Pathogen Environmental Monitoring Programs: Establishing a PEMP

PEMP Requirements

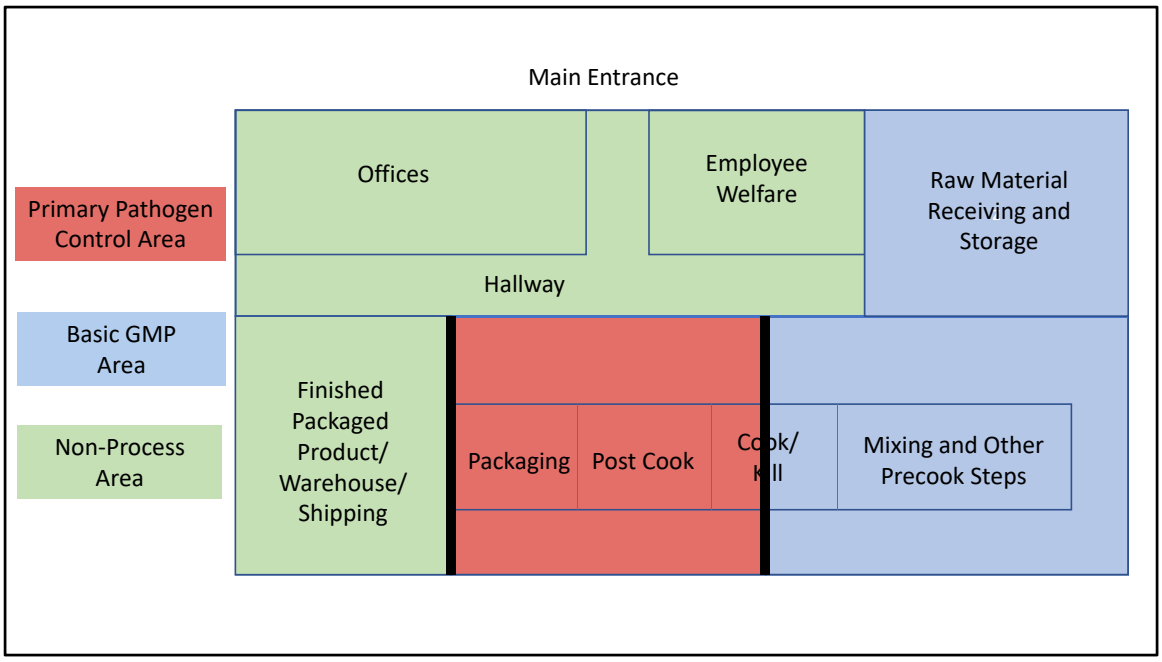
- Written, scientifically valid procedures
  - Test methods and testing laboratory identified
  - Locations and number of samples
  - Critical limits defined
  - Corrective action procedures identified

There are several things to consider when establishing a Pathogen Environmental Monitoring Program. The scientifically valid procedures and approaches you will be using should be documented in writing. Include your chosen test methods and testing laboratories. If you are contracting an outside laboratory they should provide you with details on the test methods they will be using. A contract laboratory may also provide sample kits and sampling instructions. The specific sample locations within your facility should be determined ahead of time and the number of locations, rotation through those locations, and the frequency of sampling should be specified. Critical limits should be defined and corrective actions identified in advance. The goal of a Pathogen Environmental Monitoring Program is to identify and reduce or eliminate pathogen niches in your facility. If your program is working you should expect to occasionally find pathogens and it is important to be prepared when you do.

