Environmental Monitoring in the Milling and Baking Industry

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Over the course of the next 12 months, an estimated one in six Americans will succumb to a foodborne bacterial disease (1), with 130,000 people requiring hospitalization and as many as 3,000 dying (2). Although the exact numbers are open to debate, more than 15 million Americans have food allergies (5), and it is estimated that an additional 3,000 people will seek medical treatment for exposure to food allergens (8). Food manufacturers, including those in all segments of the milling industry, try to provide safe products to their customers. Toward this end, the quality manager or director at any food manufacturing facility would state that they employ stringent safety and quality processes for every aspect of their production facility. Despite these efforts and commitments to food safety, 2016 saw 764 food recalls in the United States (7). In a recent survey conducted by the Grocery Manufacturers Association, it was reported that of the companies subjected to a major food recall (class I), roughly one-quarter of the respondents estimated their direct financial costs at more than $30 million (4), whereas the majority of food recalls were estimated to cost between $10 million and $30 million. This same report showed that 81% of respondents believed the financial risk from a major recall could be significant—if not catastrophic—for the company, thus encouraging them to take a proactive approach to food safety.

The big question, then, is what can be done to prevent the production of contaminated or unsafe foods? When picturing the entire process involved in a milling facility, the potential sources of contamination are many. Some are out of the production facility's control. Therefore, the focus should be on what can be controlled—the product (including raw ingredients) once it enters the facility. The goal is to provide a manufacturing environment that is as free of any type of contaminant as possible.

Good hygiene throughout the mill is vital, and cleaning schedules should be set up, if they are not already in place, to cover all areas of the facility. The key is to remember that milling is food manufacturing and to take the same approach as other food manufacturers. Two of the biggest risks are the introduction of microbes and allergens. Therefore, a key component of any sanitation or HACCP (hazard analysis critical control point) program is the development of an environmental monitoring plan to look for the presence and occurrence of contaminants.

Why Monitor the Production Environment?

The purpose of environmental testing and monitoring programs is 1) to determine the efficacy of general cleaning and sanitation for the removal of transient contaminants; 2) to monitor for the presence of specific pathogens that may be present as transient or resident microorganisms; and 3) to reveal potential sources of contamination. Potential contaminants are ever-present in food-handling environments. They can be introduced into the food manufacturing environment through raw materials, water, the physical environment (HVAC or heating, ventilation, and air conditioning systems), pests, other food products, and employees. Therefore, food processors need to employ environmental sampling programs to monitor production areas for general levels of hygiene and the presence of contaminants, even areas or materials that are not immediately obvious potential sources of contaminants.

For example, because flour is a low-moisture product some might think that there is no reason to be concerned about the presence of pathogens. The basic premise is that there is a key water activity level required for bacteria to grow. It is true that most bacteria cannot grow in low-moisture foods; however, they are able to survive in low-moisture environments. Species such as *Salmonella* bacteria are capable of slowing their metabolism to the point that they become resistant to common antimicrobial treatments. When looking at the mean values for more than 100 flour samples (unpublished data), Great Plains Analytical Laboratory obtained a water activity value of ≤0.60, a level that will not support active microbial growth. However, if bacteria are present, growth can occur when the flour is processed further into a food product that has a higher moisture content.

The next argument against microbial contamination is that flour most often undergoes a kill step, either through baking or cooking, at some point during production and is generally not considered a ready-to-eat product. Despite this perception, in 2008 *Salmonella* spp. in flour was indicated in food-poisoning outbreaks in New Zealand (2) and the United States (9). In 2009 and as recently as 2016, hemorrhagic *Escherichia coli* was also associated with flour recalls (11). The general thought was that the raw flour would go through a kill step before consumption, and producers relied on the public to facilitate the final process required to guarantee a safe product. The U.S. Food and Drug Administration (FDA) has issued a number of warnings and statements directed to the public about the potential dangers of eating raw flour in products such as cookie dough (11). Consumers, however, do not always heed these warnings, which places the responsibility for ensuring a product is safe to consume back on the producer.

There are many steps along the way at which pathogens can enter the food manufacturing process, from the field to the end product. Obviously, millers have control only once the grain enters their custody. While the grain is under their control, it is the miller's responsibility to prevent the introduction of pathogens into the product. This is best achieved through a vigorous and effective HACCP system. The standard for the grain industry is outlined in the Home Grown Cereals Authority guide, which describes the steps recommended by Codex to establish an effective HACCP program (6). Of particular interest is the declared need to monitor manufacturing processes, including sanitation procedures. The entire facility is part of the process

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that contributes to the safety of the products millers are manufacturing. This is where an environmental monitoring program comes into play.

