BUL 985

Developing a Pathogen Environmental Monitoring Program for a Food Manufacturing Facility

Janna Verburg-Hamlett
Extension Specialist, Department of Animal, Veterinary, and Food Sciences, University of Idaho

Catherine Cantley
Former Extension/TechHelp Assistant Professor, Department of Animal, Veterinary, and Food Sciences, University of Idaho

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University of Idaho Extension

Introduction

A PATHOGEN ENVIRONMENTAL PROGRAM (PEM) is known by many names and acronyms, including PEMP (Pathogen Environmental Monitoring Program), EM (Environmental Monitoring), EMP (Environmental Monitoring Program), and EMPC (Environmental Monitoring Pathogen Control). The purpose of a PEM is to proactively seek and destroy microorganisms in the environment before the product is compromised. Just as manufacturing facilities vary greatly across the industry, so too do PEM programs. That's because a PEM program is based on the risks unique to that company's facility, product, and process. A facility making dry blend infant formula is going to have a very different program than a facility that manufactures sugar from sugar beets. A PEM program can be very expensive and, if not configured properly, may not be functional or useful, which is why it is important to ensure the program is effective so that you have a good return on investment.

PEM programs are required by regulators and are often required by customers and third-party auditors. Most in the industry have heard about the United States Food and Drug Administration's (USDA) swab-a-thons during inspections. This activity is meant to verify that the risk-based PEM program is functioning properly, in accordance with the Food Safety Modernization Act (FSMA) (21 CFR 117.165 (3)):

> Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system: [. . .]

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples.

The USDA requires swabbing as part of a verification of sanitation in a facilities food safety plan (see Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems final rule [9 CFR Part 417]). Global Food Safety Initiate auditing schemes also require PEM programs. For example, Safe Quality Foods edition 8 (2.4.8.1) states, "A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes." The code then goes on to explain further the requirements.

Benefits

There are many benefits to a robust PEM program, including the following:

Prevents recalls. A facility is often the root cause of a contamination, the instigator of numerous recalls. A facility that has developed a robust PEM program, and actively monitors the results, can avoid contamination issues, thus avoiding a costly recall or sickness outbreak (e.g., Peanut Corporation of America in 2009, Blue Bell Ice Cream in 2015).

Provides an early warning system to prevent microbial outbreaks. Environmental sampling can help to prevent product contamination, thus again avoiding damaging recalls and/or costly product loss, an important benefit of any food safety program.

Provides a strong key prerequisite program that can help to reduce the number of hazards requiring preventive control in a food safety plan. According to the FMSA and the Preventive Control (PC) rule for Human Food, if a hazard exists a facility must put in preventive controls to mitigate the hazard. A robust PEM program can reduce the number of hazards and thus reduce the number of preventive controls needed to protect the product.

Improves the identification of harborage points and the detection of maintenance issues like damaged floors, open floor-to-wall junctions, or pooling water before microorganisms aerosolize and impact a product.

Verifies the sanitation program and sanitary design of a facility. Regulations and HACCP principles state that one must substantiate that all key prerequisite programs are functioning as expected. A PEM program can provide data that confirms that a facility and its equipment have been sanitized.

Provides a methodology for data collection and trending for personal and operational-type procedures and policies.

A PEM program is a key prerequisite program regardless of the types of products that are made, e.g., ready-to-eat, animal feed supplements, dry blend infant formula, fresh pack potatoes, cheese, dried milk products, or granola bars, just to name a few. All can benefit from an effective PEM program.

Sampling Locations

Most facilities determine risk based on the proximity of an item or piece of equipment to an open product. Indeed, monitors analyze equipment and facilities based on zones. They start by evaluating product contact surfaces in each successive zone. Table 1 explains the four zones and describes the example surface locations they test.

For further conceptualization of the way monitors use zones to test surfaces, see Figure 1. Think of a dartboard, with product contact in the center and, as you move further way from the center (less points in darts), you move further away from a product contact surface.

An effective PEM program uses a mix of standard sampling sites and randomly selected sites. For sanitation verification or routine situations, the same sampling locations may be checked repeatedly. Encourage staff who are collecting samples to look around the facility. Have them look for areas that they think may be problematic and have them sample those sites. Remind them to not look solely at eye level. Take 20%–30% of swabs from above

Table 1. Explanation of zones.

