

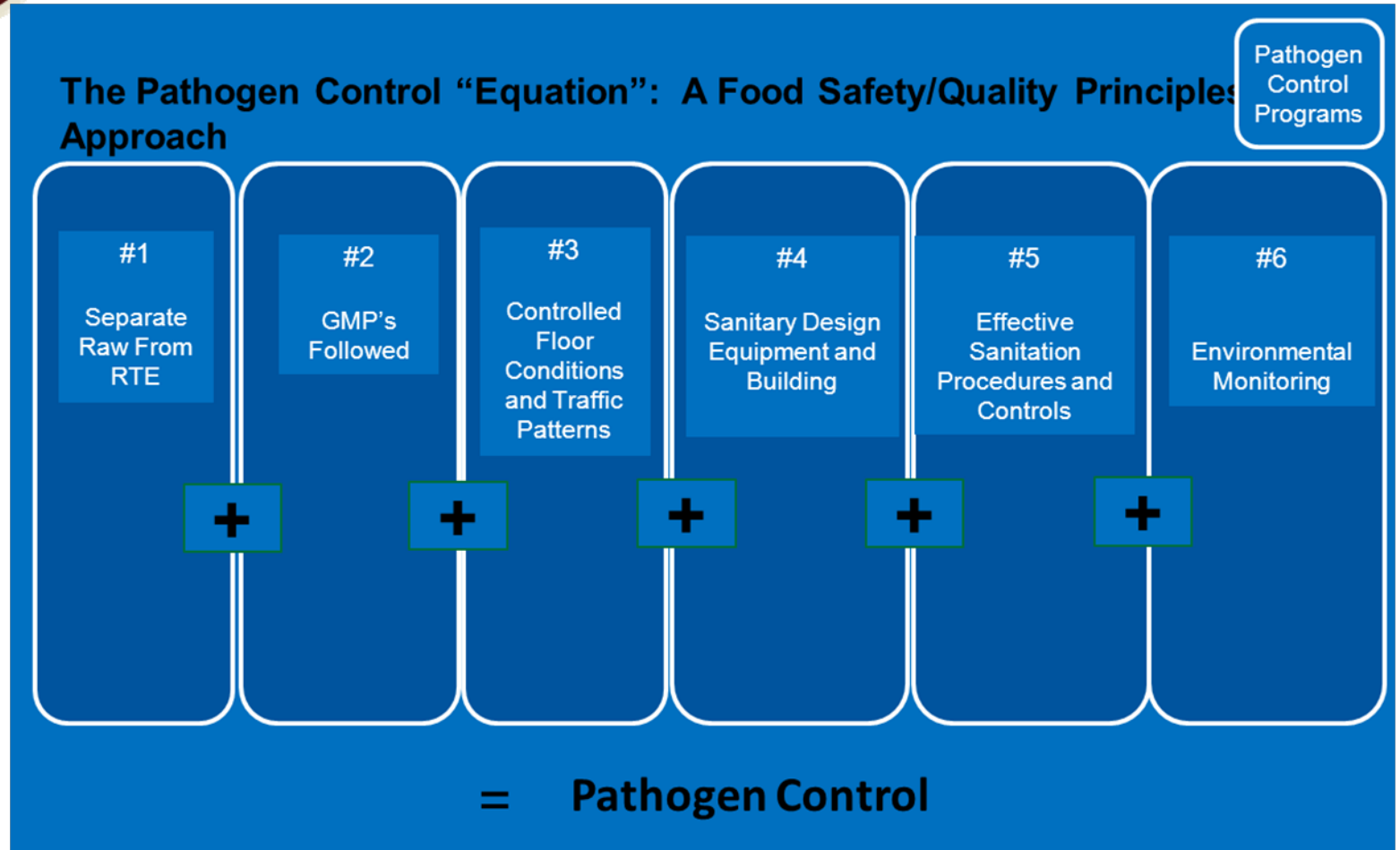


Reducing Risks for Microbial Contamination in the Environment

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Pathogen Control Equation





PREVENTIVE CONTROL GUIDANCE FOR LOW MOISTURE FOODS*

* Adapted from Grocery Manufacturers Association Salmonella Control Guidance

1. Prevent ingress or spread of *Salmonella* in the facility
2. Enhance the stringency of hygiene controls in the Primary *Salmonella* Control Area (PSCA) (RTE)
3. Apply hygienic design principles to equipment and facility
4. Prevent growth of *Salmonella* – control water !!
5. Establish raw materials/ingredients control program
6. Validate control measures to inactivate *Salmonella*
7. Establish procedures for verification of *Salmonella* controls and corrective actions



- The manufacture of pet foods requires the use of animal by products that may or may not have received heat treatments.
- The separation of RAW vs. RTE areas is critical to prevent the spread of pathogens
- Processing temperatures typically exceed 100°C, killing all vegetative microorganisms including *Salmonella*.
- Typically contamination of finished products is as a result of post-process contamination (presuming CCP's are effective and validated) or the addition of raw materials post heat kill such as vitamins, minerals, fats and oils ,etc. that may have not been free of the organism.



