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FARM TO FORK SAFETY

Components in a Pathogen Environmental Monitoring Program

February 18, 2014 • By Timothy Freier, PhD and Joseph Shebuski, PhD

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Food safety for food manufacturing facilities has changed and evolved greatly in the last few decades. A large part of that change involved moving toward a more preventive food safety strategy. The application of hazard analysis has shifted the emphasis from finished product testing to more proactive approaches such as the use of validated critical control points with science-based critical limits to consistently reduce risk. In conjunction with this there has been an increased use of environmental monitoring as a means of verification of the prerequisite programs that serve as the foundation for Hazard Analysis and Critical Control Points (HACCP). Today many facilities are adding or strengthening their pathogen environmental monitoring programs (PEMPs) to enhance their food safety risk reduction efforts.

The two most common types of PEMP are Listeria spp. monitoring as an indicator for *Listeria monocytogenes* and *Salmonella* monitoring. Monitoring programs for other pathogens or indicators, such as monitoring for *Cronobacter sakazakii* in infant formula manufacturing facilities, share many similarities with the PEMPs discussed here. Monitoring for more generic indicator groups, such as sampling for total

Environmental Monitoring Decision Tree

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this article. For food manufacturing facilities where there is a science based reason for a PEMP, there are some common components that should be built into the PEMP to make the program as effective as possible.

Management Commitment

The first component of an effective PEMP is management commitment. Corporate and facility leadership need to understand and support this program and supply appropriate resources and recognition to ensure that it is viewed as an important part of the food safety culture for the organization. These programs can involve significant cost and major implications for production. For example, if the PEMP findings indicate an elevated risk for contamination of the finished product, product may need to be placed on hold and tested, or even reprocessed or destroyed. Effective corrective action could require an investment in new equipment, a product reformulation, or an improvement in the facility's sanitary design. In other words, management commitment means more than agreeing to pay for some lab tests. One never knows what will be found when a diligent environmental search for a potential product adulterant is conducted, so everyone involved must understand the risks and implications of a finding and be willing to support the program before the first swab is taken.

Determination of Need for PEMP

Not every food manufacturing facility needs to have a PEMP. More testing does not necessarily equal more safety. Rather, the judicious use of food safety resources requires interventions and verifications to be targeted to the most appropriate areas for the greatest risk reduction. A thorough risk evaluation should be conducted to lead the food safety team to a determination of whether or not a PEMP is necessary, which organism or indicator group to monitor, and the degree of stringency of the PEMP. Any type of sampling and testing has the potential for "false" results. This is especially true for microbial testing. Therefore, if a product or process can be designed that precludes the need for a PEMP; this option should be carefully balanced with other considerations such as product safety and quality, consumer acceptance, regulatory requirements, and production expense. An example of a process change that could eliminate the need for a PEMP is to eliminate product exposure to the plant environment (hot filling or aseptic filling versus cold or ambient temperature filling) or pasteurization of the product in its final package. Another example is the reformulation of a product or changing distribution from refrigerated to frozen to prevent the growth of *L. monocytogenes.*

Risk Evaluation

The next component is a complete evaluation of the science-based food safety risk. We have designed a simple decision tree that can be used as a first step to aid in this risk evaluation. This decision tree has been used for hundreds of products in numerous production facilities and has been found to work

well for most p

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risk evaluation and not used to replace a complete evaluation.

