

Food Manufacturing Environmental Air Quality Monitoring Programs:  
A Literature Review and Best Practice Recommendations

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## **ABSTRACT**

Poor air quality in food production environments can pose food safety and quality risks if not properly monitored and managed. With little regulatory guidance, it is up to manufacturers and processors to define if air will be tested, organisms to test for, how sampling will be performed and how often. There is a variety of testing equipment and methods available, and it is difficult to find an unbiased guide to help set up a new program or improve current air quality monitoring practices. This literature review investigated the availability of easy to understand guidance materials and sought to create unbiased guidance to food industry professionals seeking to understand the key components of microbiological air quality monitoring programs and some of the options currently available. Relevant research is presented to help readers understand why it is important to monitor microbiological air quality, testing equipment available, organisms to monitor for, sampling location considerations, budget and staffing considerations and more. Furthermore, the project referenced throughout this paper provides additional insight into how these best practices may be applied as food safety and quality professionals seek to create or improve the microbiological air quality portion of an environmental monitoring plan.

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# I. Introduction

## Background and Setting

Food manufacturers carefully assess and manage risks of contamination in production facilities. Sources of possible product contamination should be identified and controlled. Food safety plans assess processes throughout the facility for three basic types of risk: biological, chemical, and physical. Food safety and quality managers work to mitigate product contamination risk. Supporting programs are designed and implemented in alignment with the Food Safety Modernization Act (FSMA), building off the principles of Hazard Analysis and Risk-Based Preventive Controls. Environmental monitoring plans, a type of supporting program, are built to closely collect, analyze, track and trend data and understand microbial risks in processing and production areas.

In food processing facilities, the facility itself, the tools, the workers, and processing areas can act as sources of biological contamination. Microbial contamination from the production or processing environment has been a major factor in many food safety incidents around the world. *Listeria monocytogenes* travelled from the environment into processed meat in South Africa (Thomas et al., 2020). *Cronobacter* spp. have been the cause of recalls of dried infant formula and have been found in the associated production and packaging environments (Lindsay, 2024). These examples are not anomalies. Microbially-caused recalls impact both humans and animals, as shown when 19 varieties of pet food were recalled when a toxigenic fungus was not only degrading product quality but producing aflatoxin, a mycotoxin, capable of causing illness and death in humans and animals (Yu and Pedroso, 2023). Reports indicate that over 40% of foodborne illness outbreaks are due to microorganisms transferred from the

equipment or environment (Cappitelli et al., 2014). Product recalls are often issued for the same reasons: microbial contamination from the equipment and/or environment, poor sanitation practices and poor employee hygiene (Zoellner et al., 2018).

While these recalls and outbreaks were food safety incidents, an effective environmental monitoring program allows you to take a more proactive approach, not just against pathogens, but against other microorganisms, like spoilage organisms, as well. A frequent quality concern, and occasional food safety concern, across the food manufacturing industry is microbiological spoilage, which can be caused by bacteria, yeasts, or molds. Yeasts and molds are primarily viewed as spoilage organisms, but some can produce mycotoxins capable of presenting a food safety risk. Acid-tolerant yeasts and molds are regularly the cause of dairy product spoilage (Beletsiotis et al., 2011). Dairy products provide a favorable growth media for fungi and contribute to both visible and non-visible product defects, including abnormal flavors and odors (Garnier et al., 2017). Growth of these spoilage organisms can present manufacturers with significant financial losses (Khan & Karuppayil, 2012) and because of that that there is a major focus in the industry to prevent fungal spoilage, or limit growth of spoilage organisms, to mitigate the associated quality and food safety risks (Garnier et al., 2017).

With the main yeast and mold contamination source being the environment (Khan & Karuppayil, 2012), manufacturing facilities monitor the environment for these organisms and work to keep it clean. Air in production or processing areas can act as a vector for these organisms, carrying yeast and mold into or onto product. This bioaerosol can be sampled and tested to support overall facility strategies to eliminate or reduce food contamination risk (Masotti et al., 2019). A proactive environmental monitoring plan can help the manufacturer

take action, improve sanitation practices and reduce the likelihood of product contamination (Mota, 2021).

Most of this literature review and the associated project focus on the monitoring of air in production and processing areas. Air is not the primary source of the microbes but helps the organisms move from the source and into or onto the product. Air quality management strategies often include chilling and filtering air as it is brought into the facility, ozonation, chemical fogging, cleaning and sanitizing air handling equipment, and regularly monitoring microbial air quality (Massotti et al., 2019). This project and literature review focus primarily on the options available when setting up or working to improve an air quality monitoring program.

### **Statement of the Problem**

Food processing facilities work to monitor microbial air quality as one means of assessing facility and equipment sanitation and hygiene programs. When managed effectively, air quality monitoring programs can help teams understand and mitigate the risk of pathogenic and spoilage organisms being present in the production environment. Regulatory and Global Food Safety Initiative (GFSI) sources do not provide very specific guidance for how to best monitor air quality. There is a variety of monitoring methods and testing equipment available for purchase and many options to assess when setting up a program. Monitoring method, frequency, and even the units that results are reported in are all left for the manufacturer to determine.

There are near endless options for creating a program custom to product, facility or type of processing but a team's available time, budget and laboratory resources may limit the options available for incorporation. While the literature highlights the importance of air quality

monitoring and various program elements, a written and unbiased review of Food Manufacturing Environmental Air Quality Monitoring Best Practices was not easily accessible when a Midwest dairy company launched an effort to review and improve the air quality monitoring portion of its environmental monitoring program. This company had multiple facilities with different monitoring programs, so food safety and quality leadership set a goal to review programs and standardize policies and processes across facilities and in alignment with regulatory, GFSI guidance and industry best practice as noted through the available literature and experience of the team.

### **Significance of the Problem**

21 CFR 117.3 defines ready-to-eat (RTE) foods as “any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards”. Environmental contamination of RTE foods can occur after any microorganism control step, such as a heat treatment or pasteurization, and can negatively impact product shelf life, flavor, appearance and more. It is important to monitor open product areas of food facilities so that corrective and preventive actions can be taken prior to consumer food safety and/or quality concerns.

While this project doesn’t aim to introduce any new technologies or ideas it does intend to provide an easy-to-use resource, supported by current literature, to food safety and quality professionals to reference during review or initial setup of an environmental air quality monitoring program. The resulting information and program setup checklist should prove useful for

food laboratory managers and other managers in food manufacturing responsible for food safety and quality.