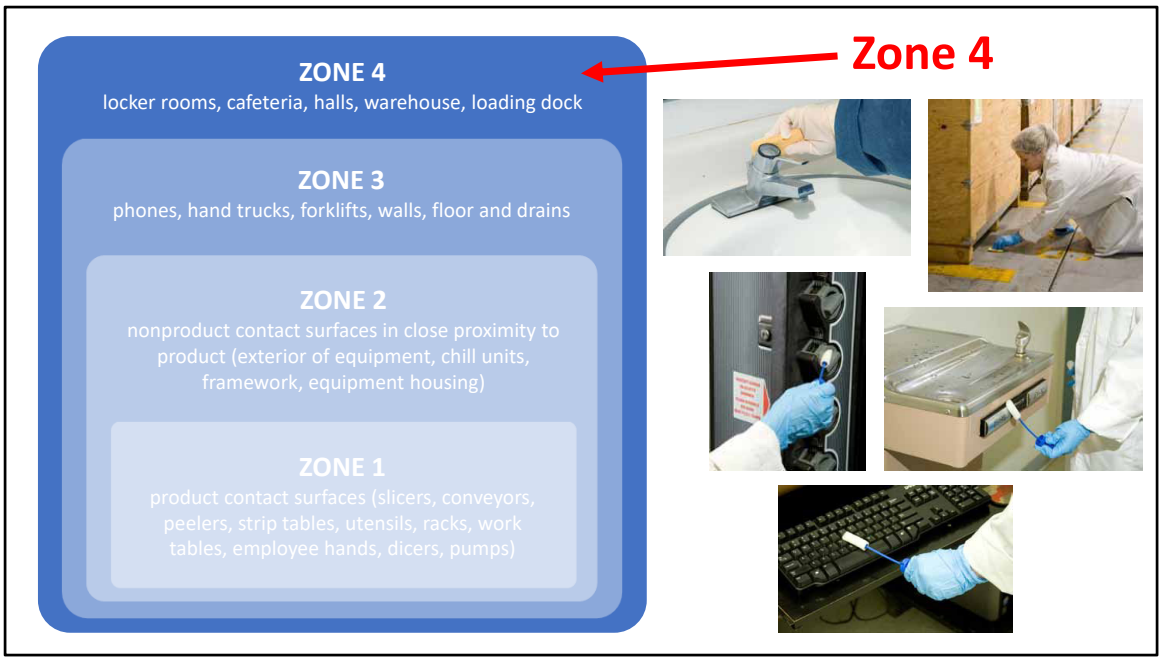
Key Steps

- Identify sample zones
- Establish sample locations
- Identify target organisms and test methods
- Determine frequency and number
  - Rotation to ensure all of facility is sampled
- Identify collection methods
- Develop a training program
- Data analysis
- Document corrective actions
  - Predetermined limits

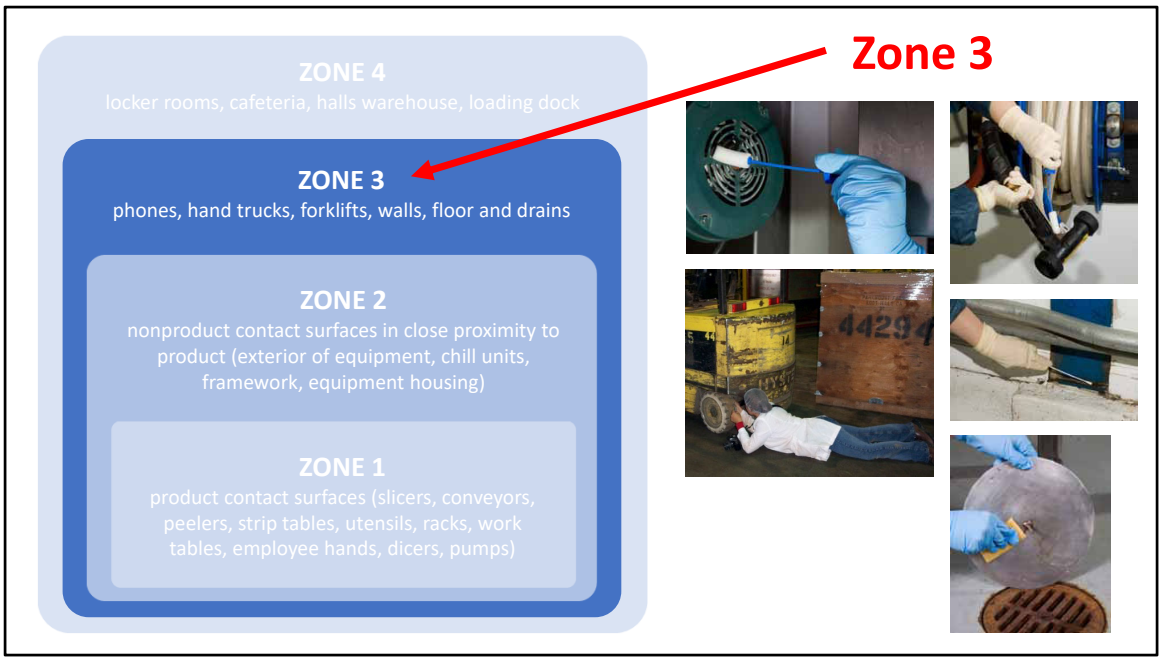
The key steps in preparing your Pathogen Environmental Monitoring Program include the following. Identify sample zones. Establish specific sample locations within each of the zones and identify the target organisms and test methods for each of the sample locations. Determine the frequency and number of samples making sure that all areas of the facility – even those that are challenging to access are included. Identify collection methods and develop a documented training program. Finally, you will need to establish ways to analyze the data and document corrective actions when sample results are out of compliance with your predetermined limits. The goal of the program is to determine if your preventive controls are effective in keeping environmental pathogens from establishing in your facility or contaminating your finished product.