Prevent ingress or spread of *Salmonella* in the facility

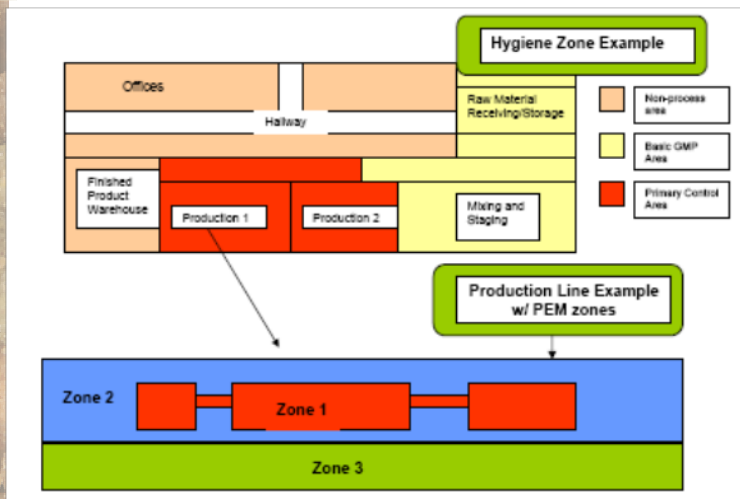


Controlled access to emergency exits, maintenance access points, mechanical control rooms. Rooftops secured and controlled with hygiene barriers.

- Control foot traffic and wheel movement
- Adequate lighting for cleaning and inspection.
- Maintain effective pest control
- Routine infrastructure inspections
 - cracks, roof leaks, access breaches immediately repaired or corrected.
- Dryer intake and building make up air
 - filtered to remove dust and microorganisms



Establishing and Managing Hygienic Zones Use Color Coding- Facility and People if Necessary



Red-Primary
Salmonella
Control Areas
(PSCA)



Yellow-
Basic GMP



Tan-Non
Process
Areas

- ✓ Know process flows
- ✓ Control where people and wheels move

Enhance the stringency of hygiene controls in the PSCA (RTE)



Restricted Access

PSCA/High Hygiene

- Dryer
- Conveying lines
- Powder storage bins
- Dry blending
- Magnets
- Bagging/Filling Room
- Powder Sampling
- Sample compositing

Post pasteurization access controls

Medium Hygiene

- Mix tanks
- Condensed ingredient storage prior to drying
- High pressure pumps

Normal access control

Non critical areas

- Raw material warehouse
- Packaging materials storage
- Palletizer room/pallet handling and storage
- Washing areas
- CIP rooms
- Hallways
- QC areas/non micro
- General personnel areas
- Locker rooms, break areas, offices



PSCA GMP's and Personnel

- **Limit non-essential personnel access to PSCA**
- **Designate & enforce proper apparel when entering PSCA**
 - **Dedicated footwear or shoe covers**
 - **Protective sleeve-guards**
- **Personnel & Materials Flow**
- **Educate PSCA Operators on Job Specific GMP's for Dry Environments**
- **Provide Proper Quick-Dry sanitizers for dry areas**
- **Dedicated tools for RAW vs. RTE**
 - **samplers, maintenance, clearing plugs, brushes, vacuum attachments.**
- **Designate & separate product contact and non-product contact tools**
- **Clean and sanitize tools before use and store in protected environment**
- **Control Maintenance, QC, Management, Laboratory personnel activities**
- **Perform internal self inspection audits**

Prevent the Growth of *Salmonella*

Water management



- Minimize wet cleaning.
- If you must wet clean:
 - **Isolate bag filters /bag house during wet cleaning.**
 - **Inspect and maintain these routinely**
 - **Provide adequate dry-out time.**
 - **Verify equipment is dry before start up**
 - **Run flush powder**
- Design CIP nozzles to self drain
- Prevent & control condensation in dry areas

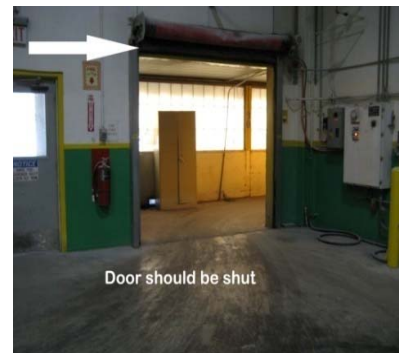
Common Water Control Issues

- Roof leaks
- Leaking sewer or drain lines
- Crossing wet/dry barrier
- Hand washing facility –drains onto floor
- Leaking water/steam valves & pumps
- Poor dehumidifying equipment control
- Improperly managed footbaths and foot foamers
- Foot traffic control
- Cracked floors which hold water



Material Handling

- Protect packaging materials designated for use in PSCA
- Dedicate sanitary pallets for transferring materials into high hygiene (HH) areas.
- Dedicate lift trucks, carts , jacks for use in HH areas.
- Use rapid roll up doors to limit HH area exposure and close when transfer completed.