### **Purpose of the Project**

The purpose of this project is to review current literature and summarize best practices for air quality monitoring programs in and near open product environments for ready-to-eat foods. Specifically, this project aims to review and summarize regulatory and GFSI requirements of air quality monitoring for food manufacturers. It also aims to provide guidance for which organisms to include in a monitoring program and employees to consider for primary ownership of the various program components. It will be key to use current literature to provide guidance to help food safety and quality teams understand options and pros and cons of various test equipment and methods and proper timing of sample collection.

### **Project Objectives**

The objectives of this project are to provide a summary of relative literature, use the literature to review key program elements and provide information and recommendation if the literature aligns appropriately. For program elements where the literature may not align on a single best method for food manufacturers, provide an overview of major options and help the reader use the published information to determine what option may work best for them. There will be special focus on some literature and examples specific to the dairy industry, this is where the author is focusing improvement efforts and working to implement applicable best practices. This project also seeks to provide readers with a simple one-page checklist to provide guidance while creating a new program or modifying an existing program.

## **II. Review of Literature**

The following literature review is intended to examine the various components that a company should be looking to define as they outline a program to monitor microbiological air quality in a food manufacturing facility.

### **Why monitor air quality**

#### **Regulatory Requirements and Industry Standards**

The Food and Drug Administration (FDA) mandates environmental monitoring as part of a food facility's Good Manufacturing Practices (GMPs) under the Food Safety Modernization Act (FSMA). This early warning system helps prevent contamination in food processing environments. Third-party audits, aligned with the Global Food Safety Initiative (GFSI), often require environmental monitoring programs for producers of ready-to-eat food exposed to the environment post-kill step. These regulations and audits emphasize the need for environmental monitoring to ensure food safety but have no specific air quality monitoring program requirements. Facilities should assess risk and build a program that mitigates the risks identified.

#### **Product Safety**

Regular air monitoring helps identify potential sources of contamination and ensures that sanitation efforts are effective. Microorganisms play a critical role in food contamination. Airborne bacteria, molds, and yeasts can travel through the air, settling on surfaces, equipment, and food products. Poor air quality allows these microorganisms to infiltrate the production environment, leading to potential contamination. (Dosland, 2018). Air with suspended particles of solids or liquids are known as bioaerosols. Microorganisms known to be found in bioaerosols

in food processing areas include these potential sources of biological contamination; yeast, mold and bacteria.

RTE food, by definition, does not require a control step prior to being consumed. According to Dosland (2018), an effective sanitation program in food plants aims to remove food debris, organic material, and soil that may support microbial growth. However, visual inspection and post-sanitation microbiological swab testing alone are insufficient. Airborne microorganisms pose a significant risk, as they can settle on food products and contact surfaces, live and grow in the food to pose risks to consumers.

Air has been noted as one of the primary vectors for contamination of RTE food (den Aantrekker et al., 2003) making it essential to understand and regularly monitor air for potential suspended biological contaminants. Air quality is key for mitigation of food safety and quality related risks (Altunatmaz et al., 2012) and should be monitored in both production and storage areas. (Asefa et al., 2009) Other major contributors to product contamination are unsanitary surfaces, both product contact and non-product contact surfaces, and employees that interact with product (Otto et al., 2011). These various sources can contribute debris and/or microorganisms and have even been shown to interact in ways that can contaminate product (Asefa et al., 2009). The interactions with air work in both directions; from air to the surface and from the surface to the air (Aarnisalo, 2007).

These microorganisms pose risks to consumers if present in finished products. Food products directly contaminated by bioaerosols or contaminated food contact surfaces plus cross-contamination can result in consumers ingesting contaminated food. Bioaerosols originating from food processing environments can even harbor foodborne pathogens.

*Salmonella*, *Escherichia coli*, and *Listeria monocytogenes* pose a significant risk. And consumers can suffer from food poisoning, gastroenteritis, or more severe illnesses depending on the organism(s) they were exposed to (Theisinger, 2020).

### **Product Quality**

As previously mentioned, a bioaerosol is air with suspended particles of solids or liquids and may contain yeast, mold and bacteria. Bioaerosol contamination of ready-to-eat dairy products can significantly impact their shelf life and customer satisfaction. Martin et al. (2021) highlights that microbial spoilage is a major contributor to dairy food waste. Microorganisms such as gram-negative bacteria (example: *Pseudomonas*), gram-positive bacteria (example: *Paenibacillus*), and various fungal organisms can contaminate dairy products during production and processing. These organisms can live and grow at refrigerated storage temperatures and produce degradative enzymes, leading to off-odors, flavors, and texture defects. As a result, consumers encounter spoiled dairy goods, which ultimately contribute to dissatisfaction and wasted products.

White (1993) emphasizes that gram-negative psychrotrophic bacteria, especially *Pseudomonas*, play a pivotal role in dairy product spoilage. These organisms cause quality defects, rendering products inedible over their refrigerated shelf life. Regardless of the method used for predicting shelf life, detecting, and controlling bioaerosol contaminants is crucial. Failure to do so can lead to premature spoilage and dissatisfied customers.

### **Bioaerosols and Employee Health and Well-Being**

While the primary focus of microbiological air quality monitoring programs is usually food safety and quality related, the literature provides an extensive list of human health risks

associated with human safety and exposure to bioaerosols. Inhalation of bioaerosols containing bacteria, fungi, and viruses can lead to respiratory infections. These microorganisms can penetrate deep into the respiratory tract, causing conditions such as pneumonia, bronchitis, and sinusitis. Individuals exposed to high levels of this bioaerosol can develop chronic respiratory symptoms and compromised lung function. (Mack et al., 2019).

Immunocompromised individuals are particularly vulnerable. Bioaerosols containing opportunistic pathogens (including *Pseudomonas aeruginosa* and *Staphylococcus aureus*) can cause life-threatening infections. A study by Peck et al. (2018) found that hospital-acquired infections due to airborne pathogens significantly impacted immunocompromised patients. Proper air quality management is crucial in healthcare settings to protect these vulnerable populations.

Bioaerosols can trigger allergic responses. Exposure to pollen, mold spores, or dust mite feces can lead to allergic rhinitis, asthma exacerbation, and skin rashes. Research by Rajput et al., (2017) indicates that long-term exposure to indoor bioaerosols can sensitize individuals, leading to chronic allergic conditions. Proper ventilation and air filtration are essential in minimizing allergen exposure. Emerging evidence suggests that exposure to certain bioaerosols may contribute to cardiovascular diseases. Some bioaerosols may trigger inflammatory signaling cascades and increase further systemic risks like heart attacks, strokes, and hypertension (Crawford et al., 2021). Research by Murphy et al. (2021) agrees and emphasizes that exposure to bioaerosols can trigger allergic reactions, exacerbate asthma symptoms, and reduce overall quality of life. Proper air filtration and minimizing allergen sources are essential.