How to Monitor the Production Environment

There are basically three types of organisms that millers can test for: pathogens, indicators, and spoilage organisms. In flour processing, the spoilage organisms of most interest are yeasts and molds, the most common being *Aspergillus*, *Fusarium*, *Alternaria*, and *Penicillium*. Testing for the presence of molds requires both air and surface testing. To perform air monitoring, either a passive system or an active system can be used. The most common passive method involves placing bacterial growth plates in key sampling areas. Upon placement, the plate is opened up to the environment, a timer is set, and contaminants are allowed to settle for a predetermined amount of time (3). Following exposure, the plates are incubated and tested accordingly. A useful rule of thumb is that one colony is acceptable for each minute of plate exposure. Active sampling is performed by passing a known volume of air across an agar strip (or plate) and incubating as with the passive method. The results are then equated back to the number of colonies per the tested volume of air.

Testing for indicator organisms is conducted to monitor for transient organisms that are constantly assaulting a facility's hygiene program. From the microbial side, this could include coliform bacteria, aerobic bacteria, Enterobacteriaceae, as well as others. Bacteria are generally thought to be associated with poor hygiene practices. Testing for these organisms allows for the monitoring or trending of data and can signal a potential issue before it arises. On the surface, trending of data is quite simple. Facilities collect an appropriate number of samples to establish an acceptable baseline. Trending the data using any number of readily available graphing programs, a quality manager can immediately observe how the data are trending compared with the baseline. A trending increase suggests that the sanitation system is not as effective as it could be, whereas a decrease clearly shows that the process is improving. Spikes in trending data may signal a lapse in the sanitation program at a given point in time.

Environmental testing to detect specific pathogens serves two important roles. First, it identifies the presence of important food pathogens that may have been introduced into a food-handling environment that have not been eliminated by routine sanitation practices and, therefore, could be passed on to the food materials being processed. Second, it assists in determining the sources of contamination with important pathogens. There is no hard-and-fast rule for determining which pathogen-monitoring program is required. Toward that end, it is necessary to determine what the manufacturer is trying to control. *Salmonella* spp. is the target organism for monitoring of product-contact and non–product-contact surfaces in a low-moisture manufacturing facility. It is the responsibility of the manufacturer to determine where the hazards are (they exist; one just has to find them). After finding the sources, it is the manufacturer's responsibility to limit their access to the product. It is counterintuitive that the goal of a pathogen-monitoring system is to find pathogens. The key here is to find them before they contaminate the product. Environmental monitoring for pathogens allows the manufacturer to assess the effectiveness of cleaning, sanitation, and employee hygiene practices.

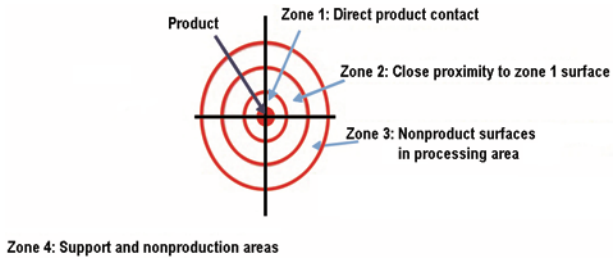

Fig. 1. Target approach used to define zones in a production facility.

When developing an environmental monitoring program, the environmental monitoring zone concept is the easiest to establish and maintain. Understanding the basis of the zone program can be confusing, however. Perhaps the easiest way to understand the zone idea is to picture the product itself as the bull's-eye on a target. In general, the classification of the zones is based on the proximity of the zone to the product and the risk of contamination (Fig. 1). Essentially, the entire facility is broken down into zones, and each zone radiates out from the product as it relates to the product. Zone 1 refers to all direct product-contact surfaces. This includes conveyors, mixers, utensils, racks, etc.—essentially, anything and everything that can come in contact with the product. Zone 2 encompasses those areas directly adjacent to zone 1. This includes non–food-contact surfaces in the processing area (e.g., carts, equipment housing and exterior, etc.). Zone 2 also refers to any pathways that lead to the area where a product is located. Therefore, think along the lines of cart, forklift, and foot traffic. Zone 3 is the area in immediate contacting zone 2. Zone 3, if contaminated, could lead to contamination of zone 2 by means of accidental human traffic or machines and includes hallways and doorways leading into food-production areas, drains, wheels on carts, etc. Zone 4 is the area immediately surrounding zone 3. Zone 4 encompasses the remaining areas that support production, including offices, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

When using the zone approach, the surfaces in direct contact with the final product are not tested for pathogens but are tested for allergens (Table I). Allergen testing is only suggested for these areas if product changeover involves cleaning the existing equipment prior to changing the product produced. If there is a dedicated line for the allergen-free product, testing for allergens within zone 1 is not necessary. The unique environment of each facility results in the need for a unique monitoring plan. The plan should clearly demonstrate the effectiveness of the established program and allow for the detection and monitoring of allergens and pathogens before they enter the food product.