Establish Raw Material Control Program

- Supplier Assurance (SA) program.
 - Suppliers have same standards as you and your customers.
 - Material specifications complement final product
- Vendor Risk Assessments
 - Material and facility safety
- Supplier Environmental Program
- Supplier testing methods and sampling plans
- COA or not? Depends on supplier confidence
- Define sampling plan per lot size
- Audit material receipts as part of SA program

Validate Control Measures

Surveillance / Verification of Proper Controls



Zone 1-EB/ATP Testing

Occasional Sampling

- (product contact surface testing)
- Powder scoops
- Bagging head brushes/vacuum
- Bagging head scrapings
- Powder cooling unit conveyor
- Sampling tools
- Air filter
- Conveyor lines

Validate CCP's

- Use of surrogate organisms and research studies

- Scheduled review of data
- Actions for non-conformance including corrective action and root cause analysis

Use EB (Enterobacteriaceae) as a routine indicator- Zones 1 and 2

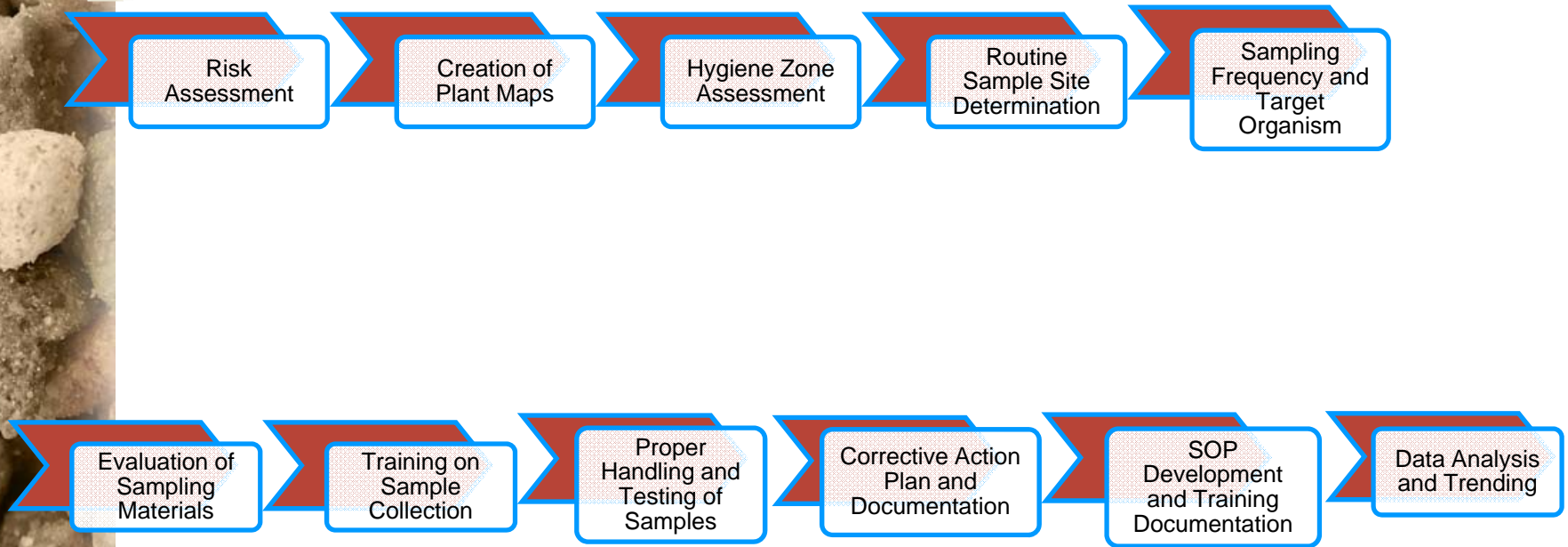


Value of a Robust PEM Program

- Meets the FSMA (Food Safety Modernization Act) requirements regarding “preventative controls”
- Verifies the effectiveness of cleaning and sanitation programs
- Uncovers niche points in equipment and the environment
- Determines the presence of pathogens in the environment and the proximity of those pathogens to food contact surfaces
- Reveals the true risk for product contamination vs. finished product testing.