Chronic exposure to bioaerosols may disrupt immune system balance. Research by He et al. (2021) indicates that certain bioaerosols can alter immune cell function and increase

susceptibility to infections. Individuals with prolonged exposure (e.g., occupational settings) may experience immune dysregulation. While less explored, bioaerosols may influence neurological health. Airborne toxins, like mycotoxins from mold, can potentially impact cognitive function and neurodevelopment. Research by Calderón-Garcidueñas et al. (2019) suggests that exposure to these bioaerosols, may contribute to neuroinflammation and neurodegenerative diseases. Indoor air quality, influenced by bioaerosols, has been shown to impact mental health. Exposure to mold spores, for instance, has been linked to depressive symptoms. A study by Mbareche et al. (2019) found associations between indoor fungal bioaerosols and psychological distress.

In summary, bioaerosols in food manufacturing settings have diverse health-related implications for across various age groups and contexts. Rigorous air quality monitoring, effective ventilation systems, and preventive measures are critical to mitigate these risks and are essential for consumer and employee health.

### **What to monitor**

While the previous section highlighted some of the many organisms that have been found in bioaerosols, it is unrealistic to expect a food manufacturing company to build a program that monitors for every possible airborne contaminant. Preventive measures in facility design, Current Good Manufacturing Practice, and effective cleaning and sanitation programs must be implemented and should be a company's primary method for minimizing bioaerosol risks. When it comes to monitoring the air for biological risks, one possible approach is to use a simple risk matrix and focus monitoring efforts on the organisms that are most likely to be found and, if present, would also have a significant impact on the finished product.

The food supply chain is intricate due to variations in food composition and processing. This complexity can lead to the emergence and re-emergence of foodborne pathogens. However, Schirone et al., (2019) notes the prevalence of airborne pathogens within food manufacturing plants remains relatively low. The main pathogens studied include *Campylobacter jejuni*, *Cronobacter sakazakii*, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella spp.*, and *Staphylococcus aureus*. This article also notes that other research also covers *Helicobacter pylori*, *Klebsiella pneumoniae*, *Vibrio parahaemolyticus*, mycobacteria, and pathogenic molds. To summarize, while airborne pathogens exist, their impact on food manufacturing plants is mitigated through rigorous control measures and adherence to hygiene protocols. The risk posed by airborne pathogens remains relatively low.

Napoli et al. (2012) conducted a study in operating theatres to assess microbial contamination levels using both active and passive sampling methods. While their focus was on healthcare environments, the findings are relevant to food manufacturing. Airborne microorganisms, including yeast and mold, can serve as reservoirs for contamination. The study revealed that both active and passive methods correlated with air quality, emphasizing the importance of monitoring bioaerosols in controlled settings. Another study notes that yeast and mold, being ubiquitous in the air, contribute significantly to microbial loads and pose a serious risk to human health (Kahn, 2012). Furthermore, air handling equipment, and how they are designed and operated, can provide a niche for microorganisms and significantly increase the airborne microbial load.

*Yeast Biofilm in Food Realms: occurrence and control* (Zara et. al., 2020) discusses the occurrence of yeast biofilms in food-related environments. Biofilm formation mechanisms and

natural compounds for inhibition are explored. Yeast biofilms can develop on various surfaces, including those in food manufacturing facilities. These biofilms act as reservoirs for yeast and mold, potentially affecting product quality and safety. The *International Food Hygiene Microbial Update* highlights the impact of yeasts and molds on the food supply chain. Fungi, including molds, are responsible for significant losses. Their ability to attack various foods underscores the need for effective control measures. In food manufacturing, airborne yeast and mold can settle on equipment, packaging, and finished products, leading to spoilage and dissatisfaction among consumers.

In summary, yeast and mold in the air are pervasive sources of microbial contamination in food manufacturing. Rigorous monitoring, preventive measures, and hygiene protocols are essential to mitigate their impact, ensure product safety and quality, and understand when something in the production environment has changed and negatively impacted air quality.

### **Who performs air quality monitoring**

Environmental monitoring, including air quality monitoring, in food manufacturing plants is a critical component for ensuring food safety, reducing the risk of foodborne illnesses, and maintaining the integrity of the food supply. The question of who should own the responsibility for environmental monitoring tasks is multifaceted and has implications for both food safety and operational efficiency.

#### **Budget Constraints and Staffing:**

Unfortunately, budget restrictions often leave many food manufacturing plants without a dedicated food microbiologist on staff. Consequently, the responsibility for environmental monitoring falls on other personnel. Quality assurance managers, laboratory technicians, or

other workers are commonly tasked with environmental monitoring due to their existing roles within the organization. However, these arrangements may not always be ideal in terms of workload and level of expertise.

### **Challenges and Considerations:**

A dedicated food microbiologist possesses specialized knowledge and skills related to environmental monitoring, including sampling techniques, pathogen detection, and risk assessment. It is ideal to have a system of checks and balances where one team owns the sanitation processes or maintenance processes, and a different team owns the environmental monitoring tasks to avoid a possible conflict of interest. Integrating environmental monitoring seamlessly into daily operations requires coordination across various departments. A designated owner can streamline processes and ensure timely sampling. Rapid corrective actions are crucial when results are over the defined limit or trending in the wrong direction. Ownership by a knowledgeable individual facilitates swift responses. Assigning ownership to a specific role ensures accountability and minimizes gaps in monitoring. It also aligns with the preventive controls required by FSMA.

In conclusion, while the responsibility for environmental monitoring tasks, such as air quality monitoring, may vary based on organizational constraints, having a designated owner—whether a food microbiologist or another qualified individual—is crucial for maintaining food safety and preventing contamination in food manufacturing plants. It is essential that the owner is properly trained to use equipment and aseptically perform sample collection and testing.

## **Where to monitor**

Yeasts and molds can live and grow in various environments. Ideally a facility's sanitation program is eliminating risks, but air sampling programs should monitor in key locations to ensure that products are not put at risk. A simple tool that can help a team identify ideal monitoring locations is a map of the facility. Helpful map information includes air handling, air flow direction, and food manufacturing hygiene zone designations. Ideally, positive air pressures are flowing from high-hygiene, open product areas to areas with lesser hygiene requirement and no open product (Byrne et al., 2008).

