

Validation of GMP Programs



Good Manufacturing Practices (GMPs) or prerequisite programs are the foundation of an effective food safety program. To ensure that your GMPs are controlling hazards related to the personnel and environment, use an environmental monitoring program to provide scientific evidence.

Environmental Monitoring Program

An environmental monitoring program provides scientific evidence that the resources and effort put into providing clean uniforms, following traffic patterns, effective hand washing, cleaning and sanitation procedures, sanitary equipment design, etc. are effective in providing an environment for the manufacture of safe food.

Where to start?

- **Sampling method:** Use the correct environmental screening or test method for your type of process. This could include the use of swabs, sponges, slides, strips or other diagnostic test kit tools.
- Sampling needs to be performed by trained personnel. You can use the services of external laboratories. They will be able to recommend the method of analysis best suited to your operation. If you need technical help, contact foodsafety@gov.mb.ca
- **Location of sampling:** Find environments where microorganisms tend to flourish, including:
 - food contact surfaces (e.g., conveyors, tables, knives, packaging)
 - processing equipment (e.g., slicers, mixers)
 - non-food contact areas (e.g., drains, floors, equipment support framework)
 - air in the production area
 - Hard-to-reach places, such as the inside of equipment, gaskets, hinges, etc., should be sampled periodically to prevent undetected contamination.
- **Frequency:** This will depend on the type of food processed. Initially, samples may be taken once a week for at least one month after cleaning, to assess baseline microbial load. Then, you can change the sampling frequency, depending on the initial results. An environmental monitoring program is a long term commitment.
- **Number of samples:** It is important to take an adequate number of samples. If the sample size is too small, the chance of detecting a problem is reduced.
- **Test method selection:**
 - Coliform and Aerobic Plate Count (APC) are recommended methods because they are nonselective, and can enumerate large numbers of bacteria.
 - Yeast and mold plates (potato dextrose agar with chloramphenicol or dichloran rose bengal chloramphenicol) are

recommended for air sampling in surrounding processing areas. Generally, plates are exposed to the air for 15 to 45 minutes.

- You may consider testing for pathogens such as *Listeria monocytogenes*, *Salmonella*, *Escherichia coli* O157:H7 or coagulase positive *Staphylococcus*. To prevent a food recall, you may hold food products until you have the test results.
- **Sampling time:** Normally, samples are taken after the cleaning process, which likely occurs after production is finished. It is recommended that sampling be done when equipment is completely disassembled.
- **Sample analysis:** The samples collected can be analyzed by an external laboratory or in your facility. You can buy a variety of tests that are already prepared with culture media. For statistical relevance in your analysis, replication of the testing (between five and 25 samples) is suggested.

Interpreting microbial results

There are different ways to present microbial results. Examples include:

- absolute number (e.g., 250 organisms)
- CFU/gram (colony-forming units per gram)
- Scientific notation (e.g., 2.5×10^2 (the base is 10 and the exponent is 2, it is 10 to the power of 2), which converts to $2.5 \times 10 \times 10$ equals 250 organisms)

Baseline specifications

Collecting data for one to three months, depending on sampling frequency is usually enough to determine a baseline for most microorganisms.

For more information on food safety please contact the Food Safety and Inspection Branch at foodsafety@gov.mb.ca.

Cleaning and sanitizing should reduce microbial loads to levels of less than 10 CFU per sponge for coliforms, aerobic plate count, yeast and mold, and coagulase positive *Staphylococcus* on product contact surface before packaging.

CFU per sponge values for other areas, including non-product contact areas will vary, depending on the plant and type of product manufactured. Aerobic plate counts of above 10,000 organisms should cause concern. An area with 100,000 organisms should be considered a microbial contaminated site.

Data analysis and validation

Once the samples are analyzed, the baseline data can be displayed on a spreadsheet or graph to demonstrate plant performance. A graph will provide easy visualization of the data.

Deviations above the baseline by a predetermined value may indicate a failure in your plant's system. You need to establish corrective actions that include: investigating the cause of the failure as well as retesting positive test areas. Finding the root cause of the problem may lead to a variety of solutions, the goal is to prevent reoccurrence.

Documentation must show how the problem was addressed and that the corrective actions were effective.