While there are many similarities in the risk evaluations for *Salmonella* and *L. monocytogenes*, there are a few key differences. One is *L. monocytogenes* can grow slowly at refrigeration temperatures, while *Salmonella* cannot. Another key difference is *L. monocytogenes* typically needs to grow to high numbers to cause infection, even in immunocompromised individuals. *Salmonella* can cause illness at relatively low numbers and often causes illness in otherwise healthy individuals. In general terms, *L. monocytogenes* has the greatest risk in ready-to-eat (RTE) perishable refrigerated products that allow the growth of this organism and have relatively long shelf lives (e. g., certain soft cheeses, salads, cooked seafood, fresh-cut produce, deli meats, and hot dogs). Alternatively a *Salmonella* PEMP has the greatest value in facilities manufacturing dry shelf-stable RTE products (e.g., nuts, nut butters, soy products, dry pet food, breakfast cereals, snacks, chocolate). Salmonellosis has also been linked to raw unpasteurized products such as meat, poultry, eggs, dairy, grains, spices, and produce. However, these product contamination events were caused by the inherent presence of the pathogen in the raw products, and not by contamination originating from food manufacturing facilities. A *Salmonella* PEMP is typically not necessary in facilities manufacturing these types of non-RTE products.

Under some circumstances, for example in dry grain processing facilities that lack a processing step to ensure the elimination of pathogens in the final product and for which the product is not intended for RTE applications, “for cause” pathogen environmental monitoring may be conducted. In these cases routine monitoring is not conducted, but “for cause” monitoring is triggered by the occurrence of an unanticipated event involving the ingress of water into a normally dry processing environment. Water could allow for the potential multiplication of pathogens in the plant environment and a possible increased presence of a pathogen in the finished product. A “for cause” PEMP would be appropriate to evaluate this heightened food safety risk but once the situation returned to a normal operating condition the need for ongoing sampling and testing would be unnecessary.

When the risk evaluation indicates a PEMP is necessary, the next component to consider is to determine the degree of stringency of the plan. Every product, process, and facility is different. The stringency of the plan is based on many factors, such as the historical linkage of the product type with illnesses (for Salmonella, often termed “*Salmonella*-sensitive ingredients or products). Another important factor is the degree of product exposure to the plant environment. Products exposed to the environment are those having a reasonable likelihood of becoming contaminated if the pathogen of concern exists in areas near product contact surfaces or in other places between the kill step and final product packaging. If product is conveyed in fully enclosed piping into the final container with little to no likelihood of contamination or “hot filled” under controlled conditions, the product would not be considered to be exposed to the plant environment. If the final kill step occurs after product is sealed in the final bacteria-impervious package, the product would also be considered to not be exposed. Other considerations include the history of pathogen findings in the facility, the amount of handling following the pathogen reduction step, the complexity and sanitary design of the equipment, packaging type, distribution conditions, shelf life, intended use of the product, and susceptibility of the

targeted consu

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of the program, the sampling plan.

A Sampling Plan

Each facility and product type should have a science-based sampling plan for any PEMP deemed necessary based on the risk evaluation. Critical components of the sampling plan include the determination of the number of samples to collect in each sampled room, area or zone, how often sampling will be conducted (daily, weekly, monthly, etc.), which days of the week, and at what time during the shift samples will be taken. Sampling sites should not be entirely random but should instead target the most likely sites to harbor the organism of concern. *Listeria* growth niches can occur on product contact surfaces, so these surfaces should be included in the Listeria PEMP sampling plan. Difficult-to-clean sites in product contact areas and close to product contact areas should be heavily targeted. Also, the sampling focus should be on the environment in the most critical area of the plant (the area between the kill step and final packaging). Areas historically associated with *Listeria* growth niches (e. g., hollow rollers on conveyors, gasket material around doors, hollow support structures, grease inside bearings, slicers, dicers) should be preferentially included in the plan.

When developing a sampling plan for *Salmonella*, target warm (non-refrigerated) areas exposed to moisture (roof leaks, condensation, over-spray from cleaning, etc.), and product residue. Sampling sites are typically concentrated in areas near food contact surfaces and other areas in the primary *Salmonella* control area (PSCA), the area between the kill step and final packaging. In contrast to *Listeria, Salmonella* growth niches do not typically occur on product contact surfaces due to the dry nature of the product and the self-cleaning or scouring nature of the dry product passing over the contact surfaces. The *Salmonella* PEMP sampling plan should concentrate on non-product contact surfaces in the PSCA.