Zones	Explanation	Example Sampling Sites
1	Direct product contact	Inside holding vessels, sampling devices, product contact side of doors/lids, product contact brushes, product contact belts, packaging, employee hands.
2	Adjacent to product contact (~<10 inches from product contact). Can serve as a transfer point to product contact.	Handle to vessel opening, underside of belt, control panels and buttons, equipment/infrastructure above the opening to product contact.
3	Nonproduct contact, adjacent to zone 2 surfaces, in the production area but further away from product contact.	Walls, floors, ceilings, drains, legs, and support structures of equipment, forklifts, trash containers, noncontact brooms/mops/brushes, condensate catch pans.
4	Outside production area	Locker rooms, breakrooms, employee entry ways, connecting hallways, maintenance shop, spare parts storage, warehousing, and finished product storage.

Figure 1. Zones on a dartboard.

eye level, and 20%–30% below it. Tell them not to swab only in places that are easy to see, right in front of them; instruct them to crouch down under equipment to investigate what lies below, then use ladders to see what that discloses above them. Design sampling devices so that workers can easily collect samples from different heights and locations. Swab areas that are the most difficult to clean (under equipment and higher than a person can reach) because people are less likely to clean it properly or at all.

Random sampling requires extra documentation for verification—for example, the content sampled and its location. Pictures are an excellent way to carry this out. Since third-party lab tests can take up to a week to return their results, thorough documentation practices, that include the use of images, help a facility act more quickly if one or more of its sites tests positive or out of specification. In addition, knowing the sample locations enables the food safety team to more accurately identify contamination trends, enhancing their decision making about how to continuously improve food safety in their facility. Because data should always drive decisions, use the results to determine more appropriate testing sites and the frequency of their scheduling.

Good sampling locations include the following:

- Cracks, crevices, niches—difficult-to-clean locations
- Tight corners, bends, and sharp edges that may harbor biofilms
- Locations that provide a transfer location between zones
- Areas that show issues with sanitary design
- Areas that are exposed due to traffic patterns (of people, trash, forklifts, etc.)
- Areas that routinely have pooling water or are collection points of debris
- Sample sites that are closest to, or could affect, open product, packaging, or ingredients
- Locations after the kill step (heat or pasteurization) and before final packaging (High Priority)
- Problem areas or areas that have historically had positive or out of specification results (exceed acceptable limits)

Timing

When you conduct a swab test is equally important. If you are verifying sanitation, then postrinse and preoperational swabs are acceptable. However, if

Table 2. Type of microbiological analysis, with example frequencies and quantities.

Zone	Types of Microbiological Analysis	Sampling Frequency	Approx. Number of Samples
1	Indicator	Daily/Weekly	Depends on Product
2	Indicators and Pathogens	Weekly	10–15
3	Pathogens	Weekly	10–15
4	Pathogens	Monthly	5–10

your intent is to measure facility sanitary design and validate its production and sanitation procedures, sample the production area when it is at its worst (dirtiest). Collect swab samples no sooner than 3–4 hours after production has started; ideally, towards the end of production. Swabs taken immediately after sanitation only verify adequacy of sanitation; they do not serve all the other purposes of an effective PEM program.

Also, vary the days and times of sampling locations. If staff know that Monday is swab day, they may alter their cleaning regimen, biasing the results. However, randomly chosen swab days eliminate bias. Collect some swabs at least weekly with all sampling locations tested by the end of a month. Table 2 suggests some sampling frequencies.

Sample Collection Instruments

It is important to use a wide variety of tools or sampling instruments to manage the many different situations and materials in a food-processing facility. The old adage, "if you only have a hammer then every problem is a nail," applies: using one device hampers your ability to sample all the possible locations. Check with your third-party testing lab and production/lab equipment suppliers to procure several types of sampling instruments. Also, remember the purpose of the swab and the types of chemical components that make up the testing product. Use that information to determine if you need to use a dry swab, a swab enriched with a broth, or a swab treated with a chemical neutralizer. See Figure 2 for examples of some of the types of collection tools you can use.

Figure 2. Data collection instruments.

Quantity of Samples

Determining the number of samples needed can be tricky and must be based on a risk assessment. One of the key factors is facility size. Industry recommendations suggest 30–60 sampling sites per 50,000 square feet. Another consideration is product risk. If a facility manufactures a ready-to-eat product, more sampling sites are required than if a facility makes a product that goes to another manufacturer for further processing. In addition, age and previous test results influence the number of samples needed. Older facilities or equipment tend to have more cracks and crevices; their repair creates more vulnerabilities. Consequently, the wear and tear will require additional swabs. A new piece of equipment or a new facility, however, may not require as many swabs.

What to Test For

Test for a mix of indicator organisms and a mix of pathogens based on product susceptibility and risk. An indicator organism denotes the hygienic

conditions of an area or a piece of equipment. Its presence means that suitable growth conditions exist to support a host of microbiological contaminants, including pathogens. Common indicator organism tests that are often used are coliforms, standard plate count, or Enterobacteriaceae.