Components of a Robust PEM Program





• Environmental Risk Assessment

Do not create your program in a vacuum-involve your employees

Assemble a Team of Cross Functional Employees

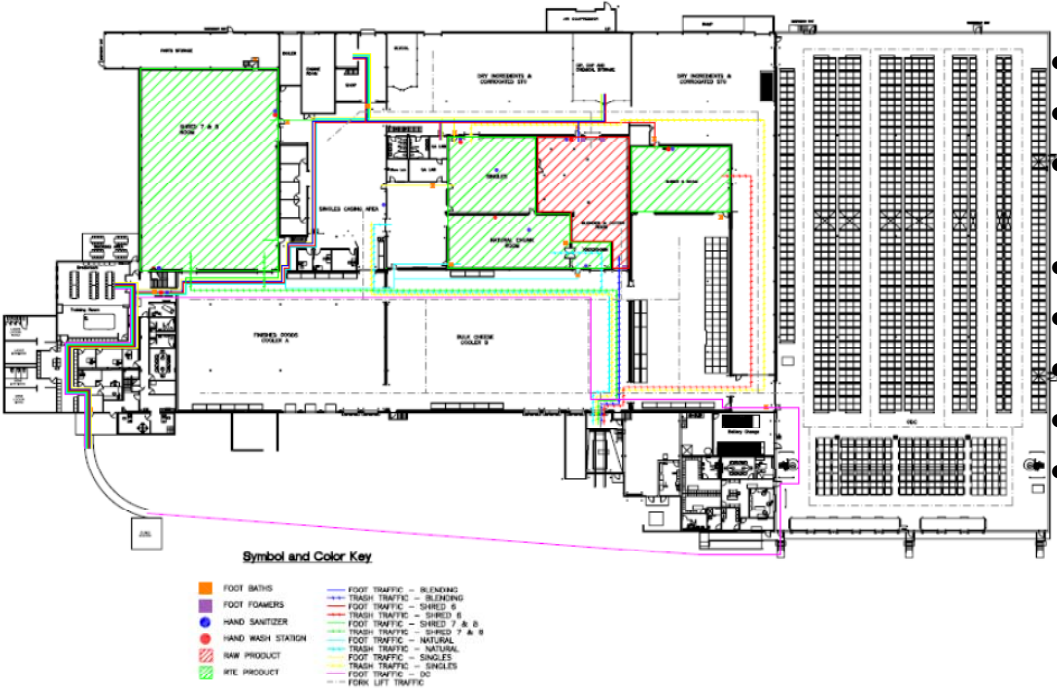
- Quality, Operations, Maintenance, Line Employees, Sanitation, Laboratory Staff, etc.



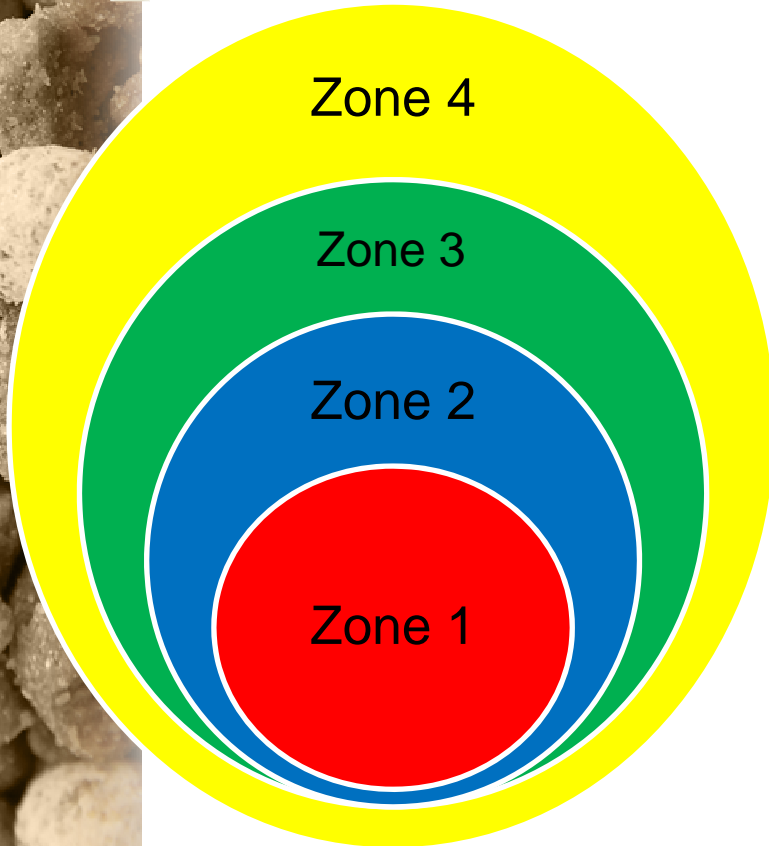
- Walk through the plant
- Bring current maps if available
- Note equipment placement
- Note process flows (raw materials, supplies, finished product)
- How are employees, wheels, etc. moving through the plant?
- Understand airflow (positive vs. negative pressures)



• Plant Maps



- Foot Baths
- Foot Foamers
- Traffic Patterns (wheels, people, trash)
- Hand Wash Stations
- Hand Sanitization Stations
- Raw Product Flow
- Finished Product Flow
- Drains- should be numbered and shown on a map



Zone 1- Product Contact Surfaces

Zone 2- Indirect Product Contact
Typically 12"-24" in all directions from Zone 1 (equipment framework, control panels, buttons, etc.)

