always add chemical to water. Place plastic bag on any electrical motor, plug, etc. &amp; secure with duct tape. Do not spray water or cleaning compounds into electrical components or bearings. Report all accidents immediately!</i>				
<b>TOOLS AND EQUIPMENT</b> 2 Portable Foam units [for Cleaner and Sanitizer [foamed PAA], Clean Squeegees				
Company Name Address City, State Zip				



***DRAIN GUARD  
Portable Cart !***

## ***What are some of the environmental biofilm issues at DRAINS***

- Most critical areas of Biofilm control??
- When the Drain is NOT the issue, but an indicator ??



***IAFP Drain  
Biofilm  
Study 2017***





***The Goal is a partnership to protect your Brand through food safety innovation and sustainable solutions.***



# Questions !!