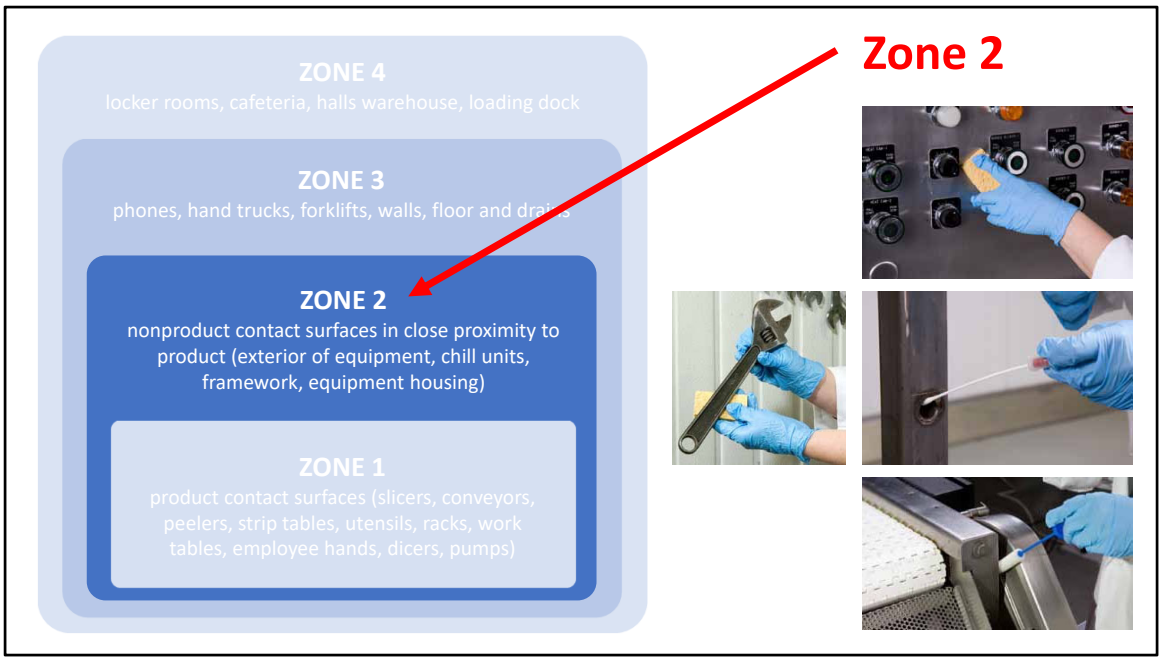
You should have already mapped out your facility and separated it into different hygiene areas. In this example, the green non processing areas include offices, a hallway, the restrooms and breakroom, and the finished product warehouse and shipping area. The blue indicates the basic GMP area that includes raw material receiving and storage, mixing, and precook steps. The raw materials then enter the cook step. In this simplified example the cook step has an entry point for raw material in one room on one side of the wall and an exit point for finished product on the other side of the cook step in a different room. The room where cooked product is exposed up to and including packaging is the primary pathogen control area shown here in red.



Within the facility you will need to further subdivide those individual areas into sampling zones. These are typically designated as sampling Zones 1 through 4. Zone 4 includes the non-GMP areas or non-production areas of the facility – including the rest rooms, halls, offices, warehouse and loading dock.

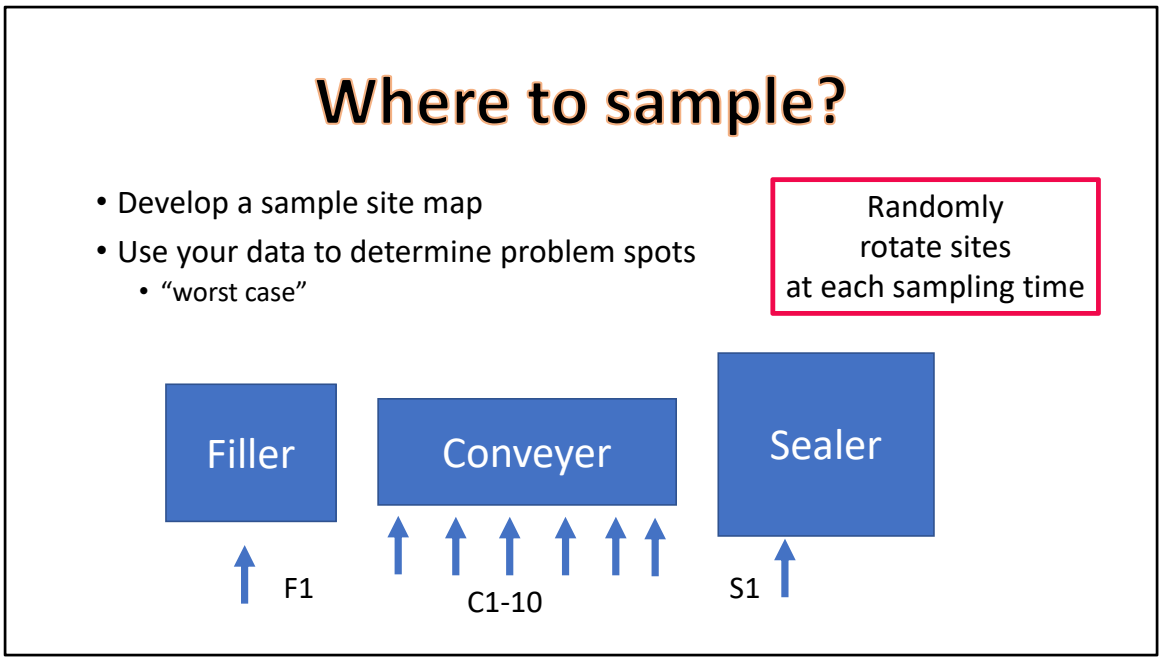


Zone 3 surfaces are within the processing facility but further away from direct contact with the product. This might include the floor and floor drains, walls, forklifts and hand trucks.