Zone 3- Non-Product Contact
(with-in the processing room)-(drains, forklifts, wheels, footbaths, toolboxes, etc.)

Zone 4- Areas outside of the processing room
(bathrooms, locker rooms, etc.)



- Routine Sample Site Determination

Ensure sites include overhead and underneath equipment and that you have the proper tools to conduct sampling in these areas

- The number and location of sites should consider the risk level inherent to the product and process (wet vs. dry area) (*Salmonella* vs. *Listeria*)

Raw to processed transition areas should be sampled

- Plan to sample the environment weekly

Plan to sample during production times, but vary sampling times

- Only composite samples from the same area and zone

Encourage employees to take a “look, dig, find” approach



• Special Consideration Sampling

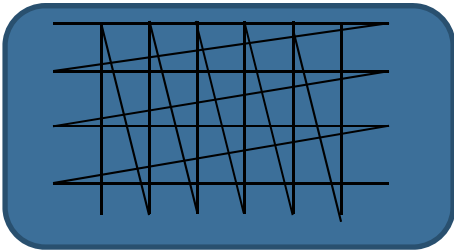
- Roof and overhead water leaks
- Production down times which exceed norms
- Plant construction and plant maintenance beyond routine
- Regulatory visits- will you pull duplicates, will you test?
- New equipment installations
- Re-processing of positive product
- Natural disasters





Evaluation of Proper Sampling Materials

- Buffers- Lethen vs. DE vs. Neutralizing (PCR issues)
- What sanitizers may be present
- Proper sampling tools for the intended use
- Drains vs. liquids vs. dry samples
- Use of only one sponge per site
- Consideration of target organism



← Proper technique

Floors, walls- 12" x 12" area

A green square on the left side of a grey arrow pointing to the right. The arrow has a green outline.

• Sample Collection

- Avoid dry quat crystals that may be present
- Compositing rules (no more than 5 sponges)
- Use aseptic techniques
- Ensure the correct sampling tool is being used (i.e.- swab vs. sponge)



• Sample Type Definitions

Weekly swabbing

Routine Sample (R)



As a result of an audit or special circumstance (construction, roof leak, etc.)

Investigative Sample (I)



As the result of a positive site. Sampling in a “starburst” around the original site in order to determine the true source of contamination

Vector Sample (V)





• Proper Handling and Testing of Samples



- Ensure samples are refrigerated as soon as possible.
- Ship samples to be received by your laboratory at $<15^{\circ}\text{C}$
- Test samples within 72 hours of sampling
- Ensure that the pre-enrichments used for the testing coincide with the product matrices.
- Discuss the proper test method for your samples. Note that there is an interference between neutralizing buffers and PCR testing. ELISA vs. PCR vs. Lateral Flow vs. ELFA- which to use?
- Test for *Salmonella* and *Listeria* species only in drains, coolers.
- Consider serotyping positive *Salmonella* samples.

Confirmation Protocols



Salmonella Presumptive



Follow FDA BAM Protocols

1. Re-grow in TET and RV Broth
2. Streak from pre-enrichment to 3 agar plates (HE, XLD, BS) + Chrom
3. Read HE and XLD plates at 24 hrs.
4. Read BS plates at 48 hrs.
5. Pick colonies off of plates and carry on to agar slants (24 hrs.)
6. Positive slants then are used to streak to agar plates for biochemical identification (48 hrs.) and serotyping. (3-7 days)



H2S (yes/no)




What if my sample clears?

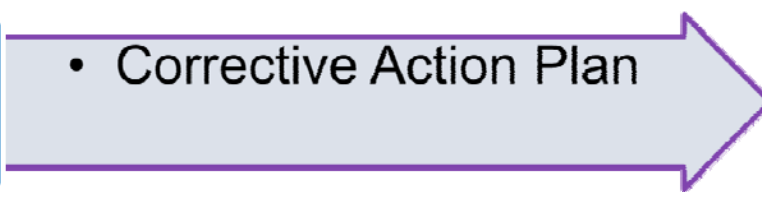


Petfood Industry


WATT



• Corrective Action Plan



- How will you handle presumptive and confirmed positive samples?
- How quickly will you react to a presumptive sample?
- If the presumptive is a composite, will individual samples be taken and for how long?
- Will presumptive samples require the same number of consecutive negatives as confirmed samples?
- For confirmed positives, how many vector swabs will be taken?
- What is your plan for root cause and investigation? Consideration of maintenance activities, sanitation protocols, out of the ordinary event, etc?
- Who is responsible for the data gathering? How will data be formatted to ensure the corrective action plan is followed?
- When will positive sites go back into rotation for routine testing?
- What is the communication process to notify the team of required actions.
- How will you mitigate further risk by controlling access and foot traffic?



