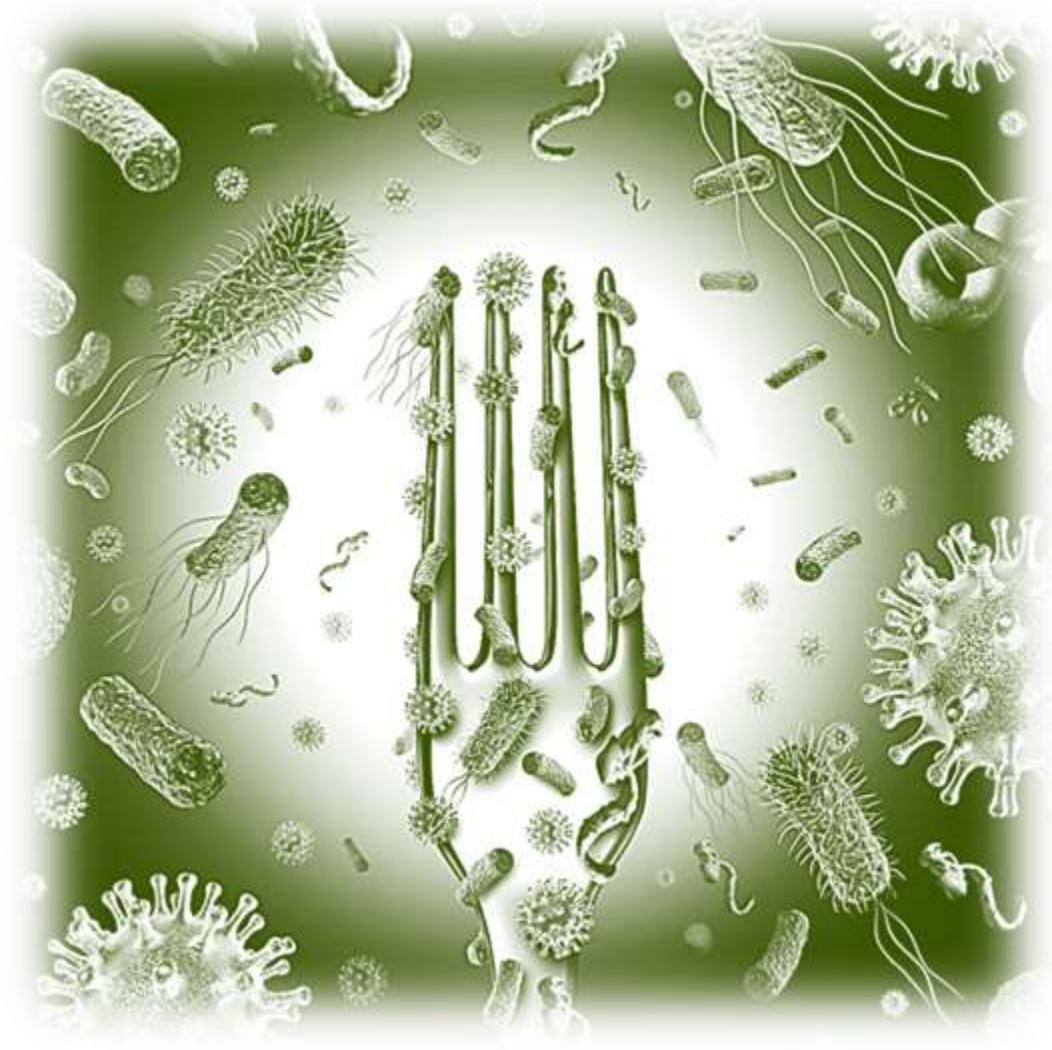

Reducing the Risk and Impact of Microbial Contamination

Kevin Lorcheim
ClorDiSys Solutions

2020 Food Safety and Microbiology Conference

RECALLS

Scenario: A pathogen was found on your finished product. A recall is initiated.

What is the ideal amount of product recalled?

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RECALLS

The ideal recall involves only the contaminated products, and nothing more.

Knowing exactly when the product became contaminated is challenging.

Proving it is another thing altogether.

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What can we do to limit the size of a recall?

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CLEAN BREAKS

A clean break is a defined production break that involves a documented, verified, and validated cleaning and sanitation process of all food / product contact surfaces.

Clean breaks are used to establish lots to trace their products and limit the quantity of product recalled in case of a contamination.

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CLEAN BREAKS

Similar to a firebreak in a forest

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WHAT IS A CLEAN BREAK WORTH?