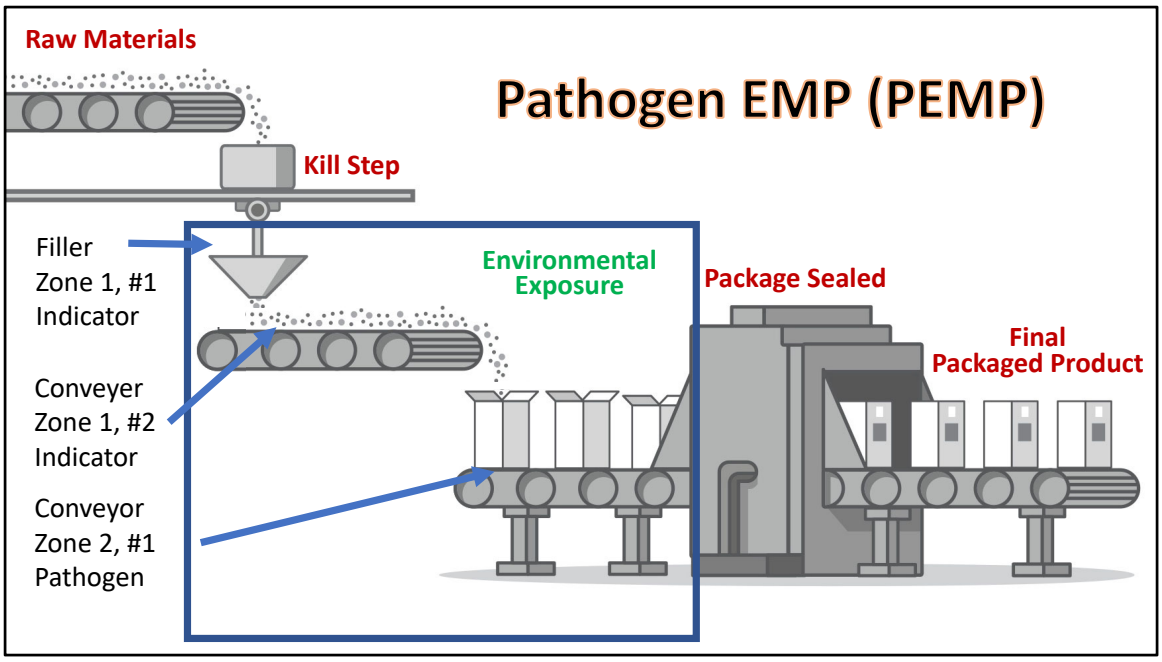


Zone 2 surfaces are in close proximity to the product but do not directly contact the product. Examples include the exterior of equipment including panels and equipment housing as well as tools that might be used in equipment maintenance.

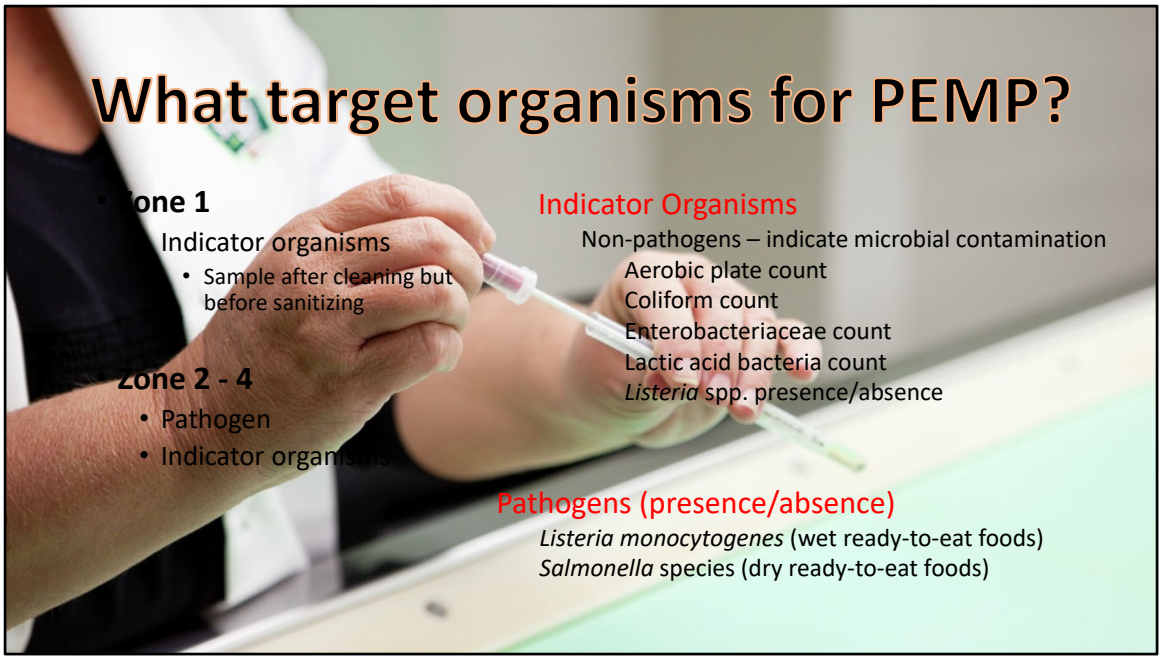
Zone 1 surfaces do come into direct contact with the product. These include items such as conveyer belts, scoops or other utensils, gloves, slicers, and peelers.