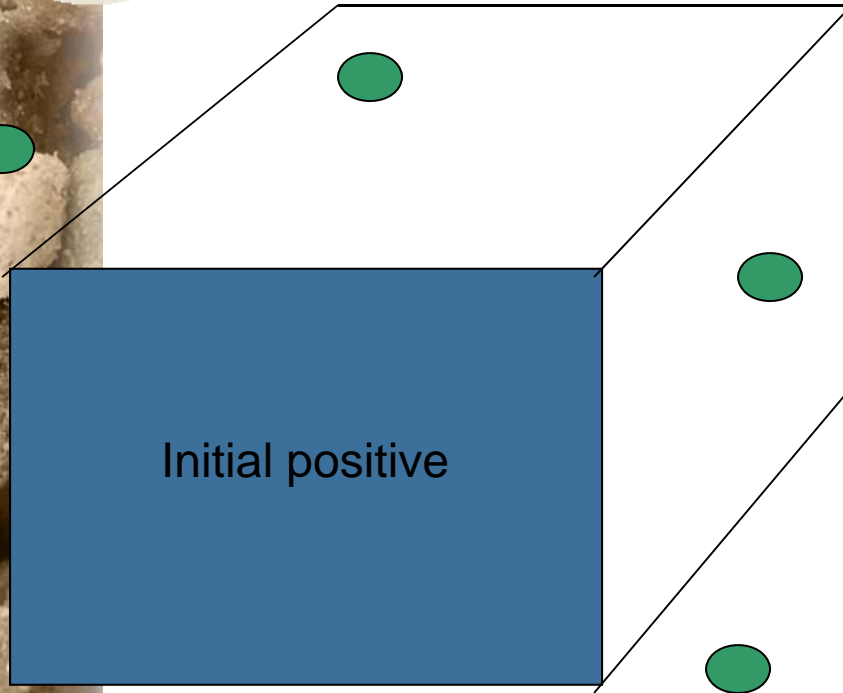
- Corrective Action Plan Suggestions

- Plot all positives on your maps. Use colored dots to visualize hot spots.
- Minimum of 3 consecutive negatives for positive sites.
- Ensure vectoring is occurring.
- Zone 2 positives may trigger product testing to prove you were not operating in conditions which may have put product at risk.
- Maintain a “master” presumptive database and all associated corrective action activities (swabbing, investigations, meetings, sanitation activities, etc.) Show the linkage and timeline of what occurred.
- Develop flow diagrams for personnel to use when non-conformances occur



Vector Swabbing

A process of investigative swabbing in order to determine the extent of contamination and root cause by extending out from the site, sampling up and down stream from the site of an original positive sample, in a starburst pattern, in order to locate the source of contamination.



Initial positive





• Data Analysis and Trending

- Total number of positive and negative samples by organism
- Percent rates (overall and by organism)
- Total number of positives by Zone
- Total number of positives by Environmental Type (Routine, Investigative and Vector)
- Positive rate by area
- Consider a once a year “heavy up” sampling conducted by a third party or corporate to validate your program.





Special Consideration Environmental Sampling

Roof and Overhead Water Leaks- Have a Written Plan

How will we re-qualify the area for production?

- If over a processing area, production should cease.
- Increased environmental sampling when leaks are found.



Special Consideration Environmental Sampling



Pre-Construction-:

Regardless of the type of construction (minor or major), the plant food safety team shall review all plans for construction and perform a risk assessment prior to proceeding with any work.

Minor construction examples (moving of equipment, replacement of interior doors, machinery repairs). Major construction examples (breaking cement, replacing drains, cutting walls, moving walls, moving structures or creating new structures).

The following should be considered:

- GMP training and documentation of the training for all construction employees.
- Preparation of the contractor's policies documents outlining GMP policies, traffic plans, tool policies and required operational guidelines.



Special Consideration Environmental Sampling

- Consideration for foot traffic control and planned paths for all workers.
- Plant maps shall be used to outline planned traffic paths.
- Footwear control for all construction workers.
- A plan for the removal of all construction debris, the containers that will be used, how the debris will be covered, the path that the containers will take leading to the exterior of the building. If containers will exit and enter the building, consideration must be taken for cleaning and sanitizing any wheels, etc.
- The need for any temporary walls that may need to be constructed to minimize dust, traffic and control of the construction zone.
- Modification to SSOP's to prepare for post construction cleaning prior to utilizing areas for production of product.



Monitoring During Construction

In addition to the normal routine PEM sites and frequency, increased sampling should occur in all primary construction areas as well as secondary adjacent traffic areas. **Sampling should occur weekly** in all primary and secondary construction areas. Typically **routine sample volumes are doubled**; however the final numbers of samples will be determined as a joint decision between corporate and the plant food safety team.