Creation of a sampling map helps train personnel where to sample and allows the team to strategically place sampling locations in areas where risk is perceived to be higher. HVAC systems are a possible point of entry for airborne fungi from the outside environment to get into a facility (Kemp et al., 2003). Filters in HVAC systems have even been shown to retain yeasts and molds when not changed frequently enough (Perez, 2004). Air ventilation systems can act as a possible source of indoor air contamination (Möritz et al., 2001). There is a plethora of literature to support monitoring the microbiological quality of air where air enters a high hygiene area in a food manufacturing facility. The information gained from these locations empowers the team to adjust air filter changes to effectively manage airborne risks. It also helps the team understand when something else may be going on. For example, dust or moisture can be present in HVAC systems and increase microbiological risks associated with that air (Liu et al., 2015).

Other risks easily identified on the map include areas over open product, areas with excess moisture, and even where employees acquire personal protective equipment (PPE) like

gloves smocks and sleeves. These items are often intended for food contact and contamination of PPE could lead to product contamination. Monitoring in these areas helps prevent cross contamination. As risk changes in the production environment, air quality monitoring should change to match. If construction or another activity increases risk, air quality monitoring should also be increased.

### **Timing of monitoring**

It is important to define when microbiological air quality will be monitored. Both the frequency of testing and the air sampling locations should be defined. Since the level of risk associated with the air will vary by product, facility and more it is difficult to recommend a single testing frequency for all food manufacturing facilities. For higher risk products or facilities with a known history of air quality risks, a higher frequency of air testing is advised, and the time and expense of increased testing will be higher up front but can be very useful in preventing much more expensive issues with the environment in the future (Bonetta et al., 2023). Personal experience in the dairy industry leads to a minimum testing frequency of monthly and more frequently in especially sensitive areas or production spaces with highly sensitive foods.

More frequent testing leads to a deeper understanding of seasonal changes, fluctuations with environmental conditions, and air filtration performance. The timing of the sampling events should not be static. To gain an understanding of changes in air quality across different production activities, shifts and sanitation events, air should be sampled across shifts, product SKUs, and different production activities. The employee performing the sampling should note

activities at the time of sampling to help with investigations tied to results that significantly differ from baseline levels.

### **How to monitor**

A variety of methods exist for examining the microbiological agents suspended in the air. Methods can be qualitative or quantitative in nature. Sampling methods can also be passive, letting the particles come to the media, or active, encouraging the movement of air and airborne particles to the test or collection device or media.

A common passive method is the sedimentation technique (American Public Health Association. APHA, 2001). This method uses settling plates, petri dishes containing microbiological growth media, exposed to the chosen environment for a specific amount of time, commonly 10 to 30 minutes. Organisms settle naturally by gravity onto the media and can grow until counted later. This method is not considered quantitative due to its gravity-driven bias towards larger particle sizes. (Asefa et al., 2009; Andon 2006.) This method is the most affordable and is still useful in industry as a baseline level of organisms in the air can be determined and then an action limit can be set at a level where risk to the hygiene of the food manufacturing processes may be compromised. This method does not control the flow of air to the media and is more easily affected by surrounding air movements. Settle plates and impactors are frequently used in by food manufacturers in conjunction with culture-based enumeration methods (Oppliger, 2014).

Active methods mechanically direct a set volume of airflow towards growth media over a set amount of time. (Andon, 2006; Pasquarella et al., 2000). Tests are repeatable and results are quantitative (Pasquarella et al., 2000). For active methods testing a specific volume, results

should be reported in colony forming units per volume sampled. Active methods are more efficient than passive methods but are subsequently representative of a shorter period in the test environment (Flannigan, 1997). Active sampling equipment is more expensive which contributes to the fact that settling plates are used by smaller food manufacturers and the active methods are more frequently used by researchers and larger food manufacturers.

There are a variety of active air sampling equipment types available for purchase including impaction, impingement, cyclonic separation, filtration, and thermal or electrostatic precipitation. These various methods will yield slightly differing results in the same environment at the same time (Verreault et al., 2011). Impaction samplers draw air in through evenly spaced slits or hole and onto the growth media of choice. Impingement samplers are especially useful in environments with a heavy bio load since this method allows for dilution of a liquid sample. Cyclonic separation pulls air into the equipment and uses centrifugal force to push airborne particle outward and onto a media strip. This is an effective method especially for larger, more easily moved particles and often yields a higher count compared to other methods. Filtration and precipitation methods rely on a mechanism, filter, or electrostatic field, to capture particles on the growth media and is especially useful for quantifying mold and bacterial spores.

Table 1, from F. Masotti et al. (2019), summarizes pros and cons of various methods and shares the frequency of each method used by food manufacturers.

**Table 1: Masotti et al., 2019 table comparing air sampler types for use in the food industry.**

Sampler	Air sampling	Pros	Cons	Use in real food industry
Settle plate	Passive	Easy and cheap device to monitor generic air bioload. No cell stress by reduced viability.	Qualitative method, based on collection by "fall out". Biased to larger particles. Sensitive to air movements.	++
Impactor	Active	Multiple choice of devices (slit and sieves). Practical in industrial use. Information on size distribution. Used to recover viruses.	Cost of device.	++
Cyclone separator	Active	Available as portable hand-held instrument. Practical in industrial use. Less cell stressing than impaction methods.	Selective for large air particles. Tendency to higher counts than other air samplers.	++
Filter	Active	Not expensive. Simple to operate. Suitable for enumeration of molds and bacterial spores. Used also to recover viruses.	Possible stress by cell desiccation.	+
Impinger	Active	Useful for heavily contaminated air environments.	Impractical in industrial use. Sterilization of the device after each use.	+
Electrostatic precipitator	Active	Useful for collection of viruses or sensitive microbial strains. Compatible with analysis by polymerase chain reaction.	Possible loss of survivability. No literature in food sector.	-

++ , frequent use; + , occasional use; - , not used.

With a variety of options available, there is no single best test method for all food manufacturers. Settling plates are a good base option for those with a limited budget. Companies with a larger budget should strongly consider upgrading to a more sensitive active method that targets the desired particle size and meets environmental monitoring risks and needs.

### **Importance of Collaboration and Continuous Improvement**

Collaboration between sanitation, maintenance, operations, engineering, and food safety & quality teams is essential for overall successful management and improvement of facility air quality programs. Regular cleaning and sanitation are key for controlling microbial growth in the environment. Proper building design and use minimize growth niches and contamination opportunities. Effective monitoring helps communicate the overall effectiveness of sanitation, air filtration and overall air quality management. An effective microbiological environmental monitoring program allows food manufacturers to use data to assess the safety of their processing environments. This knowledge enables the implementation of corrective and preventive actions before finished products are impacted.

