



Effective testing components of an environmental monitoring program

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What you'll learn from this paper

There are currently no regulations that require U.S. Food and Drug Administration (FDA) regulated food and beverage manufacturing plants to conduct environmental monitoring and testing. However, there are current requirements for environmental testing for U.S. Department of Agriculture (USDA) Food Safety and Inspection Services (FSIS) ready-to-eat (RTE) manufacturing facilities, and it is expected that these rules may be part of the final Food Safety Modernization Act's (FSMA) package. Both the FDA and the FSIS prescribe regulations that contact surfaces be contaminant- and allergen-free, that RTE food products not be exposed to pathogens, and that the environment be clean and sanitary. The FSMA proposed rules cite instances where the lack of environmental control has contributed to cross-contamination. It also requires verification of the above - a verification that can be achieved through an environmental monitoring program.

An environmental monitoring program not only verifies cleanliness and sanitation, it is a critical component for the protection of your brand.

A well-designed, regularly scheduled environmental monitoring program helps organizations maintain and verify their sanitation programs are working. A working sanitation program helps reduce risk and enhance protection of your brand.

This paper is designed to help protect your brand through environmental testing and monitoring, by

- Providing the basic background information on environmental monitoring programs, including:
 - What environmental monitoring is and why it is important.
 - The role of pathogen testing, with emphasis on four zones and particular concerns of food contact surfaces (FSC).
 - How to seek and destroy
- Detailing tests used in environmental monitoring and where and why to use them, including:
 - Aerobic plate counts (APC) as a bacterial indicator
 - Adenosine triphosphate (ATP) detection to indicate the presence of organic material
 - DNA/RNA amplification and detection for direct pathogen testing

The Environmental Monitoring Program

Pathogens can be introduced into the environment in raw materials, ingredients and supplies as well as by the equipment or vehicles that bring them in. They can also be carried into a facility by employees, visitors, or pests.

Therefore, it is critical to test not only for pathogens, such as *Salmonella* and *Listeria*, but also for the overall effectiveness of the facility's standard sanitation operating procedures (SSOPs) through a well-designed, ongoing environmental monitoring program. This testing not only verifies the effectiveness of sanitation

controls, it helps to refine the frequency and intensity of cleaning and sanitation, identify "hotspots", validate food safety programs, and provide early warning of trends that may need corrective action.

Protecting your facility and products from contaminants that may be introduced through any of the above vectors is the primary premise of environmental monitoring. As methods of sampling become faster and easier to execute, environmental monitoring as a process control tool becomes faster and easier as well. But regardless of the method, the reason to develop and maintain an effective environmental monitoring program is brand protection: By protecting your environment, you are protecting your product, thereby protecting your brand.

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Although FDA does not have specific requirements for environmental monitoring and testing in food plants yet, it is evident from hazard analysis and critical control point (HACCP), good manufacturing practices (GMP), and FSMA documents, as well as recommendations in FDA warning letters, that environmental monitoring is a best practice, or at the very least, a corrective action that will be taken into consideration in inspections and/or if contamination should occur. Following are just a few examples of this:

- **FDA warning letters.** In warning letters issued for violations found at food facilities during regulatory inspections, particularly where any evidence of *Listeria monocytogenes* is found, the development of an environmental monitoring program seems to have become a fairly standard recommendation for corrective action to the root cause of deficiencies, with the following wording appearing in several such letters in recent years: "The FDA recommends that your sanitation controls include effective environmental monitoring programs designed to identify and eliminate and/or control pathogens such as *L. monocytogenes* in and on surfaces and areas in the facility where contamination could result in food product contamination." (from www.fda.gov)
- **The Food Safety Modernization Act (FSMA).** The proposed preventive controls rule of FSMA does not explicitly require that environmental pathogen testing be part of the written food safety plan. However, the appendices in the rule include evidence of the value of testing, and list appropriate circumstances for testing and actual incidents in which environmental testing could have potentially detected a pathogen presence and prevented a public health issue.
- **GMPs.** Although FDA's statements in the proposed rule also note that current good manufacturing practices (cGMPs) are not adequate to control environmental pathogens, especially if they have established a niche in the production environment, general testing for sanitation is considered part of cGMPs and environmental testing can be a significant part of that.
- **Global Food Safety Initiative (GFSI).** The GFSI-benchmarked schemes include mention of environmental testing to varying degrees, with the British Retail Consortium (BRC) having a general requirement for a "scheduled program of testing covering products and the processing environment," and Safe Quality Food (SQF) requiring environmental monitoring for high-risk foods.