It is critical to develop a detailed sample site map that covers each of the zones. Each unique individual site should be listed in a database or spreadsheet and there should be some mechanism to randomly select sites at each sampling time. This will prevent oversampling of sites that are easy to access and will make sure that all sites in the database are included in the rotation. Other site-specific information could include details on whether a swab or sponge or other sample mechanism should be used and the type of test – either indicator organism or pathogen.

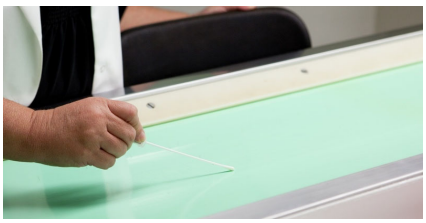


To make sure that there isn't any question regarding the location of specific sampling sites you might take photographs or develop diagrams of the various pieces of equipment or areas of your facility. Photos or diagrams with the marked sample location identifier can then be used for environmental monitoring training and will ensure consistency in sampling among different technicians. In this example diagram the equipment, the zone, the sample number, and the type of test – either indicator organism or pathogen has been noted.

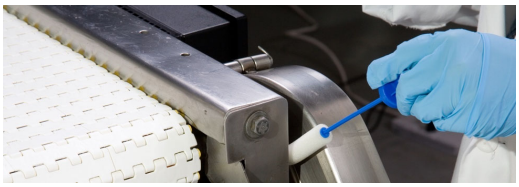


The target organisms is usually determined by the Sample Zone. For Zone 1 surfaces it is typical to test for and enumerate indicator organisms. These are non-pathogenic microorganisms that should be much more common in the environment than pathogens. The choice of indicator organism will depend on several factors specific to your product, equipment, facility, and the pathogen of concern. You can use general guidelines or an analysis of your own data to set limits for your chosen indicator organisms. Usually quantitative data for the indicator organisms is expressed in numbers – most often colony forming units or CFU per square inch or square centimeter or per volume in some cases. If Listeria monocytogenes is your pathogen of concern you may choose to test for presence or absence of Listeria species on Zone 1 surfaces. Indicator organisms can also be used in Zones 2 through 4 but often, in these zones, you are looking for the presence or absence of your pathogen of concern – usually Listeria monocytogenes for wet ready-to-eat food processing facilities and Salmonella for dry ready-to-eat food processing facilities.

Tools – Swabs



Inefficient for
Large Flat Surfaces

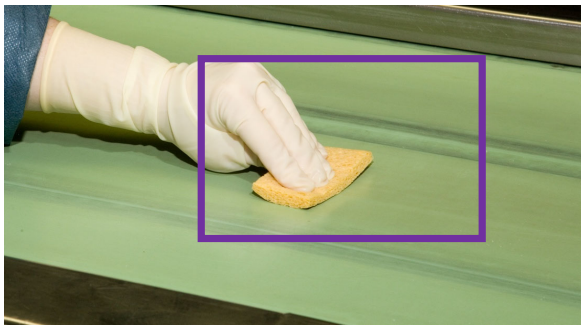


Very Useful for for Smaller and Challenging to Reach Surfaces

There are variety of sponges available that much better suited to larger easier to access surfaces. Sometimes these sponges are attached to a disposable applicator. In other cases, you will need to outline a procedure for holding the sponge as you are collecting your sample. One option is to carefully put on clean gloves at each sample location before handling the sponge. The companies supplying these types of sponges or the laboratories doing the analysis should provide instructions for proper use.

Instead of swabs there are variety of sponges available much better suited to larger surfaces that are easier to access. Sometimes these sponges are attached to a disposable applicator and in other cases you will need to first put on clean gloves before handling the sponge. New gloves would be used for each sample location.