Monitoring Post Construction

Prior to using the area for food production, the entire area will be cleaned, sanitized and sampled for the target pathogen of interest (*Salmonella* and or *Listeria*). Food contact surfaces shall be verified with ATP and or indicator testing to ensure food contact surfaces have been properly cleaned and sanitized. If positive sites are found, the corrective action requirements outlined in this document is followed until all sites receive three consecutive negatives.



New/Used Equipment Installations

Prior to bringing new equipment into the manufacturing facility, recommend sampling for *Salmonella* to ensure that the equipment is not contaminated. If the equipment tests positive for pathogens, determine cleaning and sanitization prior to installation.





- Control Measures



ELIMINATE WATER WHERE POSSIBLE

Ensure proper sanitizer strengths are used and those concentrations are documented and reviewed

Minimize the use of vacuums-if you use them, stainless only and keep them clean

Use tools that are stored properly, kept clean

Inspect equipment and ensure hygienic design (no niches, hollow legs, pinch points, treaded legs, etc.)



• Control Measures



Strict adherence to GMP's

Manage foot traffic

Manage maintenance activities

Physical separation of raw and RTE

Train, Train again and retrain



- Control Measures



Do NOT use high pressure hoses

Ensure foot foamers are the correct pressure and have residual time

Footbaths if not maintained, will serve as vectors. Swab underneath.

Maintain pallet control.

Drains collect- they are usually not the true source of the contamination, just where the organisms end up. Vector appropriately.



• Regulatory Expectations

1. Do what you say you are going to do.
2. Ensure you have current SOP's that are being followed.
3. Ensure you have a dynamic program that is being reviewed, revised and updated on a scheduled frequency.
4. Prove through the use of data, not opinion that your program is robust.
5. Ensure that all employees are properly trained. Document the training and retrain.
6. You must follow all defined corrective action protocols every time.
7. Be able to prove that if you are having positives in your environment, you followed your corrective action protocols and that the location of those positives did not put product at risk.
8. No "acceptable" level of positives has been defined.





Lessons Learned from PEM (Pathogen Environmental Monitoring) and Regulatory Visits when FDA Requests Data



Presentation and Format of Data Including Positive Rates

- Want to present the full picture
- Present Routine Trend First, followed up with Vector
- 10-15 Vector samples is acceptable
- Provide trends by month, showing only current years data and include total # of samples and # of positives
- Keep verbiage descriptions of sample sites in a separate report
- FDA will not say what acceptable positive rates are, however we are finding that (<1.5 to 2%) for high medium/volume routine sampling seems acceptable.



Corrective Action and Follow-Up

- Minimum of three consecutive negatives on the original routine sample site positive.
- Want to see a Master Corrective Action Spreadsheet (document) that includes original positive, consecutive negatives, all vector swabs and Corrective action steps- investigation, sanitation/cleaning and root cause analysis
- Typically leads to a **review of training records, verification of sanitizer strengths**
- Want to see that you have “special consideration” sampling and qualification plans (construction, natural disasters (flooding, tornados), roof leaks, powder re-processing.



Example- Master Corrective Action Spreadsheets

Routine and/or Investigative Sampling

Original Positive Sample Number	COA Number	Original Sample Date	Zone	Env. Type	Sample Description	Individual Site Locations from Composite	Follow-Up Set 1				Follow-Up Set 2				Follow-Up Set 3			
							Result	COA Number	Sample Number	Sample Number	Result	COA Number	Sample Number	Sample Number	Result	COA Number	Sample Number	Sample Number
533140		08/03/2009	3	I	Insulation High Pressure Pump- Dryer		09/14/2010	Negative		727679	09/17/2010	Negative		730185	09/20/2010	Negative		731883
533621		08/04/2009	3	I	Dryer- blue broom bag room		09/14/2010	Negative		727664	09/17/2010	Negative		730203	09/20/2010	Negative		731884
533622		08/04/2009	3	I	Dryer-Filler floor		09/14/2010	Negative		727687	09/17/2010	Negative		730190	09/20/2010	Negative		731886
555739		09/28/2009	3	R	2SD-B Dryer- Composite	AIR INTAKE AIR HANDLER-CEMENT DECK	10/01/2009	Negative		557415	10/05/2009	Negative		558621	10/08/2009	Negative		560026
						DRAIN BY LM FILTER-CEMENT DECK		Negative		557413		Negative		558620		Negative		560024
						NORTH DOOR BY CONDENSER-CEMENT DECK		Negative		557407		Negative		558616		Negative		560025
						TOP OF SCRUBBER-CEMENT DECK		Negative		557410		Negative		558614		Negative		560029
						PRESSURE HOSE CEMENT DECK-CEMENT DECK		Negative		557404		Negative		558612		Negative		560028
572312		11/09/2009	2	R	1SD-E Dryer- Composite	SIFTER-MAIN FLOOR	11/12/2009	Negative		573818	11/16/2009	Negative		574737	11/19/2009	Negative		576409
						FLUIDIZER-MAIN FLOOR		Negative		573816		Negative		574738		Negative		576410
						NO 4 AIR LOCK-CAT WALK DECK		Negative		573815		Negative		574739		Negative		576412
						TAILINGS PIPE-MAIN FLOOR		Negative		573814		Negative		574740		Negative		576411
						CONVEYOR FAN-LOWER STEEL DECK		Negative		573813		Negative		574741		Negative		576408
588208		12/21/2009	2	R	1SD-A Dryer- Composite	ELBOW DOOR-MAIN FLOOR	12/28/2009	Negative		590554	01/04/2010	Negative		592683	01/07/2010	Negative		595343
						INSIDE CABINET-BY ELBOW-MAIN FLOOR		Negative		590555		Negative		592985		Negative		595344
						TOP DRYER DOOR-TOP STEEL DECK		Negative		590556		Negative		592986		Negative		595346
						AREA UNDER FLIPPERS-MAIN FLOOR		Negative		590557		Negative		592987		Negative		595347
						CONVEYOR LINE-LOWER STEEL DECK		Negative		590558		Negative		592988		Negative		595349