Preventive measures are always hard to value.

Like insurance, its hoped to be a sunk cost that has no ROI.

But if its used, its value is tremendous.

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CLEAN BREAKS

The cost to put in this firebreak is inconsequential compared to the value it supplied.

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CLEAN BREAKS

October 2018, McCain Foods recalled 63 different products that were shipped all the way back from January 1, 2016.

34 MONTHS WORTH OF PRODUCTION!

A clean break date every January would have saved **24 months** of recalled product cost.

$$$$

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ESTABLISHING A CLEAN BREAK

You can only establish a clean break if you can prove that the facility was truly clean on that date. If later on your facility comes up positive for the same strain of a pathogen that was previously found, logic will point to the problem having never fully gone away.

You're playing microbial whack-a-mole!

What type of sanitation method is necessary to establish a clean break?

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REQUIREMENTS FOR EFFECTIVE SANITATION

In order for any sanitation method to be effective, the following points must be satisfied.

The decontamination method must:

- **Be able to kill the organism in question**
- **Achieve good and complete distribution**
- **Achieve thorough and total penetration**
- **Achieve sufficient contact time at the correct concentration**

Recurring pathogens due to resident strains within the environment only exist because the current sanitation method either isn't strong enough, or isn't reaching the pathogen.

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TRADITIONAL CLEANING METHODS

Traditional sanitation methods can have difficulty guaranteeing that all organisms have been contacted or contacted with the proper effective dosage

The decontamination method must:

- ✓ **Be able to kill the organism in question**
- ? **Achieve good and complete distribution**
- ? **Achieve thorough and total penetration**
- ? **Achieve sufficient contact time at the correct concentration**

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TRADITIONAL CLEANING METHODS

Liquid based sanitation methods (vapors, mists, fogs, sprays) can all have difficulty reaching organisms in cracks and crevices and other hard to reach locations due to condensation and lack of mobility around obstacles in the environment (e.g. equipment)

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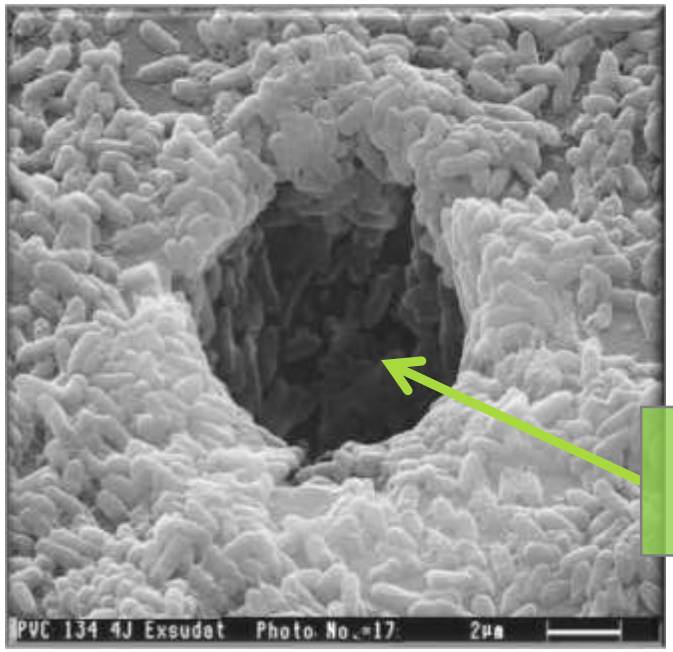
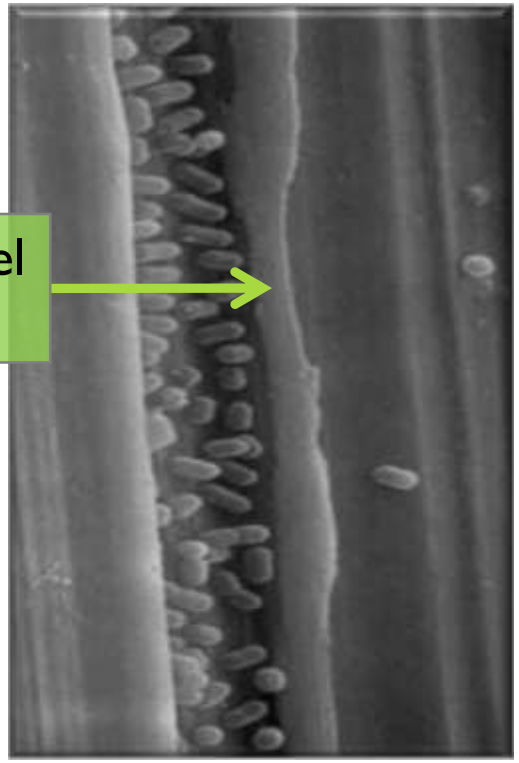
GROWTH NICHES

