International Association for Food Protection WEBINAR

Sanitation Break: Legal Interpretation and Industry Practices

Moderator: Cari Rasmussen, Food Safety Director, Commercial Food Sanitation

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This webinar is being recorded and will be available to IAFP members within one week.

International Association for Food Protection

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IAFP Webinar

Sanitation Break:
Legal Interpretation & Industry Practices

Presenters

Maile Gradison, Panelist	Hogan Lovells
Yue Zheng, Panelist	Commercial Food Sanitation
Jeff Kornacki, Panelist	Kornacki Microbiology Solutions, Inc.
Cari Rasmussen, Moderator	Commercial Food Sanitation

June 3, 2025

Meet the Speakers

Dr. Jeffrey Kornacki

Maile Gradison

Yue (Joy) Zheng

Agenda

- Legal Framework and Considerations (Maile Gradison)
- Alternative Sanitation Methods in Sanitation Break (Joy Zheng)
- Practical Considerations When Relying on Clean Breaks to Bracket Implicated Product; Before and After Considerations (Dr. Jeff Kornacki)

Legal Framework and Considerations

Maile Gradison
Partner
Hogan Lovells US LLP

Hogan Lovells

What is a Sanitation Break (aka, a Clean Break)?

- This phrase is not defined in the Federal Food, Drug, and Cosmetic Act, nor in FDA's corresponding implementing regulations

- It is generally understood to mean a validated sanitation event that separates production runs to prevent cross-contamination and/or allergen cross-contact
  - The concept is inferred from regulatory expectations around sanitation, allergen controls, and preventive controls.

Why do Sanitation Breaks Matter?

- Sanitation breaks have an important role in product safety, recall management, and regulatory compliance.
  - Allergen preventive controls (i.e., prevent allergen cross-contact)
  - Sanitation preventive controls (i.e., prevent cross-contamination)
  - Limit the scope of recalls
  - Support lot segregation

Preventive Controls for Human Food Rule

- Corrective Actions require the evaluation of "all affected food" (21 CFR § 117.150)
  - Sanitation breaks help you support your conclusion of what food is affected by a problem
- Validation and Verification
  - The PCHF rule does not require you to validate food allergen controls and sanitation controls (21 CFR § 117.160(c)) – **but if you don't have validation, how will you show that your sanitation break is effective?**
    - "Clean up to clean up" can be challenged if you do not have supporting data to show the efficacy of your efforts

Validation: *Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards*

Verification: *The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan*

FDA Guidance

- Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - Chapter 9: Validation of a Process Control for a Bacterial Pathogen (Coming Soon)
  - Chapter 10: Sanitation Controls (Coming Soon)
  - Chapter 11: Food Allergen Program (September 2023)
- **Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event: Guidance for Industry, Draft Guidance (January 2025)**
- Prior Enforcement
  - Warning Letters
  - Recalls

Draft Guidance (2025): Sanitation Programs for Low-Moisture Ready-to-Eat Foods

- "**Sanitation break**: Stopping production to **clean and sanitize** all [food contact surfaces] FCSs in the production system."
  - Cleaning techniques are distinct from sanitizing treatments.
    - **Cleaning** techniques remove soil, including food residue, dirt, grease, or other objectionable matter, from the FCS;
    - **Sanitizing** treatments destroy (i.e., kill) microorganisms, such as pathogens, that contaminate that surface.
- This draft guidance discusses establishing routine sanitation breaks in which you stop production to clean and sanitize all FCSs in the production system
  - "Routine sanitation breaks can eliminate pathogens from FCSs and prevent contamination of food. They also can limit the amount of potentially affected food if you experience a pathogen contamination event"
    - "Non-continuous production systems: establish and implement a sanitation break at the end of your daily production."
    - "Continuous production systems: establish and implement a sanitation break at intervals that are frequent enough to help limit the amount of food that could be affected by a contamination event."

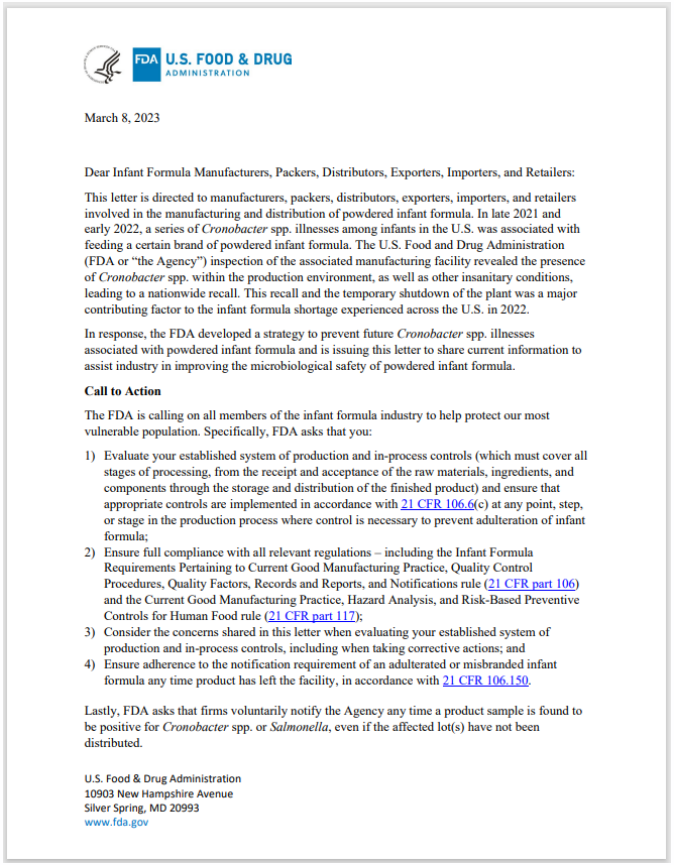
LMRTE Draft Guidance, cont'd

- "To identify affected food, we recommend that the steps you include in your corrective action procedures:
  - consider that all food produced since the last sanitation break is affected; and
  - when appropriate, consider expanding the scope of affected food to beyond food produced since the last sanitation break based on the findings of your [root cause investigation] RCI. For example:
    - If the root cause investigation implicates a contaminated ingredient as the source of the contamination, then all food produced using that contaminated ingredient could be affected; or
    - If the RCI identifies a resident strain in or on an FCS that was not cleaned and sanitized during the sanitation break, then all food produced since the last time that FCS was cleaned and sanitized could be affected."

- "There are limited circumstances in which it might be possible to limit the scope of affected food based on the outcome of an RCI or root cause analysis. Examples of such limited circumstances could include:
  - If you conclusively identify when the production system became contaminated, and you determine that all food produced before that contamination event was not subjected to the insanitary conditions created by the contamination event, then you could have a basis to conclude that food produced before the contamination event is not affected."