## **Tips to Maximize Air Quality Monitoring Program Benefits**

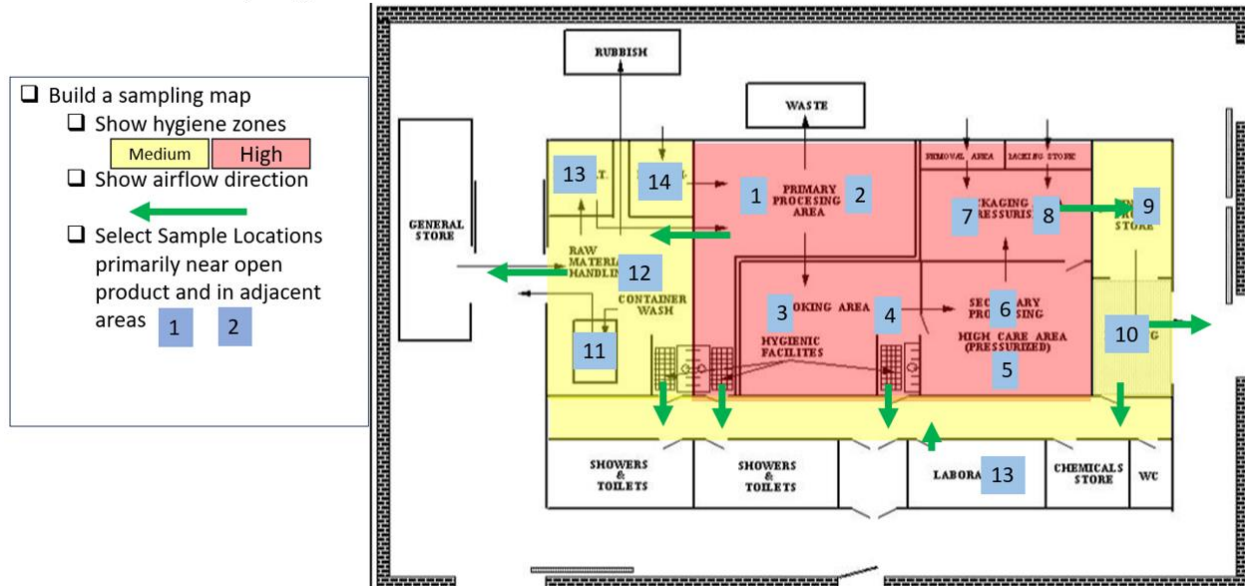
Begin by defining the goal of the monitoring program in writing. A typical food manufacturing goal likely addresses the desire to produce safe and quality food, to identify actionable air quality trends, and/or provide feedback to allow for the continuous improvement of maintenance, sanitation, manufacturing, and quality team practices. Defining the goal, or the Why, is important as it will help shape other aspects of an air monitoring program.

Use your pre-defined program goal to help identify a test method and media appropriate for achieving that goal. If the goal is to positively support product shelf life by limiting the introduction of yeast and molds in high hygiene environment, then a method should be selected that allows for the quantitative measurement of larger particles present in the air.

A facility specific cross-functional team should be assembled to create a detailed sampling map. This map should show key features that represent varying levels of product risk and features that impact air movement and quality including, but not limited to, hygiene zones, air sources, and air flow directions. Sampling locations should be identified near open product, between open product and air handling units and other possible sources of contamination. It is also good practice to regularly include random, unscheduled sampling locations so that the monitoring program is always exploring new areas. This keeps the program from ever remaining static and empowers the team to continuously reshape and improve sampling locations based off new incoming data. See figure 1 for an example. These maps should be incorporated into a written sampling guide along with a written description and photo of sampling location. This makes it easy to train new hires, ensures consistency among samplers, and serves as a sensible

starting point for follow up investigations. Analytical laboratory software is expensive but can support the analysis and trending of data.

**Figure 1: Example of an air quality monitoring map image including hygiene zone, airflow direction and sampling location numbers.**



It is not common, but makes sense, to apply practices often applied to pathogen swabbing programs to environmental air monitoring programs. Embracing a seek-and-destroy mindset makes for a more aggressive and proactive program. Review sampling sites for changes and consider new sampling sites at least annually. On a monthly basis, include one or more random, unscheduled locations outside the predefined sampling location list. Test air quality across shifts and during different production activities. Increase sampling during times of potential higher risk, such as construction or demolition events.

Select a sampling method and be sure to include control samples during every sampling session. Build custom critical limits based off three to six months of baseline data. Consider implementing different limits for different hygiene zones. It may make sense for more sensitive areas to have tighter critical limits. Have a written plan of action for when results exceed the

limit. Maintenance and sanitation teams can have a series of inspections and cleaning activities predefined making responses quick and standardized.

### **III. Project Outcome, Discussion, and Recommendations**

#### **Summary**

There is no one size fits all approach to air quality monitoring. There is minimal regulatory and GFSI guidance. Risk assessments are required for food manufacturing facilities and the processes happening within them. The specifics of monitoring programs are left open for food manufacturers to customize to the level of risk identified with their products and processes. These risks are easily affected by many variables including, but not limited to, the facility age and condition, the sanitation and hygiene controls, environmental surroundings, employee practices, maintenance program effectiveness and more.

Project work was organized in table format to make misalignments more apparent and allow for easy comparisons between facilities, regulatory and GFSI expectations and knowledge gained from data reviews throughout this project. Table 2 was current state of eight dairy manufacturing facilities, prior to project work beginning.

**Table 2: Comprised of Table 2a and Table 2b, this table compares information from across the company. Each column represents a single facility and the rows populated with information specific to one component of the air quality monitoring program.**