Scratches[2,3] - Crevices - Punctures[1]



Pseudomonas growing in a conveyor belt

Scratch in stainless steel harboring bacteria



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2. JENNY SCOTT, U.S. Food and Drug Administration-CFSAN, Washington, D.C., USA, "The Significance of Persistent Bacterial Strains in the Food Processing Environment", Presented at IAFP Session 21 (8-2-2011) Milwaukee.
3. Solioz, M, Biochimica - Copper kills bacteria: end of hospital-acquired infections? Scienza in rete, 18 April, 2011, Accessed on 6-26-2013 http://www.scienzainrete.it/en/content/article/copper-kills-bacteria-end-hospital-acquired-infections

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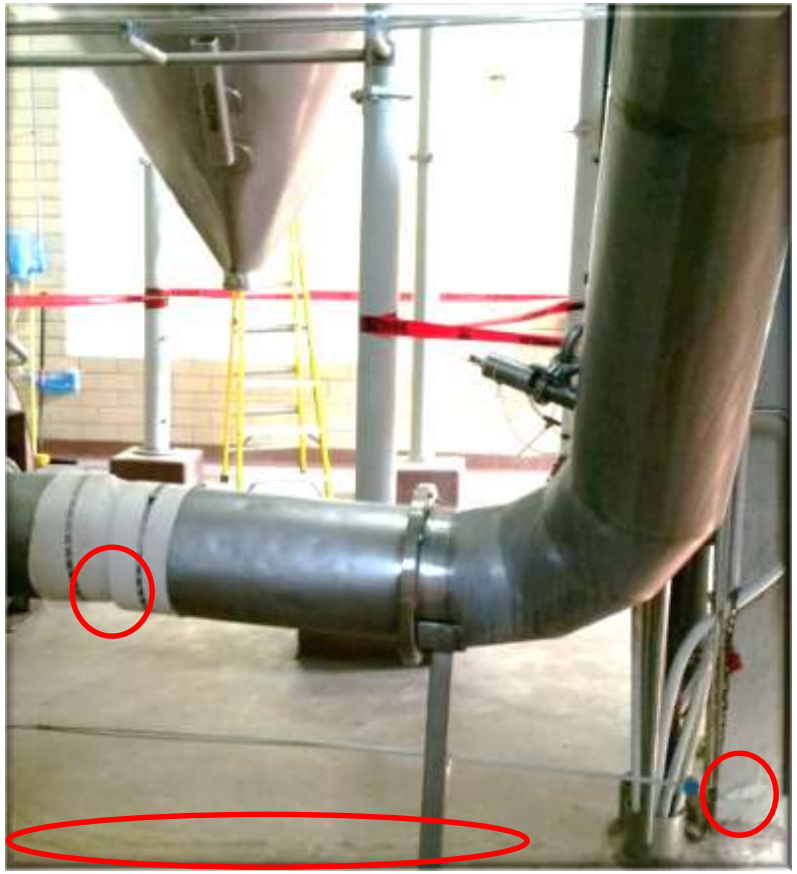
POTENTIAL GROWTH NICHES



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CHLORINE DIOXIDE GAS

Chlorine dioxide gas is a dry gas decontamination method.

BENEFITS

- True gas at room temperature
- Molecule size smaller than the smallest microorganisms
- US EPA registered sterilant
- The unique ability to retain its sterilization capacity in water
- Offers superior process control

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VALIDATION – SCIENTIFIC EVIDENCE

Principles of Decontamination	Chlorine Dioxide Gas
Be able to kill the organism in question	There are chlorine dioxide gas products that are US EPA registered as sterilants proven capable of eliminating all microbial life
Contact all pathogens	As a true gas, it will evenly and completely fill the space its introduced into, including niches and crevices.
Achieve sufficient contact time at the correct concentration	Chlorine dioxide gas can be measured very accurately in real-time using a photometric device

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VALIDATION – ANALYTIC EVIDENCE

Data Type	
Concentration Monitoring Data	Chlorine dioxide gas can be measured at multiple points within the environment to guarantee the right dosage was achieved at all sample locations
Biological Indicators (BI's)	Biological Indicators (spore strips) can be placed in challenging locations to illustrate antimicrobial kill at that location
Environmental Monitoring Results	Swab results can provide further verification

BI's contain over 1 million *geobacillus stearothermophilus* spores, providing the ability to show a 6-log (99.9999%) sporicidal reduction.