Additional FDA Guidance

- Letter to Infant Formula Manufacturers (March 2023):
  - "During the production of powdered infant formula where the product is in a dry powder form, manufacturing activities may operate for extended periods of time between complete sanitation activities. Although limited dry cleaning may be conducted between some production lots (e.g., vacuuming, brushing, tapping, sweeping, or flushing equipment surfaces), **FDA has observed during inspections that many production lots may be processed on such equipment without an intervening sanitation break that would involve the application of a sanitizing treatment to all food contact surfaces** (hereafter referred to as sanitation break). The best current available science demonstrates that the **only adequate remediation for food contact surfaces contaminated by a bacterial pathogen is the application of a sanitizing treatment** (e.g., a thermal treatment or a chemical treatment). To date, other remediation procedures, such as physical dry-cleaning techniques, have not proven effective against eliminating pathogens from equipment surfaces."



U.S. FOOD & DRUG ADMINISTRATION

March 8, 2023

Dear Infant Formula Manufacturers, Packers, Distributors, Exporters, Importers, and Retailers:

This letter is directed to manufacturers, packers, distributors, exporters, importers, and retailers involved in the manufacturing and distribution of powdered infant formula. In late 2021 and early 2022, a series of *Cronobacter* spp. illnesses among infants in the U.S. was associated with feeding a certain brand of powdered infant formula. The U.S. Food and Drug Administration (FDA or "the Agency") inspection of the associated manufacturing facility revealed the presence of *Cronobacter* spp. within the production environment, as well as other insanitary conditions, leading to a nationwide recall. This recall and the temporary shutdown of the plant was a major contributing factor to the infant formula shortage experienced across the U.S. in 2022.

In response, the FDA developed a strategy to prevent future *Cronobacter* spp. illnesses associated with powdered infant formula and is issuing this letter to share current information to assist industry in improving the microbiological safety of powdered infant formula.

Call to Action

The FDA is calling on all members of the infant formula industry to help protect our most vulnerable population. Specifically, FDA asks that you:

1) Evaluate your established system of production and in-process controls (which must cover all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product) and ensure that appropriate controls are implemented in accordance with 21 CFR 106.6(c) at any point, step, or stage in the production process where control is necessary to prevent adulteration of infant formula;
2) Ensure full compliance with all relevant regulations – including the Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications rule (21 CFR part 106) and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117);
3) Consider the concerns shared in this letter when evaluating your established system of production and in-process controls, including when taking corrective actions; and
4) Ensure adherence to the notification requirement of an adulterated or misbranded infant formula any time product has left the facility, in accordance with 21 CFR 106.150.

Lastly, FDA asks that firms voluntarily notify the Agency any time a product sample is found to be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Other Considerations

- No “right” answer, but it helps to have:
  - Validated procedures
  - Clear SOPs for when and how to perform clean breaks
  - Employee training on sanitation protocols
  - Strong documentation that you are following your programs
- Cascading/expanded recalls and WLs show there are many variations of the “wrong” answer
- Document sanitation breaks
  - If you don’t have strong data, the agency can and will poke holes in your bracket
- Involve experts in your planning and evaluation

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Alternative Sanitation Methods in Sanitation Break

Yue (Joy) Zheng

June 2025

Objectives

- Explore different sanitation methods to isolate production lots
- Discuss verification and monitoring expectation

Understand the Cleaning Objectives

Process	Visual	Micro	Allergen	Odor	Flavor	Color	Pest	Fire	Quality	Function	Equip Damage	Non-Kosher	Non-Organic	Vitamin Changeover
Sugar Slurry Mixing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Blending	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Forming	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cutting	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Baking	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cooling	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Drizzle/Topping	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Wrapping	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Dry Mix	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Conveying	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Wet Blend	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Popping	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Enrobe (slurry)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Enrobe (oil/seasoning)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Drying	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Assess Equipment Design and Condition

IDENTIFY “HANGING POINTS” AND DEAD ENDS

EQUIPMENT MATERIALS

MAINTENANCE CONDITION

ASSISTED CLEANING SYSTEM

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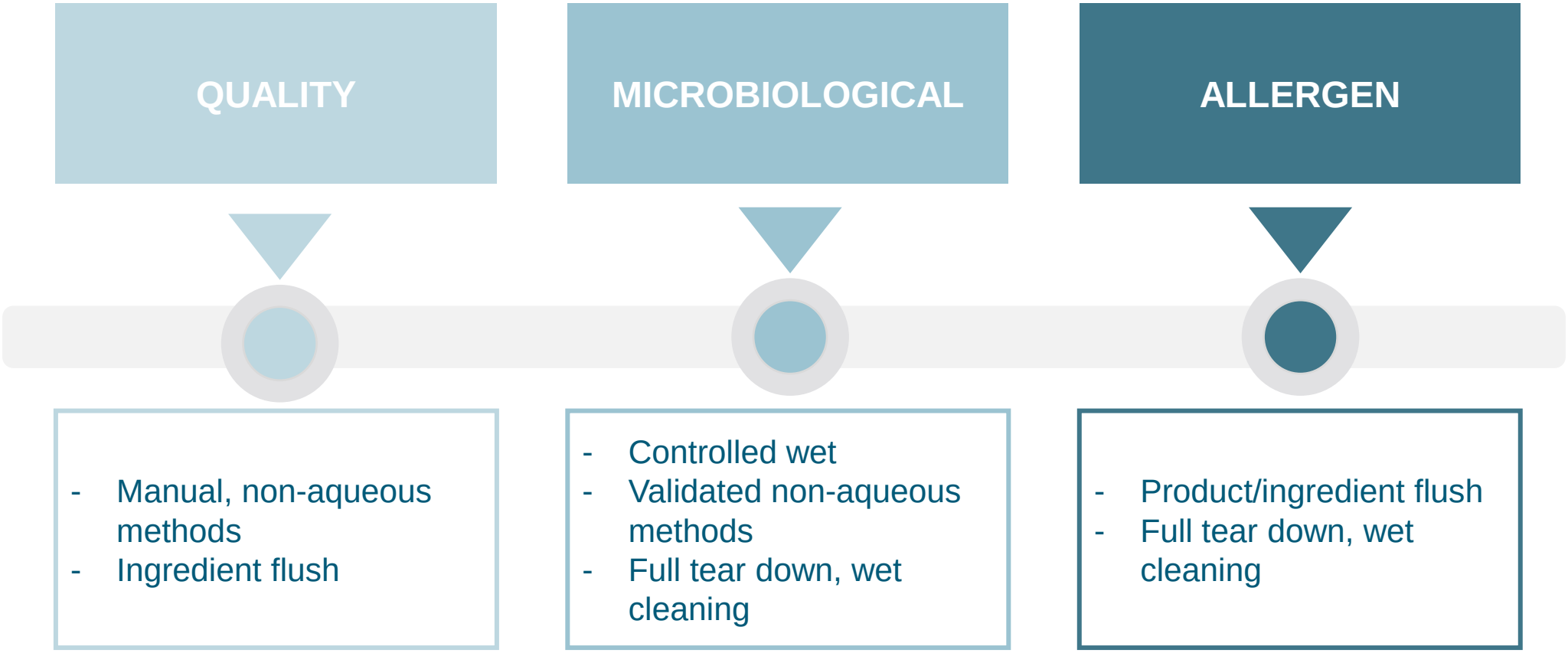
Sanitation Methods Based on Objectives and Design