If your facility tests positive for indicator organisms, analyze your product to determine the pathogens of concern based on your product's chemical and physical properties. What is its pH, moisture, or water-activity level? At what temperature is it stored? Common pathogens to routinely test for in a PEM program include *Listeria*, *Salmonella*, *Cronobacter*, and *Staphylococcus* species, etc. Indeed, a strong PEM program tests for not only one but a multitude of pathogens. For example, *Listeria* testing should top the list of facilities that manufacture a wet product. In fact, it is not unusual for them to test swabs for it ten months out of the year. To accurately verify the prevalence of another common bacteria, *Salmonella*, test swabs twice a year. Suggested regimens for dry-product manufacturing include routinely testing for *Salmonella* and possibly *E. coli* (for flour products) and *Cronobacter* and *Salmonella* (for dry-blend infant formula plants). The overall takeaway: always determine the pathogens of concern to target based on the product(s) your facility manufactures and processes.

Also, know that different areas of a plant often require different kinds of pathogen testing. For example, a dry facility may test for *Salmonella* routinely in the processing area while checking for *Listeria* in wet areas. As has been discussed previously, ensure an effective PEM program by basing your testing decisions on the risk level of your facility and its product(s).

Advantages and Disadvantages of Compositing

Compositing means sampling several sites using only one **enrichment** (growth media, like agar). Because several sites are tested for the cost of one, this method can be used to save money. There are two common procedures: 1) using one sampling instrument on several sites and 2) using multiple sampling instruments and then combining them in one sample bag. Regarding the first, if sponges are the sampling instrument, testers may use one sponge per sampling site and then put each in its own bag. When compositing, however, they put several sponges in the same bag. Both approaches are valid, but using several sampling instruments is preferable, because it allows for the least amount of cross-contamination as the person moves from site to site. In addition, using multiple sampling instruments instead of just one has a greater chance of capturing the microbiological contaminant.

Although compositing may seem like a sound cost-saving strategy, it has its disadvantages. It isn't as precise: a positive test only indicates the presence of a pathogen in a facility; it does not identify which sampling site tested positive. Thus, additional vectoring and time will be required to find the root cause; consequently, this strategy could add cost, time, and increased risk to production.

Results

Any presence of a pathogen is cause for concern; without a doubt, lab techs consider it out of specification. The value for an indicator organism that is considered out of specification depends on the sampled zone. For example, see Table 3 for the common specification limits in cfu (colony-forming units) for Enterobacteriaceae (EB).

If the results show a positive or out-of-specification indicator organism, begin a root-cause analysis. In order to find the root cause, determine the likely locations that could be causing the contamination and conduct a series of vector swabs. First, sample

Table 3. EB out-of-specification results based on zone.

Zone	EB Specification Results
1	<10 cfu
2	<100 cfu
3	<1000 cfu
4	Typically not tested for indicators

the compromised location and then fan out the swab tests from there, swabbing a series of locations to find the actual one which caused the microorganism to proliferate. For example, after testing a floor surface at the bottom of a set of stairs, odds are the floor is not the root cause. Something near, or draining toward, the floor is harboring the microbiological contaminant. To find the cause also test the equipment near the floor area. A trained analyst must observe the area and seek out the microbiological harborage location. Think of the floor as the center of a bullseye and explore its outer rings to identify the actual source.

Even if a test does not come back positive, don't ignore the negatives. Trend the data—note the problem areas so you can tackle them and project what may develop or deteriorate or become susceptible. Many commercially available software packages can do this for you. However, you can also use Excel. Whatever trending tool you use, the important thing is to review your sampling-site data to make decisions. If a sampling location is routinely negative, you might opt to lessen the frequency of testing on that site and spend your money on other areas that merit more scrutiny. If a site is routinely tested every week, but for the last six months has not been out of specification, then you might want to adjust its sampling frequency to monthly and focus on a location that needs more attention.

Conclusion

Though expensive, PEM programs should be part of your facility's commitment to continuous improvement. Indeed, they are a key prerequisite to any facility's overall food safety program. No one-size-fits-all program for facilities exists, however. Risk factors and the product manufactured dictate the protocols you'll need to follow.

Good documentation and records are very important to prove to customers and regulators that the PEM program is functioning and actively looking for microbiological contaminant in the environment. The key to any good program is to catch the microbiological contaminant in the environment before product is impacted. Don't be afraid to routinely sample random sites and ensure analysts are trained to look for any potential problem areas. Also, understand that getting a positive is not necessarily bad and is usually expected. In fact, a program that has never had a positive test likely indicates an ineffective PEM program. Good luck and get sampling!

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BUL 985 | Published October 2020 |