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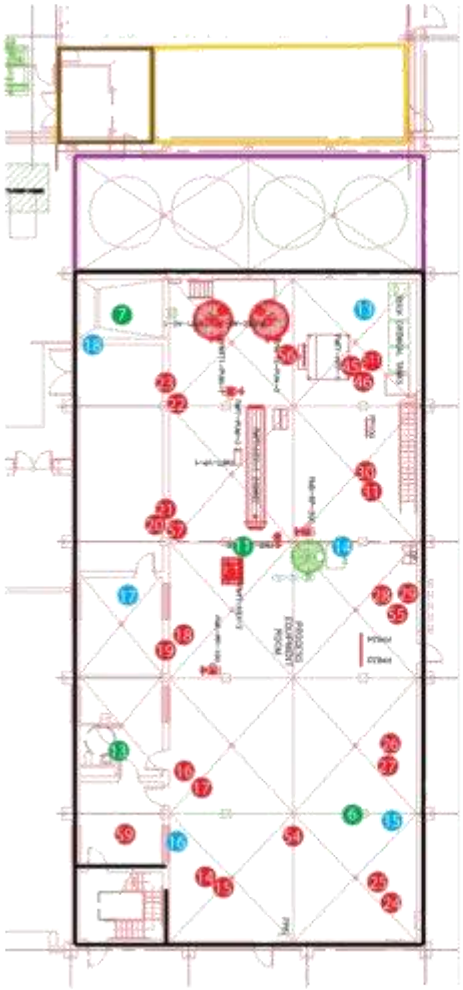
FLOORPLAN



NIRO
Main Floor Level

- Inject Location
- Sample Location
- Spare Inject
- Bio Indicator

Recon Annex

Recon

Bin Room

NIRO

NIRO
Upper Levels

- Inject Location
- Sample Location
- Spare Inject
- Bio Indicator

Recon Annex

Recon

Bin Room

NIRO

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CONCENTRATION MONITORING DATA

Hot Spot ↘ (Sample 6)

Hot Spot ↘ (Sample 11)

Hot Spot ↘ (Sample 19)

Sample	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
4:45	.0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5:00	.013	.07	.08	.05	.08	.06	.07	.07	.07	.08	.09	.10	.10	.13	0	0	0	0	0	0
5:15	.24	.15	.18	.13	.17	.15	.15	.15	.15	.15	.17	.17	.19	.21	.01	.01	.01	.01	.01	.01
5:30	.35	.27	.27	.25	.28	.24	.23	.25	.24	.24	.26	.27	.28	.29	.43	.40	.33	.36	.51	.52
5:45	.45	.37	.35	.33	.37	.33	.33	.35	.35	.35	.36	.37	.39	.38	.48	.44	.35	.38	.64	.64
6:00	.62	.67	.62	.58	.51	.49	.51	.52	.50	.50	.51	.53	.54	.51	.61	.59	.50	.53	.75	.73
6:15	.75	.78	.75	.67	.66	.67	.69	.67	.65	.65	.67	.67	.69	.69	.69	.64	.55	.58	.78	.77
6:30	.79	.81	.78	.72	.68	.70	.73	.75	.73	.73	.76	.76	.78	.72	.80	.75	.62	.65	.84	.81
6:45	.85	.88	.88	.82	.79	.78	.80	.81	.85	.82	.82	.84	.88	.80	.94	.86	.69	.76	.92	.88
7:00	.96	.99	1.00	.85	.82	.82	.85	.89	.86	.85	.88	.89	.92	.85	.96	.90	.78	.81	.98	.95
7:15	1.08	1.11	1.08	1.01	.93	.93	.99	1.02	.98	.98	1.02	1.02	1.05	.98	1.15	1.05	.82	.89	1.07	1.04
7:30	1.14	1.18	1.13	1.05	1.02	1.06	1.09	1.12	1.10	1.09	1.12	1.13	1.17	1.08	1.17	1.17	.89	.94	1.09	1.04
7:45	1.18	1.21	1.19	1.07	1.03	1.10	1.12	1.17	1.12	1.10	1.16	1.14	1.18	1.12	1.29	1.21	.92	1.02	1.09	1.04
8:00	1.18	1.21	1.19	1.07	1.03	1.10	1.12	1.17	1.12	1.10	1.16	1.14	1.18	1.12	1.30	1.24	1.00	1.05	1.10	1.06
8:15	1.14	1.12	1.09	1.01	.94	1.06	1.06	1.09	1.05	1.03	1.08	1.08	1.10	1.05	1.21	1.18	.85	.94	1.06	1.03
8:30	1.10	1.08	1.05	.98	.92	1.00	1.00	1.04	1.01	.99	1.03	1.04	1.05	1.00	1.15	1.12	.83	.90	1.00	.98
8:45	1.06	1.05	1.02	.96	.88	.96	.96	1.05	.98	98	1.01	1.00	1.03	.98	1.11	1.09	.74	.79	.94	.93
9:00	.91	.92	.94	.92	.84	.86	.87	.92	.91	.85	.94	.95	.96	.90	.94	.96	.70	.72	.88	.82
9:15	.89	.88	.84	.80	.73	.79	.82	.82	.80	.79	.85	.82	.84	.71	.75	.71	.33	.35	.58	.55
9:30	.72	.51	.46	.57	.56	.60	.44	.69	.37	.51	.22	.47	.32	.40	.40	.36	.22	.23	.53	.50
9:45	.31	.17	.17	.30	.24	.13	.01	.04	.03	0	.03	.03	.04	.13	.11	.12	.11	.11	.10	.09
10:00	.05	.03	0	.07	.07	0	0	0	0	0	0	0	0	0	0	.05	.06	.09	.09	.05
10:15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	.04	.05	.04	.04	.02	.02
10:30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Dosage	1401	1413	1366	1283	1192	1210	1216	1283	1219	1215	1243	1263	1288	1228	1383	1327	975	1049	1328	1285