**Table 2a: Information collected from the laboratory and facilities 1, 2, 3, and 4.**

	Current Practice				
Facility	CORP LAB	Facility 1	Facility 2	Facility 3	Facility 4
Air Testing Equipment	RCS High Flow Touch Air Sampler with airstrips	RCS High Flow Touch Air Sampler with airstrips	RCS High Flow Touch Air Sampler with airstrips	RCS High Flow Touch Air Sampler with airstrips	RCS High Flow Touch Air Sampler with airstrips
Air Quality Tests Performed	SPC & Y/M	SPC and Y/M	SPC and Y/M	SPC & Y/M	SPC & Y/M
Air Volume Tested	100L, 1 minute	100L, 1 minute	100L, 1 minute	160L, 1 min 30 sec	160L, 1 min 30 sec
Air Quality Results units	SPC: cfu/ft <sup>3</sup> Y/M: cfu/ft <sup>3</sup>	cfu	cfu	SPC: cfu/ft <sup>3</sup> Y/M: cfu/ft <sup>3</sup>	SPC: cfu/ft <sup>3</sup> Y/M: cfu/ft <sup>3</sup>
Hygiene Zone Specific Pass/Fail Thresholds?	N/A	YES	YES	YES	YES
Action Limits	<10 Y/M, <100 SPC	High Hygiene areas: <10 Y/M, <100 SPC All others: <50 Y/M, <200 SPC	High Hygiene areas: <10 Y/M, <100 SPC All others: <50 Y/M, <200 SPC	High Hygiene areas: <10 Y/M, <100 SPC All others: <50 Y/M, <200 SPC	High Hygiene areas: <10 Y/M, <100 SPC All others: <50 Y/M, <200 SPC
Control Samples?	YES	YES	YES	Monthly	Monthly
Where are results recorded?	LIMS-Labware	EM Monitoring Binder (Pending request to add page to ELN)	EM Monitoring Binder (Pending request to add page to ELN)	LIMS-Labware	LIMS-Labware
Trending of Results (hyperlink to example)	None	None	None	Tableau EM Report can filter to results but results are not trended for you.	Tableau EM Report can filter to results but results are not trended for you.
Recommended corrective and preventive actions	Contact maintenance to review filter change PM completion	GEMBA walk, sanitation review, air handling PM review, team discussion of CI opportunities	GEMBA walk, sanitation review, air handling PM review, team discussion of CI opportunities	Observation of testing location and testing practices. Review air handling equipment PM's in the area. Review filter changes in the area.	Contact maintenance to review filter change PM completion

**Table 2b: Information collected from facilities 5, 6, 7, and 8.**

Facility	Current Practice			
	Facility 5	Facility 6	Facility 7	Facility 8
Air Testing Equipment	RCS High Flow Touch Air Sampler with airstrips	RCS Microbial Air Sampler	RCS High Flow Touch Air Sampler with airstrips	RCS Microbial Air Sampler
Air Quality Tests Performed	SPC & Y/M	Y/M. SPC was discontinued after finding Lactic Acid Bact in the air.	SPC & Y/M	SPC & Y/M
Air Volume Tested	160L, 1 min 30 sec	160L / 4 minutes	160L, 1 min 30 sec	4 minutes. ? Volume
Air Quality Results units	cfu/cu ft	cfu/cu ft	SPC: cfu/ft <sup>3</sup> Y/M: cfu/ft <sup>3</sup>	SPC: cfu/ft <sup>3</sup> Y/M: cfu/ft <sup>3</sup>
Hygiene Zone Specific Pass/Fail Thresholds?	YES	YES	YES	YES
Action Limits	>10 cfu in Packaging area, >50 cfu in other areas	>10 cfu in Packaging area, >50 cfu in other areas	High Hygiene areas: <10 Y/M, <100 SPC All others: <50 Y/M, <200 SPC	High Hygiene areas: <10 Y/M, <100 SPC All others: <50 Y/M, <200 SPC
Control Samples?	Controls are in rotation but not collected every week	NO	Every time samples are collected	NO
Where are results recorded?	LIMS-Labware	LIMS-Labware	LIMS-Labware	On Paper, Excel Spreadsheet
Trending of Results (hyperlink to example)	Tableau EM Report can filter to results but results are not trended for you.	Excel Spreadsheet	Tableau EM Report can filter to results but results are not trended for you.	None
Recommended corrective and preventive actions	GEMBA walk, sanitation review, team discussion of CI opportunities	Annual Calibration by Manufacturer, Head sent to corporate lab for autoclave	Contact maintenance to review filter change PM completion	Contact maintenance to review filter change PM completion

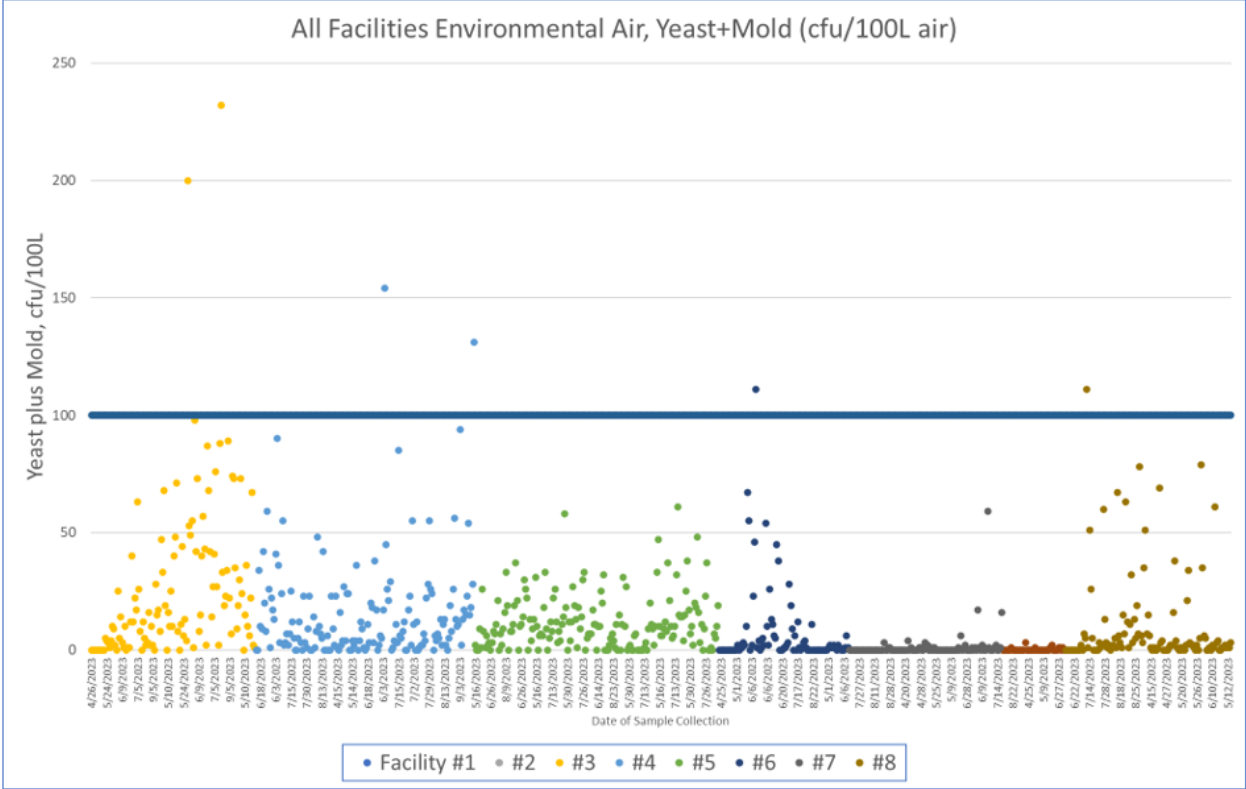
Work continued with a review of regulatory and GFSI requirements or expectations. As mentioned earlier in this article, regulations do not get prescriptive for environmental air monitoring. A risk assessment should be performed, and environmental monitoring programs should address the risks present in the processes/facility. This work was captured in Table 3.