Vector Sampling

Original Positive Sample Number	Zone	Sample Description	Follow-Up Set 1				Follow-Up Set 2				Follow-Up Set 3			
			Result	COA #	Sample Number	Sample Number	Result	COA #	Sample Number	Sample Number	Result	COA #	Sample Number	Sample Number
703609	3	Z3-W1-5-Investigative Sample <i>10 vector swabs taken</i>	08/13/2010	Negative		709087	09/03/2010	Negative		720454	09/07/2010	Negative		722504
	3	Chemgrates to Tanks	09/02/2010	Negative		720439								
	3	South Wall	09/02/2010	Negative		720440								
	3	Compressor Top	09/02/2010	Negative		720441								
	3	Compressor Bottom	09/02/2010	Negative		720442								
	3	Chemgrate to Chamber U	09/02/2010	Negative		720444								
	3	Product Hoses	09/02/2010	Negative		720445								
	3	Grey Cart	09/02/2010	Negative		720446								
	3	Yellow Steps & Structure	09/02/2010	Negative		720477								
	3	Plastic Pallet	09/02/2010	Negative		720448								
	3	Floor between HPP & Chamber	09/02/2010	Negative		720449								



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Salmonella

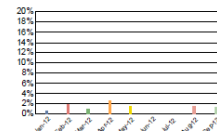
01/01/2012 - 09/30/2012

Invoice Month	Product Samples Invoiced	Number Confirmed Positive	% Product Positive	Env. Samples Invoiced	Number Confirmed Positive	% Env. Positive
Jan-12	41	0	0.00	656	4	0.61
Feb-12	60	0	0.00	943	17	1.80
Mar-12	43	0	0.00	632	6	0.95
Apr-12	49	0	0.00	650	23	2.42
May-12	79	0	0.00	289	4	1.38
Jun-12	208	0	0.00	395	0	0.00
Jul-12	327	0	0.00	276	0	0.00
Aug-12	46	0	0.00	398	8	1.55
Sep-12	59	0	0.00	409	5	1.22
Total	912	0	0.00	4,836	65	1.32

% Product Positive



% Environmental Positive



10/16/2012 10:25:57AM

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Example- Monthly Trend Report- Salmonella Product + Environmental Data



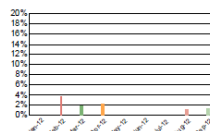
Example- Environmental Trend Report- Routine Samples by Zone

Phone: 417-829-3788
 Fax: 417-829-3787
 www.chestnutlabs.com

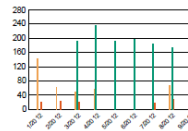
01/01/2012 - 09/30/2012
 ROUTINE

Invoice Month	Env. Samples Invoiced	Number Confirmed Positive	% Env. Positive	Zone 1	Zone 2	Zone 3	Zone 4
Jan-12	383	0	0.00	0	143	210	21
Feb-12	282	10	3.55	0	62	195	25
Mar-12	283	5	1.90	0	50	191	21
Apr-12	320	7	2.19	0	58	237	16
May-12	288	0	0.00	0	44	191	33
Jun-12	283	0	0.00	0	47	197	19
Jul-12	253	0	0.00	0	51	185	17
Aug-12	209	3	1.12	0	65	174	29
Sep-12	333	4	1.20	0	57	252	24
Total	2,834	29	1.10	0	578	1,841	205

% Environmental Positive



Env Type Sample Count



[Generate Sample Confirmation Detail](#)



Thank You

Contact Information

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