BI LOCATIONS

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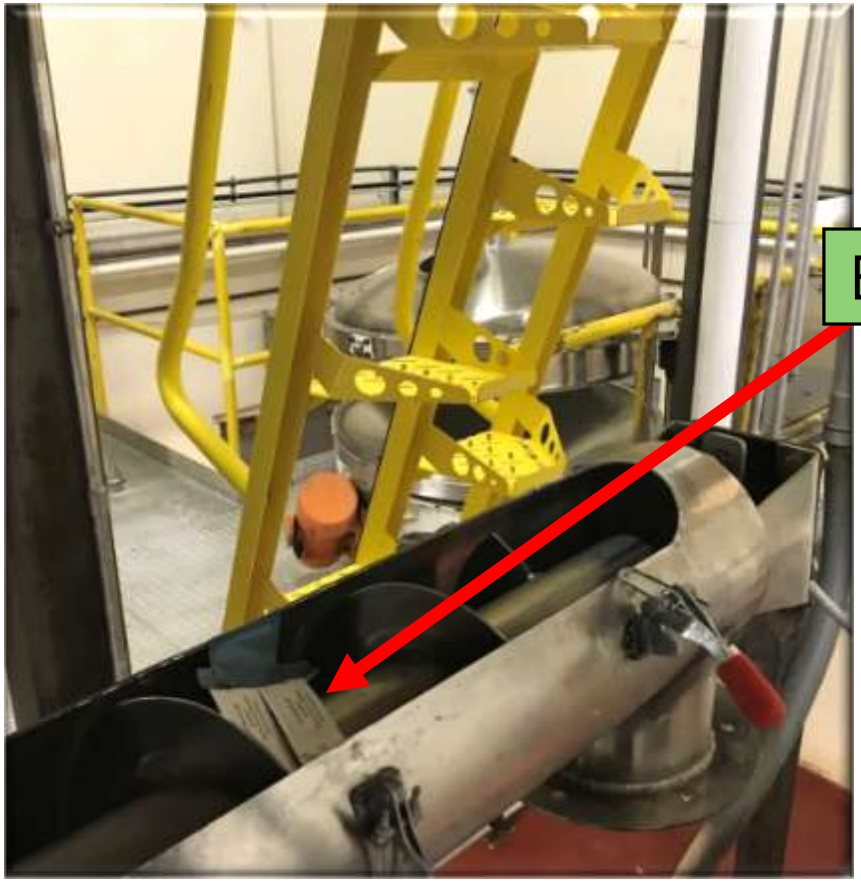
BI LOCATIONS



BI Killed

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BIOLOGICAL INDICATOR DATA

(Locations can again be at "hot spots")