**Table 3: Regulatory and GFSI expectations for air quality monitoring in food manufacturing.**

Regulatory (FDA)	<p>FDA: No specific recommendations. Risk-Based Prioritization</p> <p>"The FDA has developed a process for considering establishment-specific potential risk to the public health. Establishments may be identified for environmental sampling using this process, which employs criteria related to food-hazard pairs (e.g., frequency of outbreaks associated with a food, likelihood of contamination, bacterial growth potential, and food consumption pattern), and establishment-specific compliance history. The FDA focuses on surfaces (product contact and non-product contact) in their search for the presence of pathogenic organism but tends to not focus on spoilage organisms or air samples." (<a href="https://www.fda.gov/food/sampling-protect-food-supply/environmental-sampling">https://www.fda.gov/food/sampling-protect-food-supply/environmental-sampling</a>)</p> <p>How to Prevent Contamination in Processing Environments</p> <p>The Preventive Controls for Human Food rule is designed to protect consumers by keeping harmful bacteria from contaminating processing environments and, ultimately, the food we eat. The rule requires that an establishment's operators take steps to prevent contamination, including from pathogens in the environment, and verify that hazards are being controlled. Environmental monitoring and product testing are examples of steps they may take to verify control of microbial hazards.</p>
GFSI (SQFI)	<p>No specific air quality monitoring requirements. Required to have an environmental monitoring program but it is defined by the company.</p> <p>SQF Code Version 9.0 - Section 2.4.8 Environmental Monitoring</p> <p><b>2.4.8.1</b> A risk-based environmental monitoring program shall be in place for all food manufacturing processes. The responsibility and methods for the environmental monitoring program shall be documented and implemented.</p> <p><b>2.4.8.2</b> An environmental sampling and testing schedule shall be prepared. It shall at a minimum: i. Detail the applicable pathogens or indicator organisms to test for in that industry; ii. List the number of samples to be taken and the frequency of sampling; iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and iv. Describe the methods to handle elevated or undesirable results.</p> <p><b>2.4.8.3</b> Environmental testing results shall be monitored, tracked, trended and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.</p>

As work progressed, the leadership team standardized air testing volume to 100 Liters and set a temporary specification that results of <100 cfu yeast plus mold per 100 Liters of air is passing. Results ≥100 cfu yeast plus mold per 100 Liters of air fail and require action. This temporary limit was set to be reviewed after at least 3 months of 100-liter collection data was acquired. Air samples were collected throughout hygiene zones two, three and four from April 2023 into September 2023 (Chart 1). 824 100-Liter air samples were tested using either the RCS High Flow Touch or the RCS Microbial Air Sampler, as cyclonic separators work well for the spoilage organisms, yeast and molds, that would be expected to present a quality risk in dairy facilities.

**Chart 1: 100 Liter air samples collected in dairy manufacturing facilities from April 26, 2023, through September 5, 2023. Temporary action limit was set at 100 cfu yeast plus mold per 100 Liters of air.**



Recommendations were made for proposed program standardization and improvement updates, see Table 4. Recommendations were ultimately updated following a review of the data in Chart 1.

**Table 4: Comparison of personal experience, current policy, and proposed program.**

Facility	Personal Experience	Current	Proposed
		Corporate Policy and Programs	Corporate Policy and Programs
Air Testing Equipment	Recommend to discontinue use of outdated equipment (RCS Microbial Air Sampler is no longer supported by Manufacturer, cannot send out for annual calibration)	No specific equipment requirements	Standardize to RCS High Flow Touch Air Sampler with airstrips
Air Quality Tests Performed	SPC and Y+M. Recommended to discuss appropriate testing frequency	SPC & Y/M	Y/M, yes. Eliminate the requirement for SPC testing of air samples at regular recurring frequency. To be considered as a tool to use during construction events that may result in dust/airborne particles in areas of concern.
Air Volume Tested	Standardize all lants at 100L of air per sample.	undefined	cfu/100L alignment
Air Quality Results units	Report out as SPC cfu/100L, Y+M cfu/100L. This is currently confusing with facilities receiving SPC results, Yeast results, mold results, and Yeast+Mold results	cfu/cu ft	cfu/100L simple, easy to understand. No conversion required
Hygiene Zone Specific Pass/Fail Thresholds?	Yes	YES	YES
Action Limits	High Hygiene Areas <25 cfu/100L Medium Hygiene Areas <50cfu/100L Low Hygiene Areas <100cfu/100L	High Hygiene areas: <10 Y/M, <100 SPC All others: <50 Y/M, <200 SPC	High Hygiene Areas <25cfu/100L Medium Hygiene Areas <50cfu/100L Basic Hygiene Areas <100cfu/100L
Control Samples?	Yes, controls with every sequence of tetts is best psactice.	No requirement	Best practice, 2 controls per sampling session. 1 unopened, 1 opened handled, insered into equipment and removed. No air drawn across plate.
Where are results recorded?	Best Practice. Store results electronically to ensure that data is not lost. This also helps woth the trending of the data.	No requirement	Report in LIMS
Trending of Results (hyperlink to example)	Best Practice: Trend monthly results out of spec by facility. Additional graphs to allow the individual facilities to "dive in" and see repeat failure and month to month site specific trends.	No requirement	Monitor and regularly discuss facility and site specific trends
Recommended corrective and preventive actions	Compile list of recommendations from all facilities, share suggested CAPA in corp policy.	Not included	Include recommendations for facility action. Duct cleaning, filter changes, review and updatte MSS or PM tasks, review airflow from zone to zone(during production and other activities), GEMBA walk with team

## Program Outcomes

To review the program proposal one section at a time, all facilities should standardize to the newer RCS High Flow Touch Air Sampler manufactured by Millipore Sigma, most facilities already owned this cyclonic separation air sampler. This sampler is portable, easy to use and

capable of meeting the company's need to monitor for yeast and mold in the air. Standard Plate count (SPC), or Aerobic Plate Count, testing was eliminated from the normal air quality monitoring program as data, not presented here, eliminated this as a risk in all facilities. However, SPC testing is still a tool that can be utilized should environmental conditions change and present a need to monitor for new risks in the air; construction activity or major facility or product change.