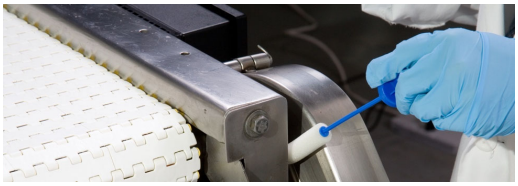
Quantification of Indicator Organisms



Swabbing a defined or consistent area – CFU/square inch or CFU/square cm

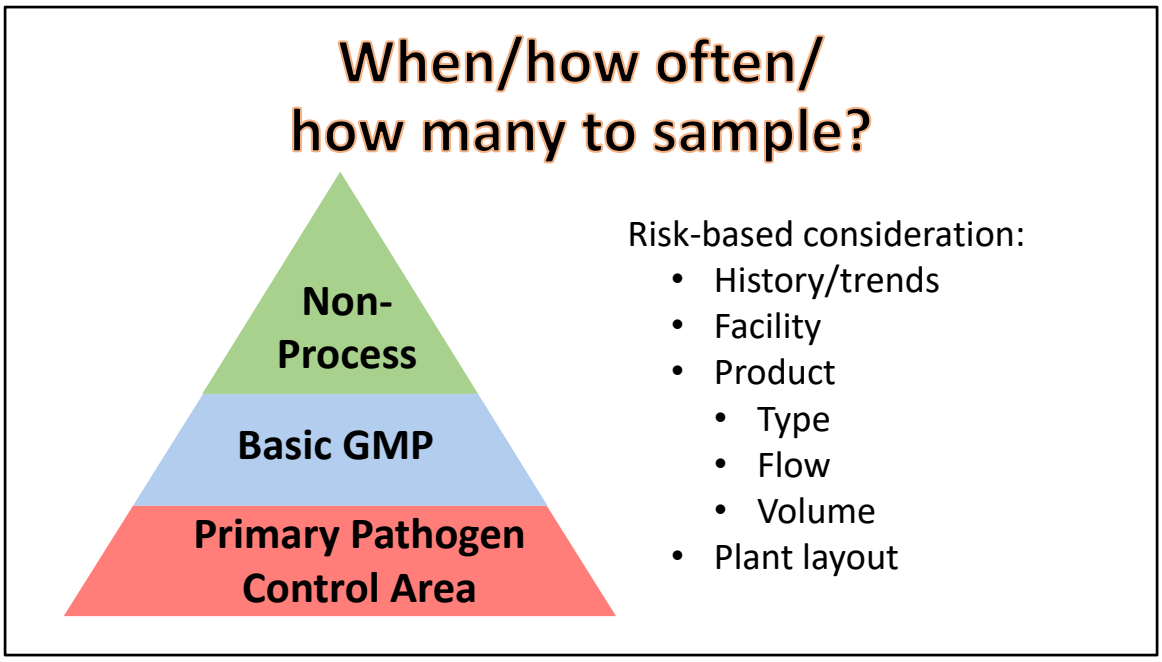
On Zone 1 surfaces or any surface where you are trying to quantify indicator organisms you need to make sure that the sample is taken within a defined area – for example 100 square centimeters or 25 square inches. The number of microorganisms or colony forming units or CFU per square inch or square centimeter can then be determined.