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Solubility in Water

Deposition	Solubility	Removal	
		Low temp.	High temp.
Sugars	Water soluble	Easy	Caramelization difficult to clean
Fats	Water insoluble, soluble in alkali	Difficult	Layer formation, difficult to clean
Proteins	Water insoluble, soluble in alkali, little soluble in acid	Very difficult	Very difficult
Salts	Variable in water, soluble in acid	Variable	Variable
Starch	Soluble in water and alkali	Easy to moderate	Sticky, difficult

Non-Aqueous Cleaning Chemistry

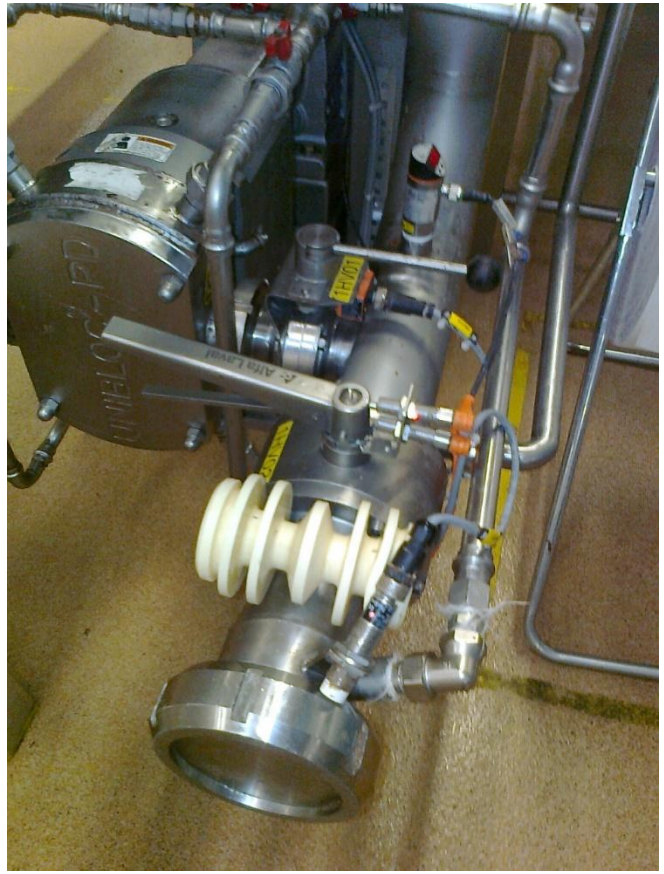
Ethanol (ethyl alcohol) / Isopropanol

- ✓ Concentration 50% and higher (detergency will increase with concentration)
- ✓ Breaks down organic materials and oil
- ✓ Non-corrosive on any metal
- ✓ Evaporates quickly, no-rinse

- X Compatibility with some rubber and thermoplastic materials
- X Flammable (safety concern)

Large Soil Removal vs. Detail Cleaning

Purging



- Removal of food stuff from product pipe systems or other closed systems
- Manual and automated compressed air delivery systems
  - “Pigging” type device with launcher, catcher, inline detectors for pipework only (bypass of pumps, valves, etc., required.
  - Needs smooth inner surfaces, always the same diameter, and certain radii at curved sections.

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journal homepage: www.elsevier.com/locate/jfp

Research Paper

Effectiveness of Dry Cleaning Treatments for Removing Milk Chocolate from Valve/Pipe Assemblies and Pilot-scale Chocolate Processing Equipment

Liyun Zhang [1], Binaifer Bedford [2], Joshua Warren [1], Girdhari Sharma [3], Allison L. Brown [4], Helene Hopfer [4], Gregory R. Ziegler [4], Lauren S. Jackson [2,*]

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[4] *Department of Food Science, College of Agricultural Sciences, The Pennsylvania State University, Rodney A. Erickson Food Science Building, University Park, PA 16802, United States*

Table 1
Milk concentrations detected in initial and second dark chocolate samples pumped through different valve/pipe assemblies with and without cleaning treatments. All cleaning treatments for each valve/pipe assembly were conducted in triplicate

Cleaning treatment	Sources of milk chocolate contamination in valve/pipe assembly	Estimated amount of residual milk chocolate in assembly[a] (g)	Milk concentrations detected in initial dark chocolate samples[a] (μg/g)	Milk concentrations detected in the second dark chocolate samples[a] (μg/g)	Amount of dark chocolate push-through to obtain dark chocolate with milk concentrations < LOQ[a] (kg)
No cleaning	Contaminated butterfly valve/contaminated pipe	123 ± 10	4,500 ± 1,500	480 ± 180	16.2 ± 2.2
	Contaminated ball valve/contaminated pipe	161 ± 15	13,000 ± 2,300	2,200 ± 550	21.2 ± 0.7
	Clean butterfly valve/contaminated pipe	116 ± 20	7,200 ± 2,000	990 ± 170	18.8 ± 0.9
	Contaminated ball valve/clean pipe	25 ± 10	170 ± 10	2,700 ± 4,000	24.9 ± 5.2
Pig purging	Contaminated butterfly valve/contaminated pipe	120 ± 13	110 ± 68[b]	63 ± 25	19.9 ± 1.7
	Contaminated ball valve/contaminated pipe	140 ± 11	<LOQ[c]	<LOQ	NA[d]
	Clean butterfly valve/contaminated pipe	108 ± 5	<LOQ	<LOQ	NA
	Contaminated butterfly valve/clean pipe	12 ± 1	83 ± 19	9.2 ± 1.9	18.8 ± 1.1
Cocoa butter flush	Contaminated butterfly valve/contaminated pipe	126 ± 7	130 ± 7	600 ± 10	18.7 ± 1.5

[a] Values are the average ± standard deviation for three experimental trials.
[b] An initial 10 sec of chocolate collection was missed in Trial 3.
[c] LOQ refers to the limit of quantitation (2.5 μg/g) of the Neogen Veratox ELISA for Total Milk kit. For all three trials, the concentrations of milk detected in the dark chocolate samples were below the ELISA LOQ.
[d] NA = Not applicable.