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While the overall food safety goal is to maintain critical processing areas free of the pathogen or

In addition to the samples scheduled to be taken based on the sampling plan, technicians should be allowed to take "creative" samples, investigating novel sites not sampled in the past. Technicians need to be trained to understand the difference in the implication to finished product between sampling a product contact surface and a non-product contact surface. Typically, if a pathogen such as *Salmonella* is found on a product contact surface, the product contacting that surface would be deemed to be adulterated and may need to be recalled if the product had not been

placed on hold

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the PEMP is to find these organisms.

The goal of the PEMP is to find the intended target. Technicians doing the sampling should be incentivized to find positives. This is counterintuitive to many people. While the overall food safety goal is to maintain critical processing areas free of the pathogen or indicator group, the goal of the PEMP is to find these organisms. In the U.S. RTE meat and poultry industry, this mentality is known as “Seek and Destroy,” and the diligent search for the target needs to become part of the food safety culture of the facility.

Investigational sampling in response to a positive routine finding should be conducted with the goal of finding the true root cause of the contamination. The stringency of the investigational sampling will depend on the circumstances of the finding. Finding the root cause of a contamination issue is often very difficult and can require intensive disassembly and sampling of equipment and the environment. This investigation can continue for several weeks and involve taking hundreds or even thousands of samples. As part of the investigation, the food safety team also needs to consider changes or disruptions to normal production such as improper employee practices, drain backups, flooding, contractor work, power outages, etc., in addition to evaluating the test results.

Special circumstance sampling may be initiated even without finding positives during routine sampling. This can include taking extra samples during non-routine events such as facility construction, installation of new equipment, power failure, roof leaks, kill-step failures, or any circumstance that might lead to enhanced risk of contamination of the final product.

Sampling Methods

The next component of the PEMP should provide details about how samples will be collected, the type of sampling device to be used (e. g., sterile sponges with sterile gloves), the type of diluent to be used, and how the samples will be stored and transferred to the lab and tested. Typically, large areas should be sampled (greater than 1 square foot) using an abrasive sampling device, such as a microcellulose sponge wetted with a diluent like peptone water or a neutralizing buffer (if residual sanitizer might be present in the area being sampled). Samples should be refrigerated, not frozen, and processed by the laboratory within three days. Technicians taking samples should be trained in proper aseptic sampling procedures. Sampling should typically be conducted by starting in the cleanest area of the plant and ending with the dirtiest area to prevent inadvertent cross-contamination of the facility. Only methods validated for use with environmental samples should be used (AOAC International or rigorous internal validation). Testing should be conducted at a competent lab with appropriate quality control practices in place. The time from test initiation to result (turnaround time) is often thought to be less critical for PEMP than for finished product testing, as product is not typically placed on hold. However, quick turnaround time can be critical during an investigation. Similar to a crime investigation, clues are most helpful when the trail is still fresh.

Evaluation

The final critical elements in a PEMP are the evaluation of the results of the sampling and corrective actions prompted by those results. The results should be reviewed on a timely basis. Positive findings should be reviewed by the facility food safety team. Results should be organized in a manner allowing easy visualization of findings. The use of data spreadsheets and facility maps indicating positive and negative findings is recommended. When routine and/or investigational and/or special circumstance sampling indicates a problem, timely and effective corrective action must be taken. This activity should target the root cause of the contamination. Most effective corrective actions will involve more than simply re-cleaning or re-sanitizing the problem area. The food safety team should also consider changes in personnel practices, training, equipment or facility modifications, process or product changes, or other activities resulting in a permanent fix of the problem. Additional testing may be necessary to verify the adequacy of the corrective actions. All activities involving the PEMP should be documented.

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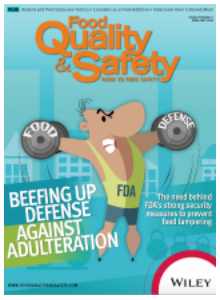

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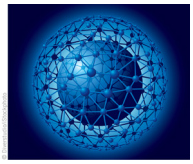

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