The temporarily utilized testing volume of 100 Liters appears appropriate for all facilities as it was enough to yield counts in the results but did not yield results in the Too Numerous To Count (TNTC) range. This empowers the team to more easily track and trend data while testing near the maximum test sensitivity for these specific production environments.

For reporting units, the literature presented no standard air quality monitoring units used by all. To keep the results simple to calculate and understand, results should be recorded in colony forming units of yeast plus mold per 100 Liters of air. This unit has no calculation since 100 Liters of air were tested and it does not require the lab team to discern between yeasts and molds. This works well since the facilities simply aim to monitor the level of spoilage organisms in the air with yeasts and mold presenting similar risks to product quality.

Action limits were initially proposed at:

High Hygiene Areas <25cfu/100L

Medium Hygiene Areas <50cfu/100L

Basic Hygiene Areas <100cfu/100L

But later updated to:

High Hygiene Areas <15cfu/100L

Medium Hygiene Areas <30cfu/100L

Basic Hygiene Areas <50cfu/100L

Following the review of the data shown in chart 1. Basic Hygiene areas are typically hygiene zone 4 locations, Medium hygiene areas are typically zone 3 and High hygiene areas are near open product and typically hygiene zone 2. The samples collected were not collected with a hygiene zone label, this would have allowed for a more powerful analysis of the data but the proposal was still updated to the tighter limits to reflect the desire to have the program identify opportunities to drive continuous improvement. At a glance, the initial proposal was unlikely to regularly identify many opportunities for improvement.

Most facilities were not regularly submitting control samples with test samples. Control sampling is a basic good laboratory practice and should be completed to provide confidence in test materials and sampling and testing practices.

Finally, the proposal includes the recommendation to record all results electronically. Not only does this help streamline reporting and communications it also allows for the creation of reports and a dashboard to track and trend air quality data in a standard fashion across all facilities and in alignment with GFSI expectations.

### **Program Impact Analysis**

Locally, this literature review and project work has successfully helped present options and summarize best practices for air quality monitoring programs in and near open product environments for ready-to-eat foods. The submitted proposal for program updates meets all regulatory and GFSI requirements, standardizes testing and reporting across all facilities and the

literature helped provide guidance to Food Safety and Quality leadership seeking to identify the right equipment and testing frequency to monitor the organisms of concern in the environment.

### **Implications, Impacts, and Recommendations**

The objectives of this project were met. A summary of relative literature was to review key program elements and provide information and recommendations to food manufacturing professionals seeking to shape a microbial air quality monitoring program. Basic program elements and various methods were reviewed to help readers understand some of the major options available. This project also aimed to provide readers with a simple one-page checklist as readers work to create a new program or modify an existing program (Attachment A). This work was also presented to food safety and laboratory professionals at the 2023 Fall Conference for Wisconsin Laboratory Association, and the program checklist (Attachment A) was made available to all in attendance.

While this work does not present every monitoring option available and project work and updates may be somewhat more specific to dairy plants and processes, the basic outline for program creation can be applied across the food manufacturing industry. The structure of work empowering a team to make literature and data-based decisions to outline program recommendations in an example that can provide guidance to current and future food manufacturing leaders. The details of the proposed updates should also help guide readers as they work to outline and detail an ideal program.

## **Recommendations and Future Work**

Future work will include additional reviews of all data to ensure that action limits continue to empower the teams, yield countable results and drive continuous improvement. Action limits will be adjusted if results are failing to meet those expectations. Also, at the time this work is being submitted, two facilities are still awaiting the new RCS High Flow Touch air samplers. Once received, equipment will be set to collect 100 liters of air per sample and staff will be properly trained to use this new equipment.

Once the program updates are approved, all test locations across all facilities will have to be identified as Basic, Medium or High Hygiene and tagged with an appropriate action limit. This work will require support from all facilities and also technology resources to update software settings for pass/fail and appropriate communication of test results.

While there is a wealth of literature reviewing the types of organisms present in food manufacturing facilities, there appears to be less work seeking novel food safe methods for control of organisms of concern in sensitive food manufacturing environments. As the knowledge related to bioaerosols continues to grow, so should the more proactive options available for control of bioaerosols and improved protection of foods and beverages. A deeper understanding of bioaerosol control may help better manage food safety and quality concerns across the food industry.

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## V. Appendices/Attachments

### ATTACHMENT A - ENVIRONMENTAL AIR QUALITY MONITORING PROGRAM CHECKLIST

#### ENVIRONMENTAL AIR QUALITY MONITORING PROGRAM CHECKLIST.

- Define the goal/purpose of your Environmental Air Quality Monitoring Program IN WRITING
- Identify organisms to be monitored to achieve the goal/purpose.
- Identify process owners (Sampling, Transport, Testing, Reporting, Action)
- Train process owners. Written training materials. Training documented and on file.
- Identify valuable sampling locations.
  - Cross-functional team meets to propose/review sampling locations.
  - Build a sampling map.
    - Show hygiene zones.
    - Show airflow direction.
    - Select Sample Locations primarily near open product and in adjacent areas.
    - Identify regular recurring monitoring locations, include 1+ flex locations / month.
- Create a written Sampling Guide with Photos and descriptions of each sampling location.
  - Set Sampling/Testing Frequency (At least monthly, weekly if possible.)
    - Include control sample(s) during every sampling session.
  - Vary the timing of sampling across shifts, product SKU's, different production activities.
  - Increase testing during construction activities or other special events.
    - Consider adding additional test types, depending on the work being done.
- Good Laboratory Practices (Audits, SOP's, Data and Equipment Maintenance, Test items, Staff, Training, Environment and PPE)
- Choose a reporting unit that is easy for your lab team to report and the facility to visualize.
- Choose a sampling and test method that fits your budget. Calibrated & mechanical can help increase monitoring capabilities.
- Trend your resulting data in a way that helps the team understand the big picture.
- Use 3-6 months of data to capture what good looks like and help set the test thresholds going forward.
- Build a program that acts off single results AND data trends.
- Identify Test Limits custom to each Hygiene Zone.
- Have a written plan for What to do when action is required.
- Schedule recurring annual review of sampling sites.
- Schedule recurring annual review of the Environmental Air Quality Monitoring Program