From the viewpoint of monitoring for allergens and their presence, it is the responsibility of the individual facility to determine which allergens pose a risk to their products and subsequently to their customers. This is particularly true if the facility is switching back and forth between production of products that contain the specific allergen and products they claim are allergen free. For example, suppose a manufacturer produces snack cakes. During the first part of the week, they produce cakes with almonds. During the last two days of the week, they produce cakes they claim are free of tree nuts. Whether they are performing a full breakdown of the production line or are producing the second batch on a dedicated line, they should demonstrate that no transient tree nut allergens have come in contact with production equipment.

Allergens can be introduced into a product or a process from the unlikeliest of sources. Recently, there was a major food re-

Table I. An example of zone labeling (targets and frequencies are presented only for demonstration and should be determined by each separate facility)

Area	Description	Examples	Possible Targets	Testing Frequency
Zone 1	Product contact	Conveyors, mixers, utensils	Indicators Allergens	Weekly New production
Zone 2	Close proximity to zone 1 surfaces	Conveyor frames, equipment handles, shields and guards, controller buttons, maintenance tools	*Salmonella* spp. *Listeria* spp. Indicators Allergens	Weekly
Zone 3	Interacts with zone 2	Drains, walls, undersides of tables and equipment, lifts, pallets	*Salmonella* spp.	Weekly
Zone 4	Support areas not in processing area	Break rooms, rest-rooms, locker rooms, offices	*Salmonella* spp.	Monthly

call resulting from the undeclared presence of peanut allergens in flour (10). This was believed to result from cross-contamination of a rail car that was used to transport product to a flour-processing facility. With regard to allergens, the best approach is to view them as if they are pathogens and monitor for their presence similar to monitoring for pathogens. The FDA labels milk, eggs, fish, shell fish, tree nuts, peanuts, wheat, and soy as the most common allergens affecting the U.S. population. Reactions to allergens can range from minor irritation all the way to death (12). Therefore, do not discount allergens from the development of an environmental testing plan.

Data Collection and Analysis

Analysis and interpretation must follow data collection. For nonpathogens, start trending the data. Trending the data can be as complicated or as simple as desired. The basics begin with establishing a baseline, which involves an investment of time on the front end. The goal here is to generate a statistically significant amount of data to determine what the actual baseline is. The next step involves setting the control limits. Again, each production facility must define these locally. A good rule of thumb for those just seeking some guidance is to set an alert at 2 standard deviations from the mean that has previously been determined. This, by definition, includes 95% of the samples tested. If something falls out of that range, address it according to internal standard operating procedures. Each production plant, production line, and product is unique and should be treated as such.

The next step when monitoring data is to look for developing trends. Graphing the results will indicate if a trend is occurring. Of course, in an ideal world, the data will trend toward zero, indicating that the processes and plans are working to their successful maximum. If, on the other hand, there is an increase in the trending line, this could be a predictor of problems down the road. An increasing trend line may indicate that additional training is required or that procedures need to be reviewed and amended. The method by which a company monitors and trends its data is an individual decision.

Summary

Monitoring the production environment for bacteria and other pathogens constitutes a proactive approach to guaranteeing the production of a safe product. In the past, these programs were not thought to be required in the baking and milling industry. However, as more recalls and adverse events occur, it is becoming apparent that the industry must reevaluate its practices. Establishing and maintaining an environmental testing plan requires not only the analysis and monitoring of sites within and around the facility. It also requires that management believe in the process. In fact, it requires total buy-in from management at all levels. When management champions a process, programs begin to take on a life of their own, and they become a part of the corporate culture.

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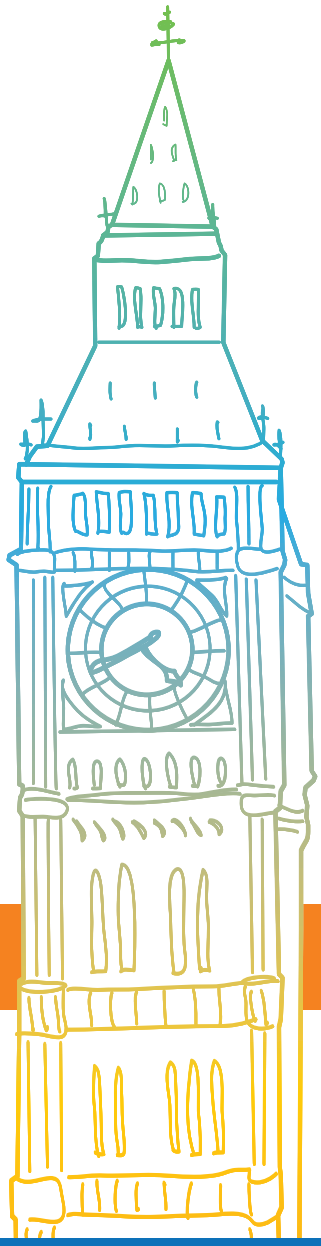

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