Flushing

- Material flushing
  - Dry abrasive material (sugar, salt, …)
  - Liquids (water, hot oils/fats,…)
  - Large mixed phase to be managed

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Oil-Based/Acidified Oil

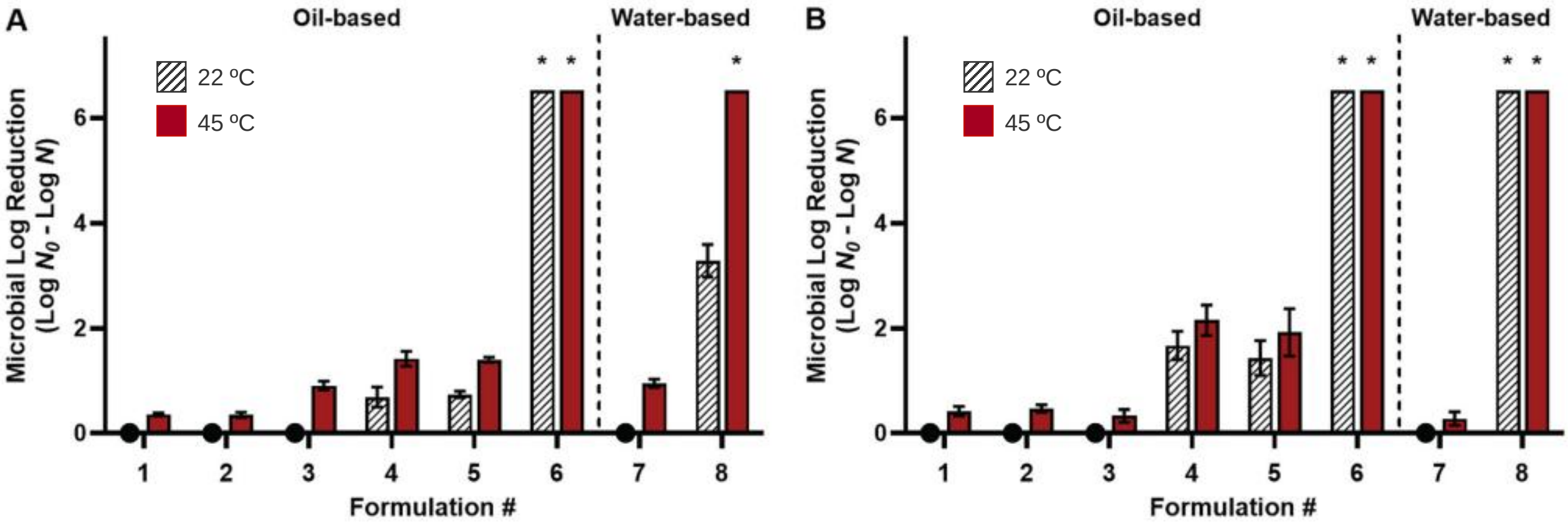
AMERICAN SOCIETY FOR MICROBIOLOGY | Microbiology Spectrum

RESEARCH ARTICLE
May/June 2023 Volume 11 Issue 3 e05293-22
https://doi.org/10.1128/spectrum.05293-22

Oil-Based Sanitization in Low-Moisture Environments: Delivery of Acetic Acid with Water-in-Oil Emulsions

Shihyu Chuang[a], Mrinalini Ghoshal[b], Lynne McLandsborough[a,*]

[a]Department of Food Science, University of Massachusetts—Amherst, Amherst, Massachusetts, USA
[b]Department of Microbiology, University of Massachusetts—Amherst, Amherst, Massachusetts, USA



A – against desiccated *Salmonella* Enteritidis phage type 30

B – against desiccated *Listeria monocytogenes* LM25

1 – pure peanut oil
2 – peanut oil with 3% (wt/wt) PGPR
3 – peanut oil with 3% (wt/wt) PGPR and 3% (vol/vol) distilled water
4 – peanut oil with 200 mM acetic acid
5 – peanut oil with 200 mM acetic acid and 3% (wt/wt) PGPR
6 – peanut oil with 200 mM acetic acid, 3% (wt/wt) PGPR, 3% (vol/vol) distilled water
7 – distilled water
8 – distilled water with 200 mM acetic acid

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Hot Oil / Fat Flushing Guidelines

- Works well for pipework; may has limitations as to tanks, conches, mixers, pumps, etc.
- Equipment (joints, instrumentation,..) designed for parameter values as to temperature and pressure without risk of damages.
- Temperature as high as possible (80-90°C very good but consider safety) to dissolve chocolate. Note: this is no thermal disinfection!
- High flow velocity required for mechanical action (approx. 3 m/s delivers good results).
- Circulate (1st flush) and/or at least 1 once through (final flush), depending on design.
- Rule of thumb: use 2-3 times the inner volume of the pipework segment cleaned to define the quantity of flushing mass.
- Manual clean out of pumps, t-pieces (dead end), strainers, probes, etc.

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Verification and Monitoring

Baseline Verification

1 SAMPLING

Sample **food contact surface and the adjacent** for pathogen(s) of concern and or indicators **after cleaning and sanitizing** (if product supports growth)

2 REPEAT

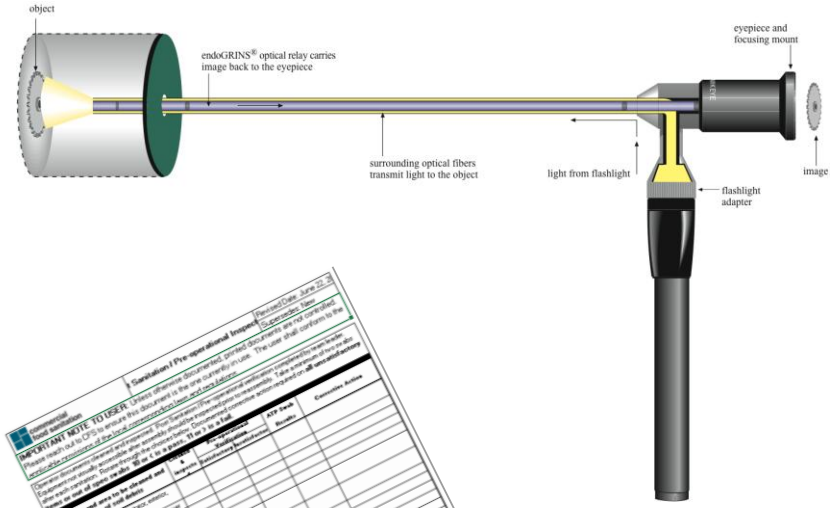
Repeat the process with **different types of products** that could be run on a given line, or minimum **3 times** for the same product