Presence or Absence of Pathogens

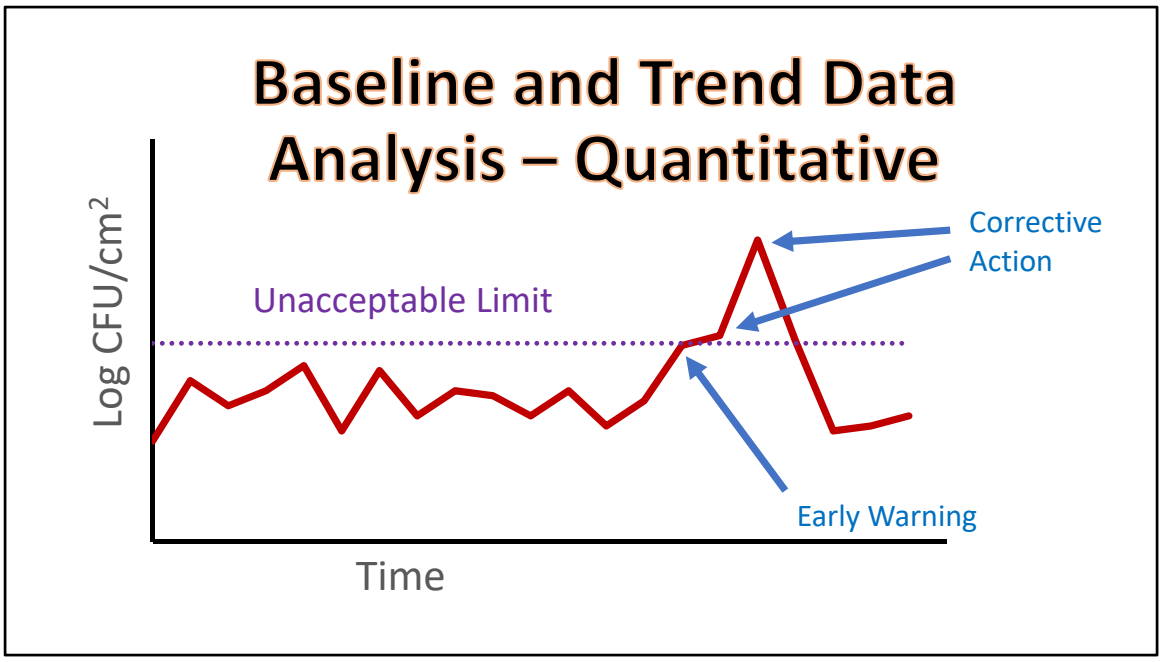


Area sampled should be consistent from time to time for each site

On Zone 2 to 4 surfaces where you are looking for pathogens the specific size of the area is less important because the test only indicates if a pathogen is present or absent. Much larger surface areas can be sampled with a sponge. It IS, however, important to specify how these areas should be sampled so that the operator is consistent from one sampling time to the next. This will ensure you can make valid comparisons for data collected at that location over time.



The frequency that you collect samples for environmental monitoring will be based on several risk factors including the history or trends for your environmental monitoring program, the facility, product and plant layout. However, because this is a Pathogen Environmental Monitoring Program it makes sense that most the samples will focus in the Primary Pathogen Control Area with fewer samples in the basic GMP area and fewer still in the non-processing area. The Pathogen Environmental Monitoring Program will be unique for each facility and product.



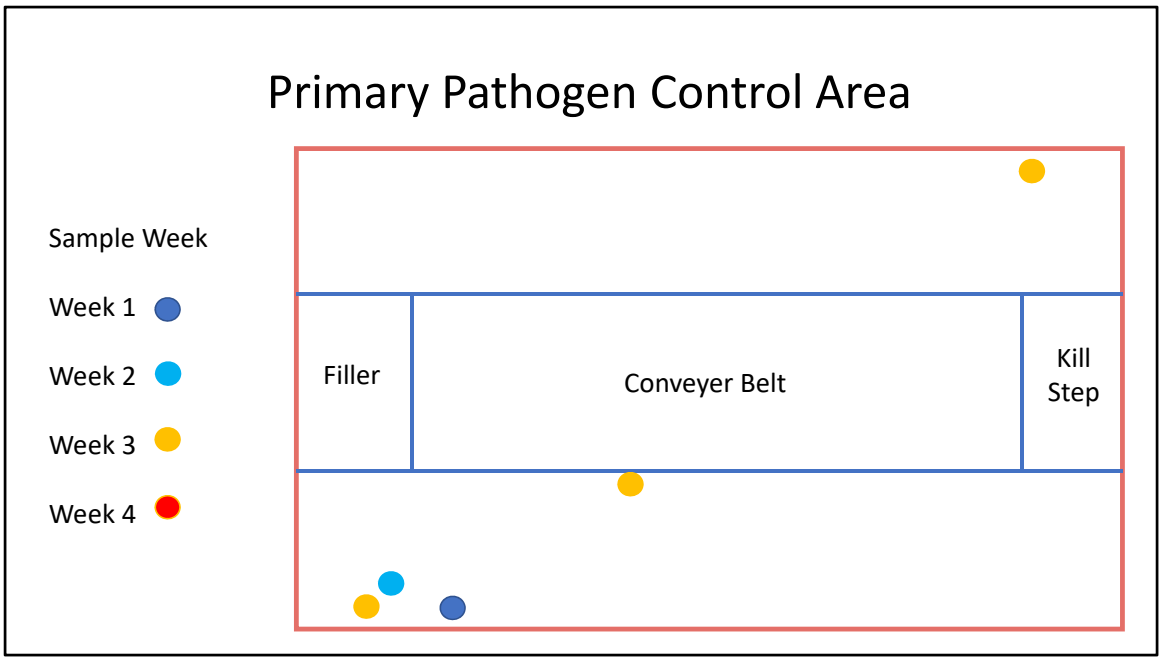
For quantitative data that you generate for indicator organisms you will want to establish baselines and trend data for each location or area. Trends are often easier to visualize if you plot your data on a graph. This will allow you to determine when to implement corrective actions and to document their effectiveness.

Example Corrective Actions – Indicator Organisms/High Counts

- Break down and inspect
- Clean and sanitize
- Resample
- Reclean, re-sanitize and resample

Photo credit: Cleanroomtechnology.com

There are several situation-specific corrective actions that might be taken if counts for indicator organisms are above the established limit. This usually involves additional cleaning and sanitizing of the equipment or area and then resampling and testing to bring the results back into compliance. It is also useful to try to identify the circumstances that led to the higher counts to see if a longer-term corrective action should be implemented such as adjusting the frequency or cleaning and sanitation procedures.