BI Location	Result
1	Negative
2	Negative
3	Negative
4	Negative
5	Negative
6	Negative
7	Negative
8	Negative
9	Negative
10	Negative
11	Negative
12	Negative
13	Negative

BI Location	Result
14	Negative
15	Negative
16	Negative
17	Negative
18	Negative
19	Negative
20	Negative
21	Negative
22	Negative
23	Negative
24	Negative
25	Negative
Positive Control	Positive

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PROOF OF CLEAN BREAK

What to submit to regulators:

- Decontamination process used
  - Process info
  - EPA Approvals
- Map of concentration monitoring/biological indicator/environmental swab locations
- Concentration monitoring data
- Biological indicator results
- Environmental swab results
- Discussion linking the results of all three

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HOW OFTEN SHOULD YOU PLAN A CLEAN BREAK?

- Monthly?
- Quarterly?
- Yearly?

Make that determination with your QA team, balancing your risk level to the cost of a decontamination and the cost of a recall.

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What's the worst part of having a microbial contamination?

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EVERYTHING MOVES SO FAST

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HOW DO WE PREPARE?

Make a Decontamination Plan!

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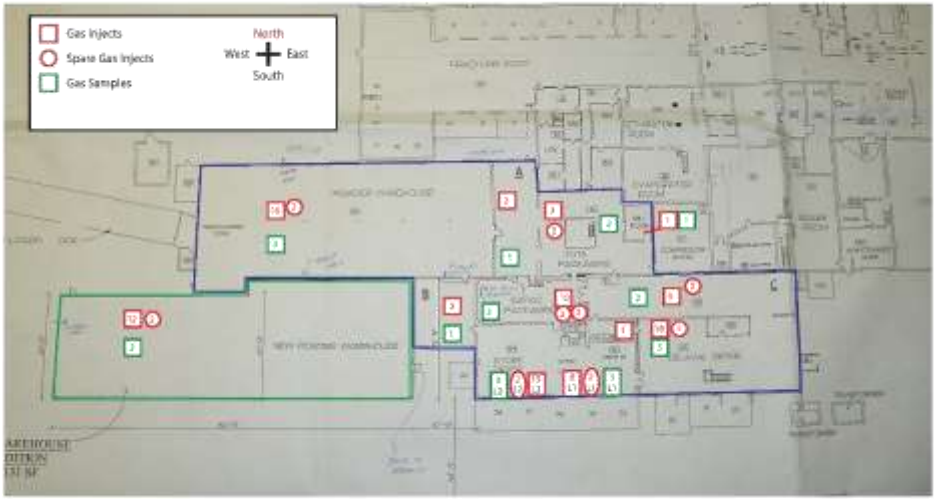
DECON PLAN – STEP 1

Establish Potential Scenarios

- Whole manufacturing area / facility
- Specific high risk areas
- Specific pieces of equipment



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DECON PLAN – STEP 2

Establish Success Criteria

- Do you want biological indicators?
- How many would you like?
- Do you want to identify a mix of locations now?
  - Some fixed locations
  - Some "hot spot" locations TBD

Under the forklift tire

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DECON PLAN – STEP 3

Work Out the Process Details

- Who gets involved on your end?
- Who does what to prep the space?
  - This has led us to recommend permanently sealing certain gaps
- What do I need to bring?
  - If we don't know if we need it or not… we bring it

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DECON PLAN – STEP 4

Establish Timelines for the Decon

- Planning ahead allows for quicker response times
  - No questions to ask, we already know what to ship
  - How quickly can we respond?
  - How soon are you ready for us?
- How long will it take to complete the decon?

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DECON PLAN – STEP 5

Establish Cost for the Decon

Better pricing as you're not in a "vulnerable" position for some companies to take advantage of

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DECON PLAN – STEP 6

Put it on the shelf!

In the end, you receive a well written procedure that can be included in your food safety plan and submitted to auditors / regulators

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BEST PART?

We do this for free*

*Unless you'd like us to come onsite, then we charge a nominal travel fee

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PREPARATION

The information we would need:

- Floor Plan
- Volume of space
- Information on exhaust system
- Photos (or potentially a site visit)

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CONSIDERATIONS

- Would you sleep better with a clean break in place?
- What is a true clean break worth to your facility?
- Can routine decontamination reduce the current deep clean downtime?
- What is an acceptable investment for antimicrobial risk management?
- Why not take us up on an Emergency Decon Plan?

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Thank you!

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