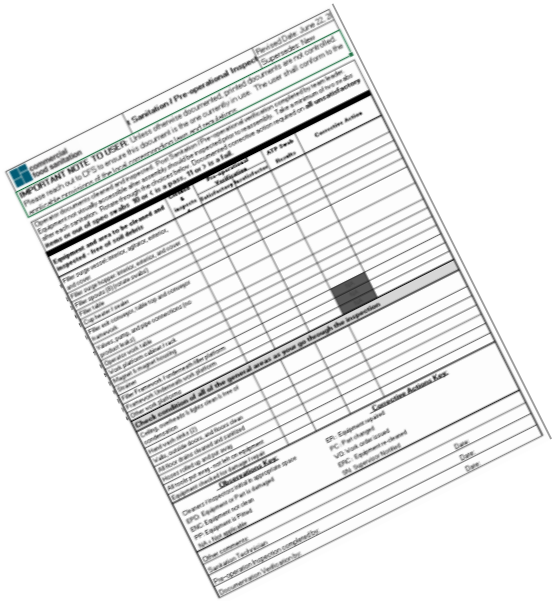
3 RE-ASSESS

Re-assess when changes occur:

- Product mix/formula
- Equipment and or process
- Sanitation practices (chemical, procedure etc.)

Verification/Monitoring





Visual inspection of the known hanging points, which are identified from extended run time validation

With the aid of Borescope

ATP, Micro, Allergen swabs *

Summary

Evaluate cleaning objectives and equipment condition

Select different cleaning methods based on equipment condition and cleaning objectives

Conduct annual sanitation break baseline verification assessment

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THANK YOU!

IAFP Webinar

Sanitation Break: Legal Interpretation and Industry Practices

Practical considerations when relying on clean breaks to bracket *implicated* product

(Before and After Considerations)

Jeffrey Kornacki, Ph.D.
President

June 3, 2025

KORNACKI MICROBIOLOGY SOLUTIONS, INC.

Root cause

One cannot be sure that ALL contamination sites or sources have been found!

One cannot see all and know all; Often finding ***a* site ≠ *ALL* the sites** of contamination

Documented eradication of all known microbial niches or contaminated post-lethality ingredients should be verified in a documented manner.

Diligently strive to irradicate *un-investigatable* areas and control them also

Sterilant gases that penetrate voids and false ceilings
Heat treatments to disinfect sandwiched areas that cannot be disassembled.

Rigorous evaluation of hygienic start up conditions is essential (can involve in-line testing as well as environmental sampling)

Rigorous initial hold and test is critical at start up (investigational sampling)

On-going EMP and Appropriate vectoring and ongoing routine testing

Implicated Product

"In Order for the Government to Feel Comfortable to Let You Operate they Need To Know that the ***Root Cause*** was *Found and Eliminated*."

You should feel the same-Even if you are not in a regulatory crisis and the product is in your control.

Need to be prepared to talk with the regulators if they visit, and for peace of mind.

If you do not, risk of recurrence after a sanitation break (e.g., hypothetical milk drying example). Rolling contamination and re-sanitation events are bad (e.g. Public health, regulatory involvement)

Root Cause - Listeria Draft Guidance

"If your intensified sampling and testing results are not all negative, conduct a root cause analysis, escalate mitigation efforts to identify and eliminate the Listeria spp. source, and consider consultation with a Listeria control expert.

Take risk-based actions to determine how the site became contaminated, including activities involved in a comprehensive investigation as discussed in section XIII.F. These actions vary depending on the risk that an FCS or food could become contaminated from the positive non-FCS site …"

[1] FDA. 2017. *Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry-Draft Guidance.* January. P. 40

Environmental Root Causes

Several types in the environment

1. The source to the product (often, though not always equipment)

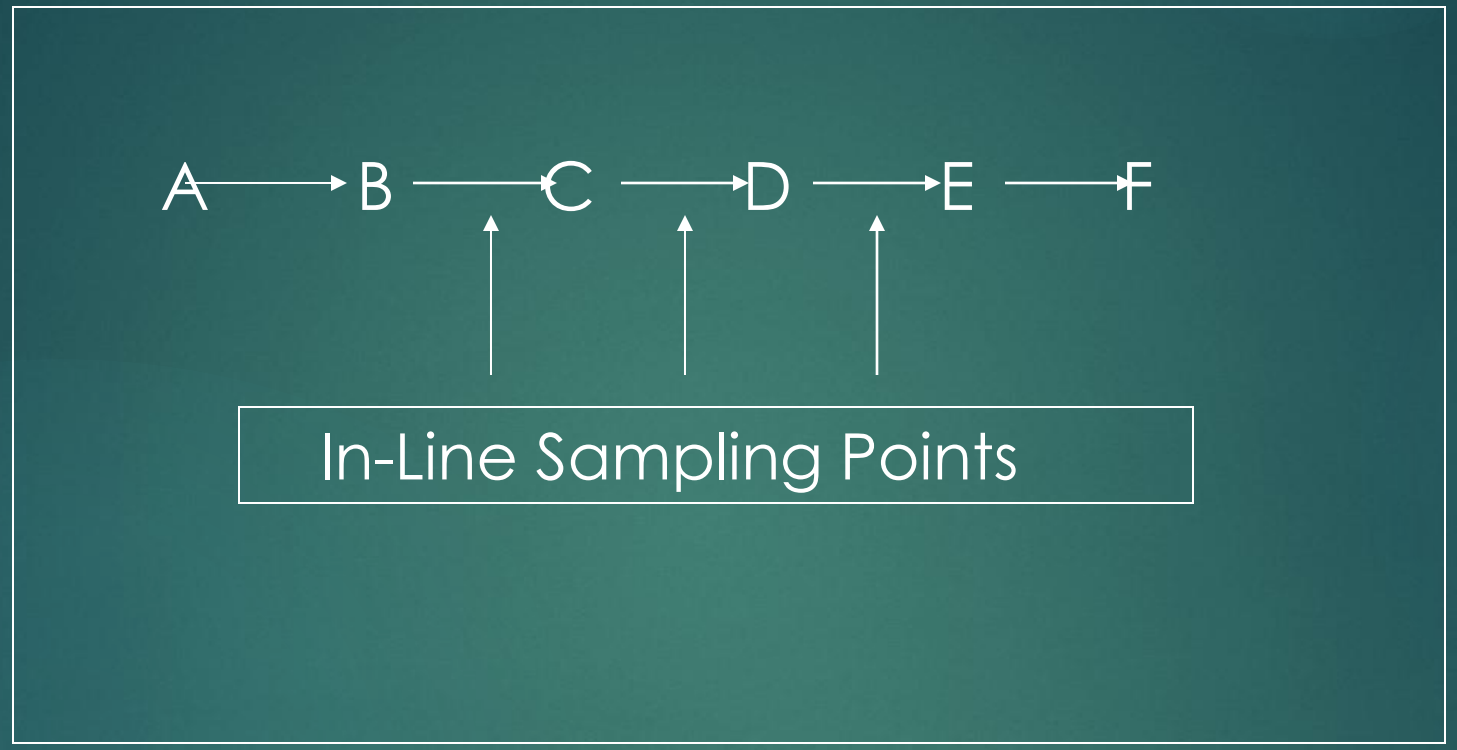
   Can be a combination of 1 or more sites

   (or can be ingredients)

2. The source from the environment to the equipment or the product

3. The source to the plant (roof leaks, drain back-ups, un-trapped drains, negative air, HVAC systems, non-captive shoe/uniform policies, etc.)

In-line Sampling



Kornacki, J. L. 2010. How do I sample the environment and equipment? Chapter 7. *In*, J. L. Kornacki (Ed.), *Principles of Microbiological Troubleshooting in the Industrial Food Processing Environment.* Springer, New York, Pp. 125-136

Root Cause - Ingredient and Finished Product Sampling- Beyond FDA BAM I: Statistical Perspective

Routine

Investigational

Acceptance Criteria, *Salmonella*

Product Category	# of Units Tested with Negatives	# of Units Tested with No More than One Positive	Significance 95% Probability of One Organism or Less in
I	60 (1500 g)	92 (2300 g)	500 g
II	29 (725 g)	48 (1200 g)	250 g
III	13 (325 g)	22 (550 g)	125 g

Test Number Needed to Detect One or More Positives per Lot

Percent positives	Number of analytical units to be tested (n)		
% Positive	90 % confidence	95 % confidence	99 % confidence
100	3	4	4
10	23	30	46
1	230	299	461
0.1	2,303	2,996	4,605
0.01	23,026	29,963	46,052

Adapted:Compendium of Methods for the Microbiological Examination of Foods 3rd ed.

What about a Supplier's Post-Lethality Contaminated Ingredient?

Danger, danger! Were the ingredients inside or outside suppliers clean-up to clean-up cycles - may include multiple lots (some perhaps used on YOUR production and are in the marketplace.

Could implicate past product- Options test with an appropriate indicator (see in talk) or test for a pathogen.

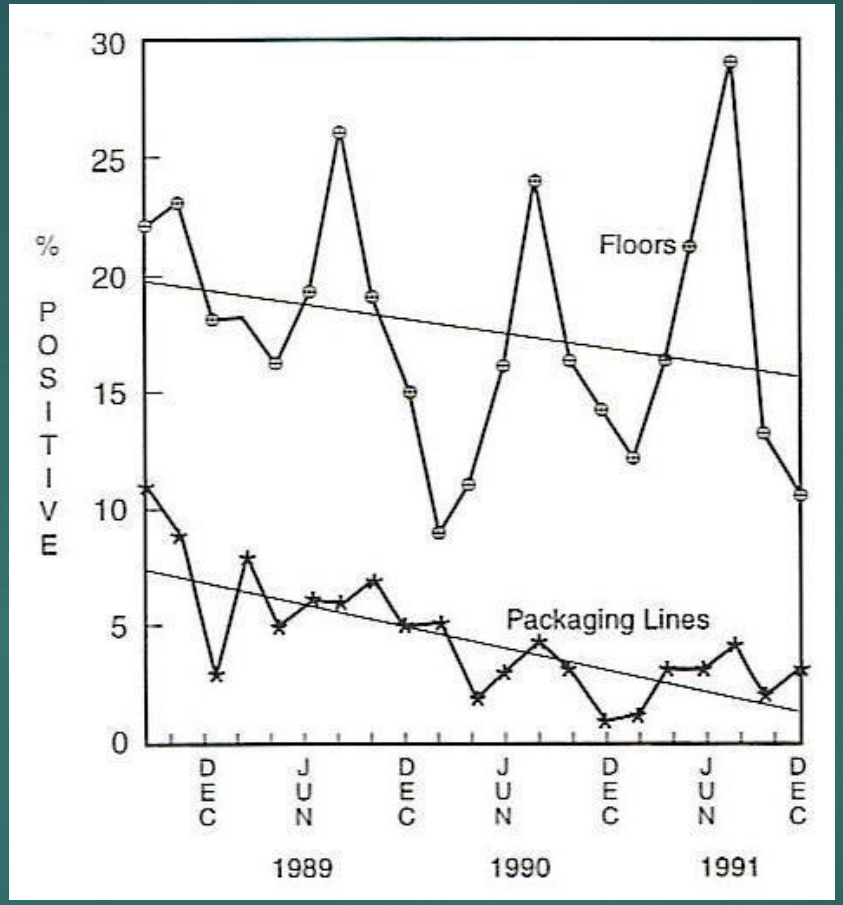
Think through all the consequences of testing before you test. Parking tickets vs parking permits!

Principal Source of Microbial Contamination in Processed Foods:

Processing Environment[1]

[1]Kornacki, J. L. 2010. *Principles of Microbiological Troubleshooting in the Industrial Food Processing Environment*. Springer, New York.

Correlation of % *Listeria spp.* Isolated from Packaging Lines and Floors to RTE Meat



Lead to in-plant risk assessment concept

Tompkin, R.B., L.N. Christiansen, A.B. Shaparis, R.L. Baker, and J.M. Schroeder. 1992. Control *of Listeria monocytogenes* in processed meats. Food Australia 44:370-376

Kornacki, J. L. and J. B. Gurtler. 2007. Incidence and control of *Listeria* in food processing facilities, Chapter 17. In, E. T. Ryser and E. H. Marth (eds.), Listeria, listeriosis and food safety, 3rd ed. CRC Press, Taylor & Francis Group, Boca Raton, FL. Pp. 681-766.(see page 729).

Correlations of % Environmental to % Finished Product Contamination

Smoked fish plant: Correlation of environmental *L. monocytogenes* to finished product ($p<0.0001$)

Thimothe, et al, 2004. Tracking of *Listeria* monocytogenes in smoked fish processing plants. J. Food Por. 67(2):328-341.

Variables Affecting Likely Contamination From the Processing Environment

"The probability of product contamination from the environment is dependent upon a number of variables…"

1. *Proximity of microbial growth niches to the product stream*
2. ***No. of niches in the factory***
3. *Spatial relationships of niches and product stream*
4. ***Microbial population in niches***
5. *Degree of niche disruption during operations*
6. ***Exposure of the product stream to the environment***

Gabis, D. A. and R. E. Faust. 1988. Controlling microbial growth in the food-processing environment. Food Technol. Dec. pp. 81-82.; 89.

Sites for Potential Sites for Contaminant Growth/Transmission

Operations

Disassembled equipment and tool on moist floor after cleaning

Floor scrubbers

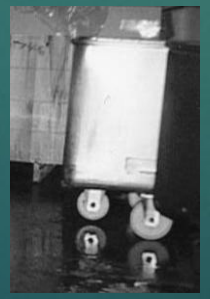
High-pressure hoses (aerosolization) and use of bristled broom

No captive shoe policy

Open back motor fan Covers

Wet residue from open air boxes

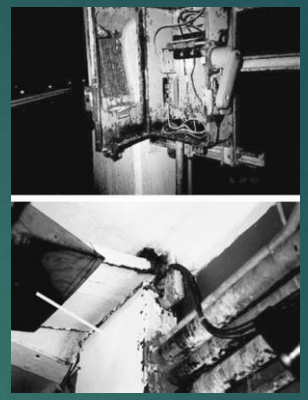
Hoses on floor



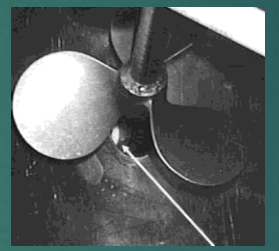
Wheeled vehicles – raw to finished

Maintenance/Repair

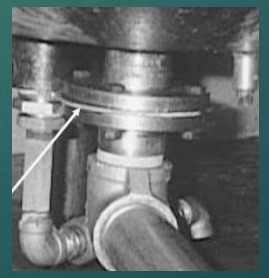
Exposed-wet insulation conveyor belt to freezer



Rusted electrical boxes



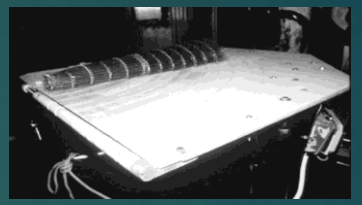
Ill-fitting gasket in product zone



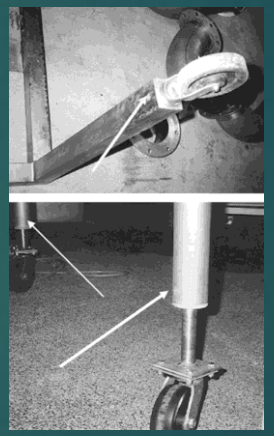
External surface of gasket

Ceiling leak

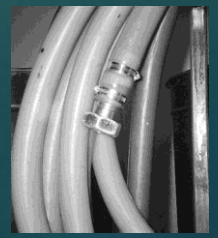
Design



Angle conveyor



Penetrations in hollow supports



Fluid between hose clamps

EMP: The Good, The Bad, and the Ugly

- The good-
  - Advances public health
  - Advances cost saving
  - Can lead to important root cause investigations
- The bad –
  - Poor regulatory guidance on how to establish programs, rules of thumb
- The ugly
  - Not all EMP findings directly correlate to finished product Contamination (could be ingredients or Zone 1 sites)

Consider hygienic indicators for Zone 1 sites

Starting Up

Ingredient supplier requalification: Review their Food Safety Plan, review the type of product (historical association with risk?), COAs. ***Ask questions about their flow diagram***. Initially, rigorously test pre-shipment lots and indicator assays of incoming lots. Are they controlling risk or is your company controlling risk. ***Trust but verify.***

Environmental Monitoring Program (EMP)

Finished product hold and test

If an EMP Hit: *Document!*

Site, result, date (be sure to use a qualified lab)

Corrective action (quality culture) Vectors

and location

Corrective actions to any positive vectors and results of retesting

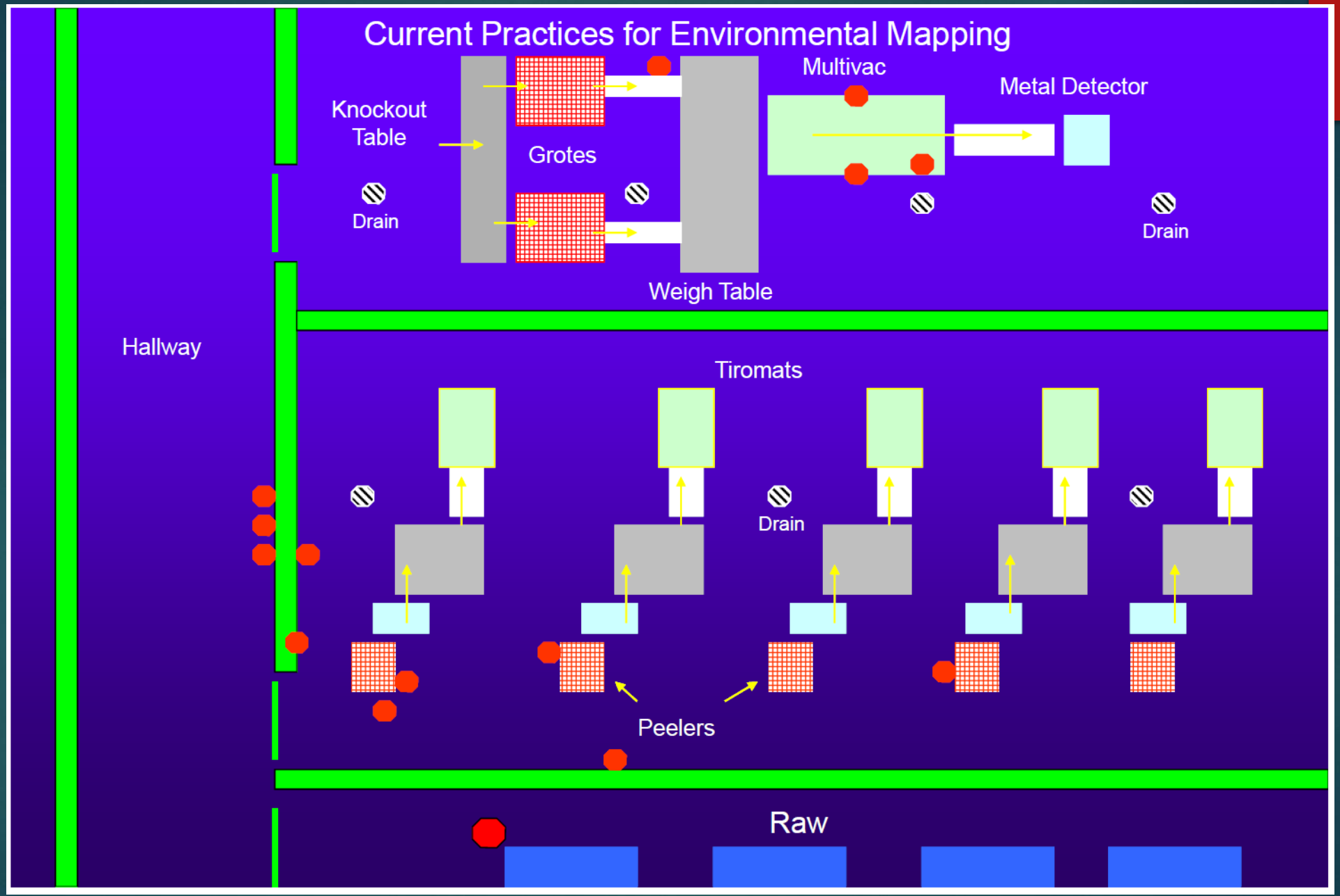
Be ready to *expeditiously* present to inspectors findings in an organized form (ppt is nice with site diagram)

The Ugly: Vectoring off EMP

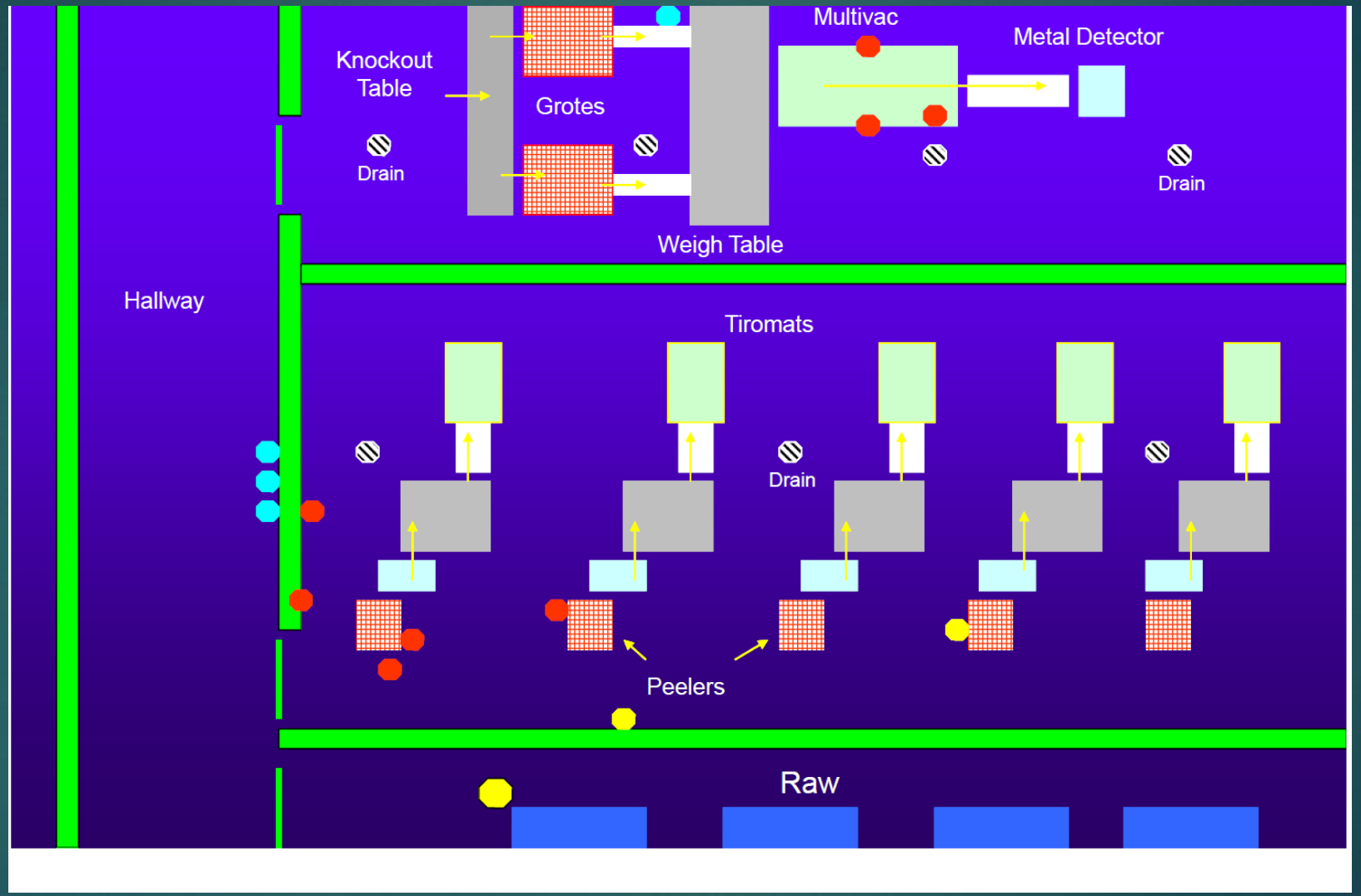
- Vectoring is the *first step* in a root cause investigation
- *Why? Most vectoring fails. Do not be content with this, especially if it recurs. Then investigate.*
- Tracking and trending EMP including vectoring
  - If repeats occur there may be more than just a need to apply a sanitizer
    - Could be equipment design, maintenance and repair practices or the design of the facility.

In-Plant Source Tracking

Allows for a deeper level of questioning- than just seek and destroy


Current Practices for Environmental Mapping
Knockout Table
Grotes
Multivac
Metal Detector
Drain
Drain
Weigh Table
Hallway
Tiromats
Drain
Peelers
Raw

Environmental Map with Comparison of Isolate Subtypes



Alternatives for Source Tracking For Those Without a Parking Ticket

- Indicators with riboprinting with unique restriction endonucleases with REP PCR, RAPD (Sirgusa, et al), etc.)

- EB

- HQA/HTEB (*Listeria*-like and *Salmonella*-like) organisms (Kornacki, J. L. 2014.)

Siragusa, G., J. L. Kornacki, N. Van Loan. 2022. Novel Approach to Source Tracking in Non-Crises Situations. Food Safety and Microbiology Conference. Dec 4-6, Washington, DC

Kornacki, J. L. 2014. An environmental approach to product risk assessment. Food Safety Magazine. Feb/March issue.

Summary - Practical Considerations To Relying on Clean-Breaks to Bracket Implicated Product

Ensure that you have done an appropriate *rigorous* Root Cause
Document effectiveness of corrective actions

Rigorously requalify suppliers

Establish a robust EMP

Respond to EMP data, vectoring, corrective action, document success, investigate recurrent hits.

Consider source tracking approaches

Questions & Discussion

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