It is important to track pathogen test results. The goal is to understand trends so that you can act upon them. Tracking also serves to document your response to positive findings and provides evidence that your response was appropriate and effective. There are several approaches to accomplishing this. In this simple example the pathogen primary control area map has been expanded and positive findings shown by sample location and week. This visual representation allows location-specific clusters or potential trouble spots to be easily identified. These data would also likely appear in a table or spreadsheet that would provide more details regarding the results and document the subsequent corrective actions that were taken.

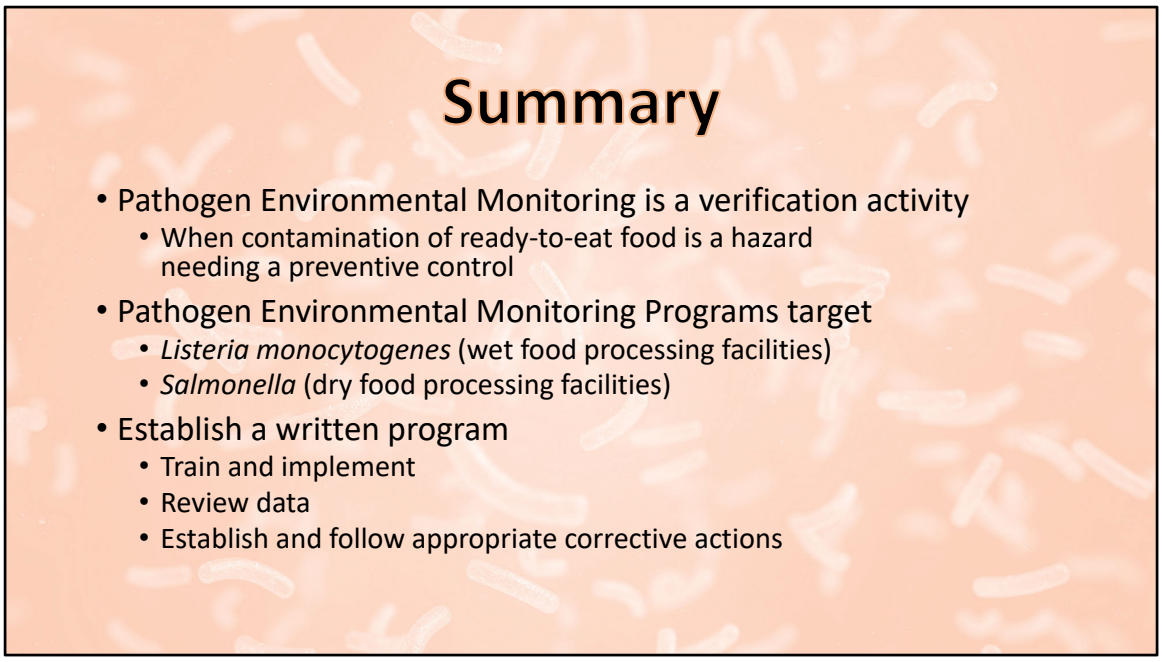
Example Corrective Actions – Pathogen Findings Pathogen Control Area

- Stop processing – put product on hold if appropriate
- Limit access
- Break down and inspect equipment
- Swab positive area and surroundings
- Clean and sanitize
- Inspect and swab
- Restart when test are negative
- Increase frequency of sampling to daily
  - After 3 consecutive negatives – return to normal

Positive pathogen results in Zones 2 through 4 might trigger a stop in processing in or around the area of the positive finding. You should assess whether putting product on hold pending product test results would be appropriate. A break down or inspection of equipment along with re-swabbing the positive area and additional surrounding areas might be done to determine if the organism is localized or has spread. The equipment or areas should then be cleaned and sanitized and inspected and swabbed. This would often be followed by increased and repeated sampling of the positive area until three consecutive negatives are determined. All corrective actions and the results should be well documented.

The initial findings and short-term follow-up results should be reviewed by the Pathogen Environmental Monitoring Team with a goal of identifying the root cause of the positive sample site and possibly also identifying if the finding was representative of a transient pathogen or one that is reoccurring and possibly established in the facility. The team should assess and implement any changes that might be needed to address the situation including modification to the Pathogen Environmental Monitoring Program if needed.

Recontamination of product with environmental pathogens has caused numerous foodborne outbreaks and led to recalls of millions of pounds of food. Investigations in many of these instances has revealed flaws in the design or execution of pathogen environmental monitoring programs. These include inadequate numbers of samples and ineffective corrective actions when positive pathogen results were found.



In summary, a Pathogen Environmental Monitoring Program is an important verification activity for sanitation preventive controls and part of a food safety plan when contamination of ready-to-eat food is a hazard needing a preventive control. This is often when a ready-to-eat food is exposed to the environment after a kill step and before final packaging. Pathogen Environmental Monitoring Programs target Listeria monocytogenes in wet food processing facilities and Salmonella in dry food processing facilities. Pathogen Environmental Monitoring programs should be detailed in writing and reviewed on a regular basis, employees should be trained in proper sampling methods, the data you collect should be promptly reviewed and corrective actions should be taken when counts of indicator organisms are above set limits or a pathogen is found.

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