Warning letters and other such regulatory documents are easily found on the Internet by consumers, media, bloggers, tweeters, and Facebook posters, and can damage a brand's reputation.

- **USDA.** In the Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products [9CFR 430], USDA lists the *Listeria* rule, control measures, *Listeria* control program testing for both *Listeria monocytogenes* and indicator organisms and enhanced sampling programs. This guide discusses testing food contact surfaces and other environmental surfaces for *Listeria* spp. and *Listeria*-like organisms, methods of testing for validating that the pathogen is not present on the surfaces, and the implementation of a risk-based verification program.

As all of these show, whether or not a federal regulation states that you must have an active environmental monitoring program, there is a continuing and ever-increasing focus on the use of environmental monitoring and testing to validate that the environment in which you are producing food is safe. Because warning letters and all regulatory infractions and documents are in the public domain and easily found on the Internet by consumers, media, and general bloggers, tweeters, and Facebook posters, the lack of environmental controls, such as monitoring and testing, can impact the reputation of your brand as much as it impacts the safety of your product.

Key Environmental Testing Methods

To guard against contamination, (including pathogens), the key elements of environmental testing are:

Pathogen monitoring – An essential part of the environmental monitoring program is that of testing for pathogens, particularly *Salmonella* and/or *Listeria* spp., depending on the circumstances. Conducting regular tests enables you to detect and correct cracks, crevices, and niches where the bacteria may harbor as well as any particularly susceptible "hot spots" for bacteria. Although there is a delay in time results, environmental monitoring measures the effectiveness of contamination control programs and provides assurance to inspectors, auditors, and customers that you are conducting due diligence to keep your facility pathogen-free.

Aerobic plate count – (APC) – (swabbing surfaces and plating on growth media): Primarily used as a sanitation verification of food contact surfaces, APC detects general microflora on the contact surfaces. It enables an assessment of whether the surface is truly getting as clean as possible, but there is a time delay for results due to enrichment and incubation required to grow the organisms to a detectable level.

Adenosine Triphosphate (ATP) – Sanitation monitoring systems that measure ATP (adenosine triphosphate – a protein found in all organic material) determines overall cleanliness of surfaces. ATP detects any organic material that is present including that which results from microorganisms or residual food. Used in any area of a facility, but mainly on food contact surfaces, ATP tests provide instant results, enabling rapid verification of sanitation standard operating procedures and the opportunity to take immediate corrective actions such as recleaning before production starts.

Molecular Testing PCR & RNA/DNA – As a more direct food safety measure, facilities can test directly for environmental pathogens such as *Listeria* and *Salmonella* spp. through molecular assays. These methods are faster than conventional methods which take several days. Traditional PCR detection can take 24 hours including enrichment and test results. In contrast, the RNA/DNA based ANSR® (Amplified Nucleic Single Temperature Reaction) technology exponentially amplifies the DNA of any target bacteria present in an enriched food sample (which takes roughly 16 hours) to detectable levels to produce positive or negative results for *Salmonella* in about 10 minutes and for

Listeria spp. in 18 minutes. These methods can save time and money on held product for verification.

The Four Zones

As a guide to the critical relationship between proximity and risk, the four-zone approach to environmental monitoring and testing has become a standard practice for the food industry, both by food facility staff as well as inspectors and auditors. As depicted in Figure 1 below, the four zones begin with Zone 1 (food contact surfaces), gradually working outward to Zone 4, which includes all areas of the facility which have no direct relation to food areas, such as offices, locker rooms, restrooms, etc. – if not immediately adjacent to production areas.

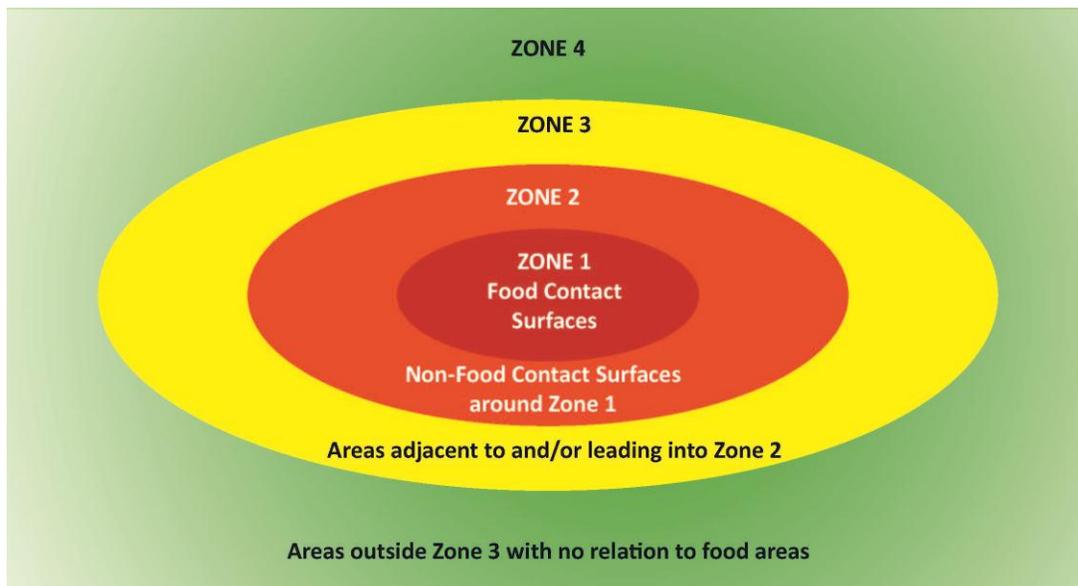


Figure 1. The Four Zones of an environmental monitoring program.

Zone 1. Direct food contact surfaces. This includes all processing equipment and lines, such as batch mixers, conveyor belts, scales, knives and other utensils. Anything that exposed food product may touch during its manufacture prior to packaging is considered to be Zone 1.

Zone 2. Areas directly adjacent to Zone 1 that exposed food products do not touch. This would include any non-food contact surface that is in the area around the lines and/or floor path that exposed food product travels such as, control panels, equipment supports, cat walks, side of a tunnel directly above a product exit. This is a critical area for monitoring, testing and control as contamination could easily cross to exposed food areas. (See Food Contact Surfaces below.)

Zone 3. The area that directly surrounds Zone 2. These are again non-product contact surfaces that are inside the processing area. They are further from food contact than Zone 2, such as, floors, walls doorways, drains, cleaning utensils, or vacuums.

Zone 4. Any areas that are outside Zone 3 that are areas that are away from food production areas. Generally offices would be considered Zone 4, and other employee areas, such as break rooms and

restrooms, receiving docks, storage areas and maintenance shops if they are not directly adjacent to Zone 2.

Zone 1, Food Contact Surfaces (FCS)

At first glance, it may seem, that the most important zone to test for pathogens is Zone 1. However, while this area obviously must be kept pathogen free to protect the product, keeping Zones 2 and 3 pathogen free is equally as important and is generally considered a better use of resources since addressing issues in Zones 2 and 3 should prevent problems in Zone 1. By the time a Zone 1 surface tests positive for a pathogen, it's too late. If proper and thorough sanitation practices are followed in the production environment, pathogens will not be native to the area; rather they will be washed away and be more likely to be detected as they pass through Zones 2 and 3.

As depicted in Figure 2 below, if you test a product contact surface, you must be prepared to deal with a positive test result. This means that Zone 1 testing should result in product being put on hold until results are received. If environmental testing detects an environmental pathogen or *Listeria*-like organism in Zone 1, the held product should be tested with a statistically valid sampling plan – and continue to be held until results are received. In RTE facilities a positive result for a pathogen in a finished product will necessitate product reconditioning or destruction, or potentially the initiation of a recall if the product was not held).

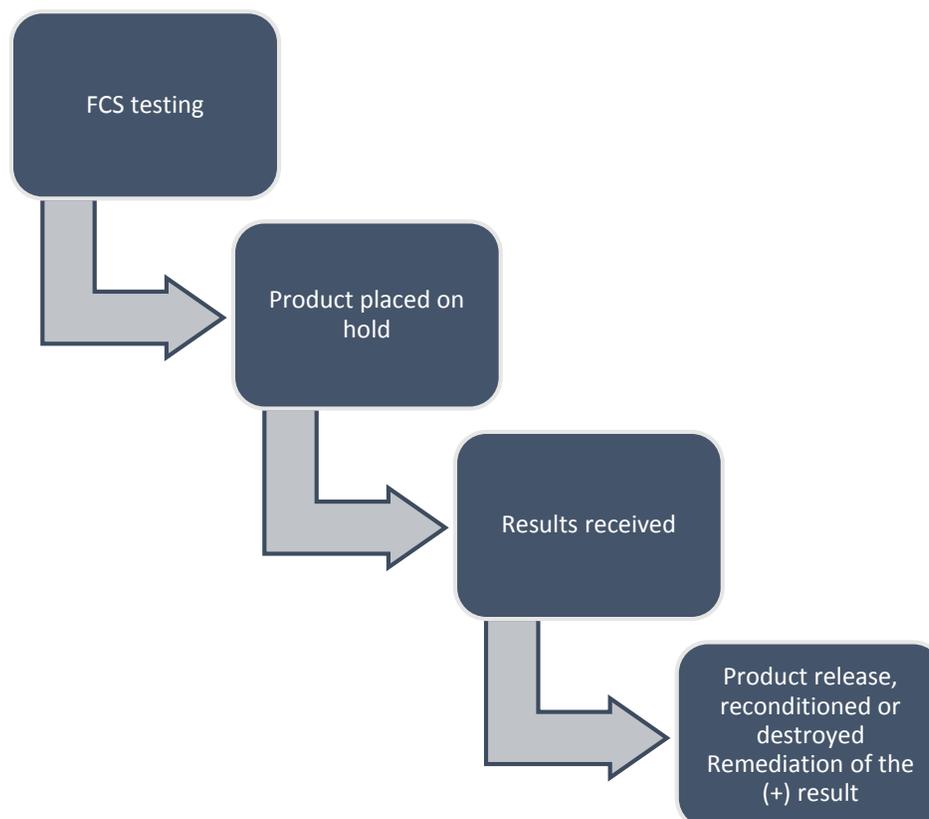


Figure 2. Zone 1 Food Contact Surface Testing

On the other hand, as illustrated in Figure 3 below, a pathogen found in Zone 2 or 3 can elicit corrective action prior to potential food contact, enabling production to continue. This proactive approach to eliminating pathogens before they have an opportunity to contaminate food both prevents a product recall or withdrawal situation and protects the brand.

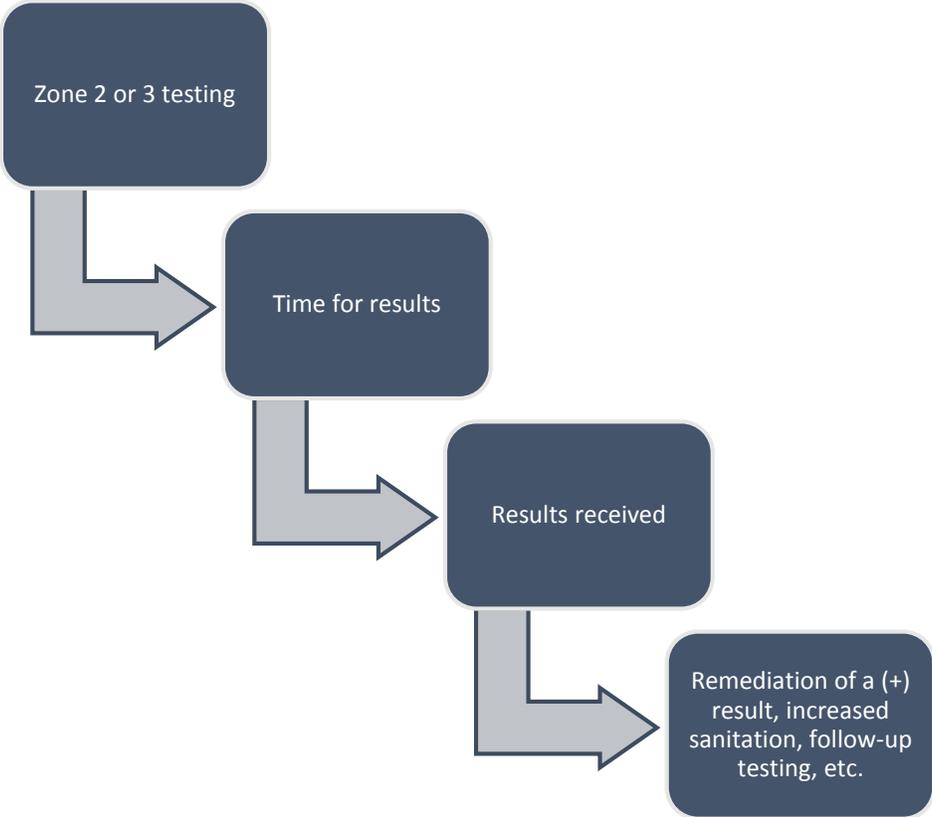


Figure 3. Zone 2 and 3 Testing

Zone Relationships

The remediation of a positive pathogen results in Zone 2, 3 or 4 is a proactive approach to eliminating or significantly reducing the hazard from contamination Zone 1 or product. The zones of the plant are interrelated. There are many ways an organisms can come into the facility such as, people, ingredients, and equipment. Once the organisms are present, they can be moved around the plant via traffic patterns for personal and equipment, air handling systems and in aerosols. For example, the receiving area (Zone 4) of a particular facility has a main thoroughfare for drivers and contractors. This area was found with a higher than average number of positive results. A few weeks later the main entrance to the facility (Zone 3) was found to have continued positive results as well. When these positives were plotted out on a plant schematic, it was realized the two areas have a shared hallway. The corrective actions to remediate this pathogen migration were applied to the shared hallway and the risk was mitigated. If each area was treated alone and not reviewed as a potential migration from one area to another, it may have been more time and more dollars until the corrective actions were effective.

Effective investigation can be seen in another example regarding RTE FCS. For two sampling periods the FCS (Zone 1) on an RTE line has been positive for *Listeria* spp. The site on the line is located near the exit of the freezer. The product on the line is not in its final packaged form. The investigation method used was a vector approach. The team was focusing on the freezer, due to the potential for condensation. The initial investigation did not find the source. The FSC and now product had positive results. The investigation vector was expanded to include all of Zone 1 and Zone 2 adjacent to the positive site. This particular line had a drain located directly under the exit of a freezer. This drain was found as the only positive site. The team observed daily GMP practices and sanitation practices. During this observation they found an employee using the high pressure hose to clean the drain. The potential overspray and aerosolized water droplets were landing on the FCS directly above. Once this was identified and the practice was corrected there were no longer positive results on the FSC or in the product.

There are numerous examples of these types of events happening in food manufacturing facilities. It is key that you understand your facility well enough to make the connection of traffic, air flow and the potential for cross-contamination. This will help in investigations and appropriate corrective actions.

Seek and Destroy

Because of the repercussion of a positive being found in Zone 1 (Figure 2), the preferred approach of extensive and thorough monitoring of Zones 2 and 3 are absolutely critical. These areas should be tested with the end goal to seek and destroy.

The process should never be a haphazard testing of the areas to be able to check off a box and say it is being monitored. Rather, you need to dig into hard-to-reach places, *look* for problems. Seek to find and destroy any issues in Zones 2 and 3 before they can hit Zone 1 before they can impact your product and reputation.

Additionally, if a pathogen or indicator organism is found in Zone 2 or 3, the faster it is detected and corrected, the less likely you are to have implicated product. Using newer faster, molecular based technology for detection, rather than traditional 48-hour or longer methodologies, enables faster response to positives, and quicker remediation through sanitation to prevent transfer from zone to zone including transfer onto food contact surfaces of Zone 1.

The quicker you can attain results during seeking, the quicker you can destroy the potential of food contact surface contamination, prevent the potential of implicated product, and protect your brand.

The quicker you can attain results during seeking, the quicker you can *destroy* the potential of food contact surface contamination, prevent the potential of implicated product, and protect your brand.

Additional Environmental Tests

In the Pathogen Testing section of this white paper, we briefly defined APC and ATP methodologies and uses. Here, we provide a bit more detail on each:

Aerobic plate count (APC)

The results of an APC test provide manufacturers with an indicator of bacteria on the environmental surface that is tested. It is called an aerobic plate count because it measures the number of bacteria that grow aerobically (in the presence of oxygen) in medium nutrient-rich environment at temperatures ideal for the growth of most bacteria. It is important to know that APC is not a pathogen detection test, thus, a low count does not necessarily mean that the sample is pathogen-free, nor does a high count mean that a product is contaminated with pathogens. Rather, APC provides a means of testing a surface after sanitation procedures are conducted to ensure the efficacy of the sanitation process. Additionally, APC testing can be used to monitor the buildup of residue on equipment during production.

While APC is a valuable testing method, there is a need in the industry for faster results. Traditional tests do not provide results for 48 hours - making it difficult to react quickly to ensure a line is clean. APC will most likely remain as a preferred testing method to verify sanitation. New technology can decrease the time to 24 hour results. