

Environmental Controls: Emerging Technologies and Predictive Analytics to Address Complex Sanitation Challenges

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SUMMARY

The Institute for Food Safety and Health (IFSH) and the Food Research Institute (FRI) of the University of Wisconsin–Madison partnered again to host a food safety-related symposium on 27 to 30 September 2021. As a follow-up to the 2019 IFSH/FRI symposium, which addressed how microbiological testing could be used to verify preventive controls, the 2021 virtual meeting focused on environmental controls used in food manufacturing facilities. Key topics discussed in the 2021 meeting included hygienic zoning, considerations for low-moisture food processing environments, elimination of pathogen harborage sites, and sanitation. Environmental sampling and testing strategies with traditional and new technologies, including the use of analytics and predictive microbiology to prevent future environmental problems, also were discussed. In addition to presentations and discussions offered by industry, government, and academic leaders, the meeting attendees participated in working groups to develop solutions to real-life sanitation and environmental monitoring challenges that face food manufacturers.

OVERVIEW

The Institute for Food Safety and Health (IFSH) and the Food Research Institute (FRI) of the University of Wisconsin–Madison hosted a food safety-related symposium as a follow-up to the 2019 IFSH/FRI symposium (1). The regulatory context for the 2021 symposium was introduced by **Leslie Smoot (Senior Advisor, Office of Food Safety, U.S. Food and Drug Administration [FDA])**. The implementation of the final rule for “Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Foods” (18) has led to a more risk-based, proactive, and systematic approach to food safety for food manufacturers. Sanitation preventive controls are a key element of this rule. Sanitation controls include procedures, practices, and processes that ensure that a food manufacturing facility is maintained in a sanitary condition. Foundational elements of sanitation controls include designing effective cleaning and sanitation procedures and hygienic zoning, which can be defined simply as “keeping the bad stuff from getting into sensitive areas” per **Duane Grassmann (Corporate Hygienist, Nestlé USA)**.

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Effective environmental monitoring plans (EMPs) and the use of root cause analysis methodology to investigate problems are also essential to maintaining sanitary control in food manufacturing facilities. As defined by speaker **Scott Stillwell (President and CEO, Stillwell Consultive Services LLC)**, an EMP involves proactively seeking and destroying targeted microorganisms, preventing the establishment of bacterial harborage sites, and preventing the reintroduction of microorganisms. Ideally, an EMP functions as “a canary in a coal mine” to provide early notice that problems might be present.

EMPs rely on robust sampling and testing methodologies. New technologies, including next-generation sequencing and sophisticated data analysis tools, can help food manufacturers better understand the unique challenges of their processing facilities and increase the predictive power of EMPs.

HYGIENIC ZONING

Hygienic zoning is a prerequisite for environmental pathogen monitoring, according to **Duane Grassmann (Corporate Hygienist, Nestlé USA)**. Pathogens do not “just miraculously appear” in a facility; they are brought to where they are found. Pathogen movement often occurs as a result of a failure in hygienic zoning. Pathogen monitoring verifies the effectiveness of the prerequisite programs that influence pathogens in our factories, such as cleaning and disinfection, hygienic design of the building, design and maintenance of equipment, and the overall hygienic zoning program. When a pathogen is found in a facility, effective root cause analysis will include all prerequisite programs and will keep the factory from playing “whack-a-mole” with pathogens.

Grassmann drew upon his own experiences to highlight sometimes overlooked areas of concern in food facilities (6) such as air handling systems, which can serve as sources or reservoirs of pathogens (5). Other important considerations include the presence of water, tool management, cleaning activities, and traffic patterns for people, materials, and waste throughout a facility.

Facilities should establish risk-based routines and barriers to make the movement of microbiological hazards between different hygienic zones more difficult. Barriers include doors and vestibules. Routines are human behaviors such as washing hands, sanitizing footwear, and putting on smocks. Adherence to such barriers and routines by all people in a food processing facility, including visitors and contractors, is critical to hygienic zoning success.

LMFS

Low-moisture foods (LMFs) have become a hot topic in food safety circles according to **Richard Brouillette (Food Safety Director, Commercial Food Sanitation)**, in part because of notable outbreaks associated with LMFs such as peanut butter and flour. Hygienic design and standards are especially important when initially designing and selecting equipment for an LMF facility and when rebuilding or refurbishing equipment

and facilities. For designing cleaning and sanitation programs for such facilities, Brouillette recommended careful consideration of whether water should be used for cleaning because trace residual moisture in equipment can foster microbial growth. However, dry cleaning methods may involve vacuums, brushes, etc., which can spread contamination that may be brought in from such items as ingredients.

Clean breaks (breaks in production during which documented cleaning occurs and distinct production lots are identified) are easier to define in wet operating environments than in dry operating environments, in which run times are often much longer. Methods used to achieve a clean break differ in LMF facilities from those in other types of food facilities. Wet cleaning may be possible for equipment, but other methods often are needed, and sampling and testing may be necessary to ensure successful contaminant removal.

HARBORAGE SITES, GROWTH NICHES, AND BIOFILMS

Growth niches are locations supporting microbial growth, even after cleaning and sanitation. Harborage sites are growth niches in which a pathogen or its indicator are found (3). **Sue Schwartz (Vice President, Quality and Food Safety, Miniat Holdings)** discussed practical tips for identifying these growth niches and mitigating risks associated with them.

Using a “wet dog” analogy, she illustrated how operating (and shaking) equipment can permit residues (including microorganisms) deep inside the equipment to find its way out into the manufacturing environment. Schwartz recommended looking for hidden “wet dogs” in facilities when trying to find harborage sites. From there, consider potential pathways from harborage sites to food contact surfaces. She recommended an iterative, corrective action cycle to find the “wet dogs,” including tearing down equipment to the base structural framework when possible, and emphasized the importance of visual observations: “If your eyes tell you that it’s dirty, it’s dirty.” The everyday experience that operators and maintenance and sanitation personnel have with the manufacturing line should be leveraged; third-party resources (such as outside laboratories, chemical suppliers, and consultants) may also be useful.

Schwartz recommended that environmental monitoring take a proactive “seek and destroy” approach, defined as “a systematic approach to finding sites of persistent strains (niches) in food processing plants, with the goal of either eradicating or mitigating effects of these strains” (14). Niches may initially contain only harmless spoilage organisms but could eventually harbor *Listeria* species or other pathogens. When growth niches in equipment are found, mitigation strategies are needed, which could include redesign of equipment, periodic equipment teardowns, and thermal or chemical interventions (*Figure 1*). Pre- and postclean aerobic plate counts (APCs) can be used to validate the effectiveness and frequency of these procedures.

Mitigation activities

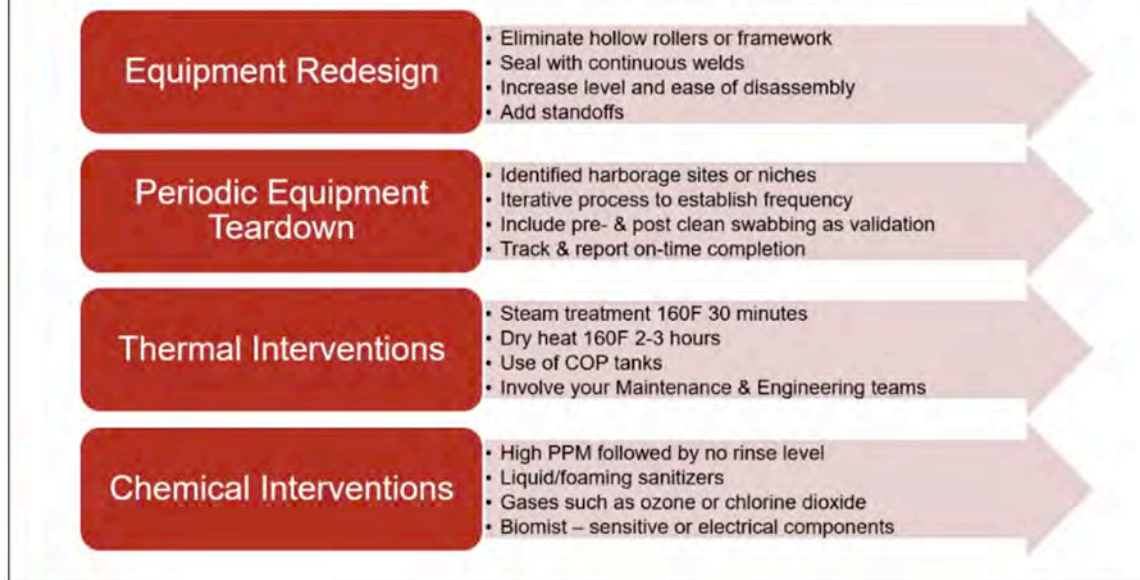


Figure 1. Mitigation activities for microbiological contamination of equipment (courtesy of Sue Schwartz).

Biofilms are specialized growth niches consisting of a complex community of bacteria attached to a surface. Potential niches for biofilm growth, as discussed by **Diana Stewart (Research Microbiologist, FDA)**, include drains, gaskets, open-ended equipment legs, abraded surfaces, the undersides of belts and conveyors, and seams or welds on equipment. Analogous to the chewable plaque detection tablets that dentists give their patients, various commercial products can be used to visually detect biofilms on surfaces and facilitate their removal.

ENVIRONMENTAL SAMPLING

Diana Stewart (Research Microbiologist, FDA) also discussed practical considerations and novel technologies that can be used for environmental sampling. Sampling may seem straightforward, but numerous aspects should be considered before sampling, including the surface type (rough versus smooth), the swab or sponge to be used (material, size, etc.), and whether (and how) samples will be composited (combined for a single analysis). Downstream testing also should be considered. What methods will be used? Could residual sanitizer on environmental surfaces affect sample testing, and if so, which neutralizer should be used? Will the samples be transported? How will transport conditions (time and temperature) impact the sample?

Stewart reviewed a variety of sponges and swabs currently available. Different swabs on different surfaces

and materials can yield vastly different results, with no single swab performing best for all combinations of surface material and food matrix. Shipping time, temperature, and transport media can all influence downstream detection of microorganisms, even when using enrichment cultures (16).

TRADITIONAL AND NOVEL ENVIRONMENTAL TESTING

Scott Stillwell (President and CEO, Stillwell Consultive Services LLC) walked through steps needed to develop an effective pathogen environmental monitoring program with the goal of protecting consumers, customers, and the brand. Stressing the importance of having an engaged and committed team (with management buy-in), he discussed the activities associated with designing an EMP. A review of outbreak and recall history for similar products should be conducted. When a potential hazard requiring a preventive control is not addressed in the EMP, comprehensive documentation should be provided to justify its omission.

The initial EMP should include a sample site list (defining zones, test frequencies, and random site testing plans). The list of target microorganisms should be tailored to both the product and the production facility. APCs are useful indicators of sanitation effectiveness. For ready-to-eat (RTE) foods, Stillwell recommends *Listeria* testing for early warning of potential problems. For FDA-regulated and dry foods, testing for *Enterobacteriaceae* and *Salmonella* is useful.

A mature and effective EMP could include composite testing to allow a broader area to be covered in the first pass and potentially reduce sample testing costs, but a newer EMP should include evaluation of individual samples, which permits identification of the exact location of a positive result. In addition to the use of swabs and sponges, he advocated using effluents and rinses when possible to increase the effective sample size. Filters can concentrate large volumes of fluid or air to increase sample size, and sterile clothes or stickers on a conveying system can be used to accumulate samples over a longer period.

Stillwell stressed that negative test results do not guarantee that a facility is free of pathogens and might mean that more samples should be collected or that samples should be collected more often or in different areas of the facility. Positive test results should be considered an opportunity for improvement and be used constructively. Facility and equipment mapping with a facility schematic or electronic database can help track sites with repeated high microbial levels or positive pathogen results. Ambiguous test results suggest a need for more frequent or thorough sampling, and newer technologies, such as genomic sequencing, may be needed to acquire more precise and detailed data.

EFFECT OF SANITATION ON THE MICROBIOME OF A FACILITY

Ganyu Gu (Research Associate, U.S. Department of Agriculture [USDA], Agricultural Research Service, Environmental Microbial and Food Safety Laboratory) described the effect of sanitation on a produce facility's microbiome. Although the core microbiome of a facility may affect pathogen survival in that facility, that microbiome is not static. Gu presented published research that revealed how the microbiome of a fresh produce processing environment was affected by routine sanitation and seasonal factors. Gu et al. (8) sampled Zone 3 locations (floors, doors, and walls) in a food processing facility before and after sanitation in both summer and winter and found ca. 8,000 bacterial species belonging to four major phyla. Although both sanitation and season resulted in changes in the Zone 3 microbiota, a Zone 3 core microbiota could be identified.

Gu also discussed the impact of sanitation on microbial dynamics during produce production. Produce such as spinach can host diverse microbial communities, as can the water in which product is washed (7). This microbiome becomes less diverse when sanitizers such as free chlorine or peracetic acid are present, suggesting the existence of a core sanitizer-resistant microbiome. The dynamics of microbial communities in wash water could influence pathogen survival and cross-contamination during processing of fresh produce; however, various pathogens inoculated in the rinse water were not part of the sanitizer-resistant microbiota.

NEWER MOLECULAR TECHNOLOGIES IN ENVIRONMENTAL MONITORING

Nick Andrews (Head of Food Safety and COVID Defence, Dawn Farm Foods, Ireland) discussed how newer molecular technologies can be integrated into EMPs to manage risk during food processing. Subtyping can be used to track and trace contamination, to identify persistent versus sporadic events in a facility, and to develop insights into contamination sources. Next-generation sequencing provides even more information. Although all *Listeria monocytogenes* strains are pathogenic, some pose a greater risk and can be identified by their clonal group and/or the presence of virulence markers (15). Some pathogen subtypes are associated with certain foods, which may help track a contamination source. Sequencing can also identify the presence of disinfection tolerance genes, and this information can be used to design effective sanitation strategies.

Metagenomics approaches can be used to look for specific risk factors and to sequence everything in a sample. These data can then be used to map the microflora throughout a facility, in various hygienic zones, at various times, and during various seasons (as was discussed by Gu earlier). Andrews cautioned that “mountains of data” will be generated, and one challenge is determining how to make sense of these data and keep them secure. Although confidentiality of such data is critical, Andrews stated that it is still better to acquire the information for brand protection.

PUTTING EMP DATA TO WORK

Claire Zoellner (Food Safety Scientist, iFoodDS) provided an answer for what to do with the “mountains” of data generated as part of a EMP: “put it to work” to improve the precision and predictive utility of the program.

The food industry is now transitioning from paper to digital EMP records, making it easier for data to be shared across teams, locations, buyers, labs, etc. These digital records can be used for more than regulatory compliance; they are the foundation for the use of advanced analytical tools. Although mapping, reviewing, and trending EMP data are not new concepts, new software tools can make these tasks easier, faster, and more thorough, thus improving the ability to monitor the persistence and transmission of pathogens within a facility.

In addition to the use of advanced analytics to improve environmental monitoring within a facility or company, Zoellner demonstrated how EMP data can be aggregated and analyzed anonymously across an entire industry, as was recently done across 27 frozen food facilities (13). This industry-wide analysis was used to identify specific sites in frozen food facilities (drains, pumps, troughs, chutes, and containers) that are most likely to test positive for *Listeria*. These findings should help guide frozen food facilities in the design of more efficient sampling plans.

Zoellner also discussed emerging tools and analytics that can be used to supplement historical data, including EnABLE,

an agent-based computer model (20). This model can create an in silico representation of a food manufacturing facility to simulate where *Listeria* is mostly likely to be found and to allow potential corrective actions to be tested virtually (17, 20), thus providing guidance for EMP design.

PANEL DISCUSSION

Leslie Smoot (FDA) commented that from the regulatory perspective, doing the “right thing” in environmental monitoring starts with a good hazard analysis, identification of those hazards that are reasonably likely to occur, and establishment of effective preventive controls. Verification of those controls requires a properly designed EMP specific for that facility, process, and food product. How the results from the EMP are used is very important. Actionable results should be distinguished from unacceptable results; the important is not the positive result itself, but how the facility responds to it.

From the legal and liability perspective, Shawn Stevens (Food Industry Counsel) discussed how food manufacturers face greater regulatory, civil, and criminal exposure now than ever before. Food-related recalls have increased in recent decades, and more recalls are occurring for products manufactured over long periods of time, with many of these recalls involving pathogens such as *L. monocytogenes*. Some large, well-established manufacturers have issued huge recalls. He predicts that the FDA and USDA will intensify their oversight activities, which will include more environmental testing during inspections. Although recalling huge amounts of product is a challenging business decision, he urged manufacturers to consider carefully what a trial jury would think if failure to recall product were to lead to an outbreak.

John Butts (FoodSafetyByDesign), an originator of the “Seek and Destroy” process (14), described a philosophy for

aggressive environmental testing and how this philosophy fits into a mature food safety culture. Fear has been associated with sampling, he says, which is unfortunate because identification of positive samples is important.

The Seek and Destroy process involves the elimination of an organism from an exposed product area, controlling the transfer of the organism, and deployment of process management techniques in which data drives the preventive controls. Growth niches must be identified to prevent them from becoming pathogen harborage sites. He described how a mature food safety culture can minimize “firefighting” by using preventive or even predictive approaches to food safety (Figure 2).

Lori Ledenbach (Kraft Heinz Company) provided advice on environmental monitoring based on her many years of experience in the food industry. First, always know what action will be associated with each potential result before you start testing: Will you hold product? Will you release it? Will you use it for trending, etc.? How will you mitigate it? Be very careful in selection of swabbing sites and think backwards from potential results that could be obtained.

Ledenbach recommended basing the testing plan on the organisms that grow and survive in the food in question and in the specific production environment (and thus potentially transferred to the food). Some of the most informative swab samples are those taken at the end of a run when equipment is taken apart. Use these data to help guide improvements to the EMP. For example, smooth surface sites that consistently produce negative results could be removed from a regular testing rotation. Ledenbach recommended that companies do a swabbing sample “deep dive” once per year to ensure complete coverage of the facility.

Cultural Stages				
Doubt	Awareness	Enlightened	Preventive	Predictive
Organization will not act on food safety without external pressure	Plant will take corrective action but not eliminate the source	Have found harborage site or Root source, but do not know how to manage or eliminate	Eliminated harborage site by redesign or application of an intervention	Data analytics of Indicator sites drives preventive action (i.e. Intervention)
Minimally sampling – trying not to find	Randomly sampling and finding transfer Point Positives	Transfer Point Action	Destroying harborage sites	Managing growth niches while controlling movement
Don't Look	Action driven by regulation or Customer – just meet their requirements	Fire fighting – solving the same problem over and over again	Systematically removing harborage sites while deploying interventions to control	Preventive action taken before a food safety risk occurs

Figure 2. Food safety culture maturity model: pathogen control (courtesy of John Butts).

Joe Meyer (Kerry) provided advice to food company personnel on how to respond when receiving a 483 notice or noncompliance record after an FDA or USDA–Food Safety and Inspection Service (FSIS) inspection. He emphasized the importance of understanding any findings that arise, ideally by talking directly to the inspector and asking questions during the inspection. Make sure the exact locations swabbed are understood and agreed upon in terms of the hygienic zones cited.

For responses to the findings, strive to avoid “firefighting.” Rather than trying to meet an arbitrary completion date, generate a detailed and realistic timeline and list of activities. Do not be afraid to ask experienced outside individuals for advice. Make sure that anything promised to regulators is realistic and can be maintained.

Meyer discussed the differences between corrections, corrective actions, and preventive actions. A correction is some kind of containment or procedure designed to be a short-term fix for a problem, for example, a temporary repair to a damaged floor. A corrective action is a long-term solution such as a permanent repair to the floor. A preventive action goes a step further and tries to ensure a problem cannot happen, for example, having a routine inspection plan for the floor to ensure that cracks are identified when they first appear and repaired before they become a problem.

The panelists discussed the 2017 FDA draft guidance on control of *L. monocytogenes* in RTE foods (19). The FDA suggested that when a zone 1 (food contact surface) sample tests positive for *Listeria* spp., the product does not have to be put on hold unless repeated positive results are obtained. However, many of the panelists said that they take a more conservative approach than the draft guidance suggests, testing first for *L. monocytogenes* before releasing product or only following the guidance when the food product does not support the growth of *L. monocytogenes*.

BREAKOUT GROUP EXERCISES

A unique component of this virtual meeting was the use of small (two to six people) breakout groups, each tasked with considering a hygienic zoning strategy and EMP for a real-life food facility during the manufacture of a specific food product. Expert facilitators (listed in the “Acknowledgments”) were assigned to each group to guide discussion. Multiple breakout groups were assigned to the same food products, with opportunity for groups to share their conclusions with others. The four food products discussed in the breakout groups represented broad food product categories.

(i) Low-moisture foods (corn tortilla chips). Discussion facilitated by Jeff Kornacki (Kornacki Microbiology Solutions), Kristin Schill (Food Research Institute, University of Wisconsin–Madison), and Elizabeth Grasso-Kelley (Division of Food Processing Science and Technology, FDA).

(ii) Frozen foods (frozen peas). Discussion facilitated by Lory Reveil (American Frozen Food Institute), Malavika Sinha (Lamb Weston, Inc.), and Stephen Grove (Nestlé USA)

(iii) Assembled product (frozen RTE sausage, egg, and cheese on a muffin sandwich). Discussion facilitated by Kara Mikkelson (Hydrite Chemical Company), Kristy Herlitzka (Kwik Trip, Inc.), and Annette Stich (Tyson).

(iv) Plant-based protein (plant-based “cheez” dip). Discussion facilitated by Cindy Austin (University of Wisconsin–Madison), Erin Headley (Schreiber Foods), and Adam Borger (Food Research Institute, University of Wisconsin–Madison).

More information (food product details, facility map, production process, etc.) regarding three scenarios can be found in the supplemental material available at <http://digital.library.wisc.edu/1793/83210>.

Breakout groups working on the same food product often came up with similar ideas, as summarized in [Table 1](#). However, differences in approaches were also noted, underscoring there are no universal “right” answers when designing environmental monitoring, sanitation, and hygienic zoning strategies. The individual facility and its history and each company’s resources and experience will drive these decisions.

CONCLUSIONS

The meeting helped participants think about and discuss hygienic zoning, microbial harborage sites (and their prevention and elimination), and environmental testing strategies in food manufacturing environments. Many of the speakers discussed causes or sites of microbial contamination in food processing environments that might easily be overlooked when sampling, including the following.

- Wheeled equipment
- Shoes
- Air handling systems
- Equipment: when acquiring new equipment, choose equipment that is easy to disassemble (preferably without tools), easy to clean, and compatible with cleaning agents and sanitizers or thermal interventions
- Tools and maintenance equipment, construction in the facility
- Potential damage (pitting, rust, etc.) to equipment from the product (especially acidic or high-salt products) or environment (moisture, humidity) that might increase the risks of microbial contamination
- Repairs (welds, etc.) to equipment that might create new bacterial harborage sites
- Tables, carts, etc. that may not be designed for the food processing environment
- Electrical panels and junction boxes (including those attached to equipment)
- Infrastructure: e.g., floor material and repairs to the floor

TABLE 1. Summary of recommendations from breakout groups^a

Food Category	Low-Moisture Food	Frozen Food	Assembled Product	Plant-Based Protein
Specific Food	Corn Tortilla Chips	Frozen Peas	Frozen, RTE Sausage, Egg, Cheese on a Muffin Sandwich	Plant-Based “Cheez” Dip
Considerations for Hygienic Zoning and Sanitation	<ul style="list-style-type: none"> • The corn tortillas are made from raw ingredients in one large production area. • Wet (raw) production areas utilized before the heat treatment (kill step) need to be kept separate from RTE areas with a barrier. • Color-coding should be used to mark wet and RTE zones (on floor, employee smocks, equipment) to keep equipment and people in their designated areas. • Consider designating separate equipment (e.g., forklifts, air-handling units) for wet and RTE areas. • Separate handwashing stations for wet and RTE areas could be installed outside of production room entrances • Eliminate floor drains where possible (or install baskets or covers) 	<ul style="list-style-type: none"> • The pre- (raw) and post-blanching areas need to be clearly separated • Workers in each area could wear different color smocks; put up a chain to separate the raw and post-lethality areas to control traffic. • Air control is difficult when both raw and post-lethality steps occur in the same large room; a curtain could be used to separate areas but would need to be maintained to prevent from becoming a harborage site. • Need to ensure the raw material is on the negative air pressure side of the production room to prevent air movement from the raw to the post-lethality side. • Exhaust fans can be used to capture condensation and should be positioned to ensure optimal air flow to prevent contamination. 	<ul style="list-style-type: none"> • The finished product contains RTE, frozen components, and the finished product is frozen. • A main concern will be keeping the environment cold during assembly. • Frozen components can be transferred from low hygiene areas (where product is de-cased) to high hygiene areas using designated totes. • Handwashing stations, door foamers/footbaths could be stationed at entrances. • Try to keep the low hygiene areas dry; consider using dry foot baths to minimize moisture. • Gloves, face masks, and hair nets should be used in the high hygiene zone but should not be needed in the low hygiene areas. • Try to segregate people and equipment in the low and high hygiene areas as much as possible. 	<ul style="list-style-type: none"> • Facility includes raw materials and RTE products in one large room which would be divided into low and high hygiene areas. • Colored smocks, etc. could ensure employees stayed in assigned zones. • Control traffic patterns so that RTE and raw employees do not have to cross through other areas. • Air should flow from RTE to raw areas. • Trench drain water should have water run from RTE to raw area. • Handwash, footbaths should be installed at entry doors to production room and packaging area. • Add a separate door for entrance to the RTE area. • Ingredients added after the cook step should be stored separately from other ingredients and should not be moved through the raw area. • Relative humidity should be kept <60% • Validate the CIP system at least 1–2 times per year.
Considerations for Environmental Monitoring	<ul style="list-style-type: none"> • In RTE production areas: <ul style="list-style-type: none"> ◊ PreOP: Test ATP, APC, and EB for verification post-sanitation. ◊ During operation: Test Zones 1–4 for both <i>Salmonella</i> spp. and <i>Listeria</i> spp. 	<ul style="list-style-type: none"> • <i>Listeria</i> will be a key pathogen of concern on the post-lethality side. 	<ul style="list-style-type: none"> • Daily/weekly during preOP: test for APC, ATP, coliforms, <i>E. coli</i>, <i>Listeria</i> spp., EB (as indicator for <i>Salmonella</i>), yeast/mold. 	<ul style="list-style-type: none"> • Weekly preOP: ATP, APC, coliforms, yeast and molds in Zones 1–3; <i>Listeria</i> spp. and EB in raw area.

(cont'd)

TABLE 1. Summary of recommendations from breakout groups^a (cont.)

Food Category	Low-Moisture Food	Frozen Food	Assembled Product	Plant-Based Protein
Specific Food	Corn Tortilla Chips	Frozen Peas	Frozen, RTE Sausage, Egg, Cheese on a Muffin Sandwich	Plant-Based “Cheez” Dip
Considerations for Environmental Monitoring	<ul style="list-style-type: none"> • Test room air and compressed air for mold/yeast, APC, EB. • Collect environmental samples from key FCS at least once every week when the plant is in operation. • Test each FCS in the plant at least once per month. • Test all non-FCS sites identified in the monitoring plan at least once each quarter. 	<ul style="list-style-type: none"> • EB can be tested to verify sanitation effectiveness in Zones 2, 3, and 4. • <i>Listeria</i> spp. should be tested in Zone 1 (FCS) in post-lethality locations. 	<ul style="list-style-type: none"> • Weekly testing for <i>Listeria</i> spp., during operations, also when equipment is disassembled and possibly before and after production depending on risk assessment. • Test air, water. • For extended runs: <ul style="list-style-type: none"> • Need to build a baseline environmental history. • Also need to consider how it might impact product quality. • Need to consider temperature maintenance during extended run. 	<ul style="list-style-type: none"> • During operation, (lean more heavily towards Zone 2 and 3), swab for <i>Listeria</i> spp. and EB. • For extended runs, test for <i>Staphylococcus aureus</i> and possibly <i>Clostridia</i> spp. • Air testing: coliform, EB, molds/yeasts weekly or as needed, changing air filters regularly. • Water testing monthly. • Monthly pathogen (<i>Listeria</i> spp. and <i>Salmonella</i> spp.) testing on Zone 1 surfaces and hold product if positive result is obtained.
How to Handle Positive Test Results	<ul style="list-style-type: none"> • Need to have three consecutive days of negative results for both the original and vector sites. • Consider WGS testing on positive isolates; they may be useful for tracking purposes. 	<ul style="list-style-type: none"> • Hold product. • Use vector swabs to try to identify contamination source. • Clean/sanitize and retest (before, during and after runs) during the next 3 consecutive days to ensure problem is gone. • Check that GMPs are being followed; check manufacturing records to ensure the blancher was operating at the correct temperature, etc. • Maintenance tools and equipment should be considered as potential contamination sources. • Could add whole genome sequencing to the vector swab data and to identify transient vs. persistent strains. 	<ul style="list-style-type: none"> • Start out with vector swabbing (5 swabs) and go from there, up to 30 feet in all directions. • May need to transition into investigational mode if multiple positives are found during the vector swabbing. • Perform a root cause analysis to assess the cause of the contamination. • Take swabs before and after sanitation to test sanitation efficiency. 	<ul style="list-style-type: none"> • Hold product. • If it tests positive for <i>Listeria</i> spp., test for <i>L. monocytogenes</i>, if not <i>L. monocytogenes</i>, release. • Perform extensive swabbing in and around processing area. • Look at traffic patterns, tools, condensation, near dust sources, etc.

^aAbbreviations: APC (aerobic plate count), ATP (adenosine triphosphate), CIP (clean-in-place), EB (*Enterobacteriaceae*), FCS (food contact surface), preOP (preoperational), RTE (ready-to-eat), WGS (whole genome sequence)

TABLE 2. Resources for Environmental Monitoring

Focus of Document	Title	URL
General	3M and Cornell University, Environmental monitoring handbook for the food and beverage industry	https://multimedia.3m.com/mws/media/1684575O/environmental-monitoring-handbook.pdf
	How and why environmental monitoring plans add to the bottom line (11)	https://www.food-safety.com/articles/7000-how-and-why-environmental-monitoring-programs-add-to-the-bottom-line
	Processing plant investigations: practical approaches to determining sources of persistent bacterial strains in the industrial food processing environment (10)	https://link.springer.com/chapter/10.1007/978-1-4939-2062-4_5
Environmental monitoring for specific food categories	American Frozen Food Institute, Pathway to environmental monitoring in frozen food facilities	https://affi.org/safety/monitoring/
	International Dairy Foods Association, <i>Listeria</i> control resources for the ice cream and frozen ready-to-eat dairy-based dessert industry	Not available
	Prevalence of <i>Cronobacter</i> spp. and <i>Salmonella</i> in milk powder manufacturing facilities in the United States (9)	https://pubmed.ncbi.nlm.nih.gov/32421786/
	Dried dairy-based products (12)	https://www.springerprofessional.de/en/dried-dairy-based-products/1920930
	Controlling pathogens in dairy processing environments	https://www.usdairy.com/getmedia/9023c332-2ae0-4883-986b-0fdac5058881/Pathogen-Guidance-FINAL-10-22-2020.pdf
Low-moisture food facilities	Processing environment monitoring in low-moisture food production facilities: are we looking for the right microorganisms? (2)	https://pubmed.ncbi.nlm.nih.gov/34500287/
	Grocery Manufacturers Association, Control of <i>Salmonella</i> in low-moisture foods	http://graphics8.nytimes.com/packages/pdf/business/20090515_moss_ingredients/Salmonella ControlGuidance.pdf
<i>Listeria monocytogenes</i> control	Alternative approaches to the risk management of <i>Listeria monocytogenes</i> in low risk foods (4)	https://www.sciencedirect.com/science/article/pii/S095671352030517X
	FDA, Draft guidance for industry: control of <i>Listeria monocytogenes</i> in ready-to-eat foods	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods
	USDA-FSIS, Controlling <i>Listeria monocytogenes</i> in post-lethality exposed ready-to-eat meat and poultry products	https://www.fsis.usda.gov/guidelines/2014-0001
	Control of <i>Listeria</i> : guidance for the U.S. dairy industry	https://www.usdairy.com/getmedia/aee7f5c2-b462-4f4f-a99d-870f53cb2ddc/control%20of%20listeria%20monocytogenes%20guidance%20for%20the%20us%20dairy%20industry.pdf.pdf
	Seek and destroy process: <i>Listeria monocytogenes</i> process controls in the ready-to-eat meat and poultry industry (14)	https://meridian.allenpress.com/jfp/article/78/2/436/174131/Seek-and-Destroy-Process-Listeria-monocytogenes

(cont'd)

TABLE 2. Resources for Environmental Monitoring (cont.)

Focus of Document	Title	URL
Testing	Microbiological testing by industry of ready-to-eat foods under FDA's jurisdiction for pathogens (or appropriate indicator organisms): verification of preventive controls	https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/NACMCF_2018-2020_RTETesting.pdf

- Pipes or pipe insulation that may leak fluids and spread contamination
- Time allotted for cleaning and sanitation activities: is it adequate, or might short times encourage short cuts that compromise sanitation?
- Activities during holidays, weekends, and nonproduction hours or with nonroutine personnel (maintenance personnel or contractors)

Meeting speakers and panelists touched on many common themes, which summarize the key takeaways of the meeting.

- Take a preventive or proactive approach to environmental monitoring to prevent “firefighting” later.
- Start with a good hazard analysis. The EMP should be risk-based for the specific product and facility.
- Effective environmental monitoring is expensive, but an expensive EMP is not necessarily a good one.
- Finished product testing is like looking for a needle in a haystack; it is a verification activity but not a control. Environmental monitoring is a control and has much more power to identify and prevent problems.
- Engage the entire team (with clear responsibilities and ownership) and have management buy-in to the EMP.
- Draw on the experience of others in designing your EMP, including outside laboratories, chemical vendors, industry peers, trade associations, consultants, and academic experts.
- Make sure sufficient time and resources are allotted for cleaning and sanitation.
- The utility of a simple visual inspection, especially with a flashlight, is often underrated.
- Seek and destroy: Facility workers must diligently try to find samples that will give positive testing results, which should not be considered failures. Negative results should not be merely the result of inadequate search efforts.
- Test for indicator organisms to identify niches early and prevent them from becoming pathogen harborage sites.
- Identified risks require immediate actions (corrections), but these are often only short-term solutions. Long-term solutions (corrective actions) are also needed, which may require significant capital expenditures.
- EMP data are not just for regulatory compliance; they can be used to:

- ◊ Generate risk-based sampling plans
- ◊ Identify entry and harborage or niche sites and track contamination pathways
- ◊ Identify trends to allow prediction of where problems could arise
- ◊ Verify preventive controls and sanitation effectiveness
- ◊ Justify capital expenditures

- Strain typing and genomics can help identify contamination sources, elucidate relationships between contamination sites, and determine whether a strain has been in a facility previously.
- Self-identification of microbial problems in the facility is preferable to identification by outsiders, even if data analysis and management for confidentiality is challenging.
- Look and learn from the facility testing data (and data obtained elsewhere) and use those data as a basis for future planning and actions.

RESOURCES

A variety of resources regarding environmental monitoring that speakers and other meeting attendees have found useful were mentioned during the meeting and are listed in *Table 2*.

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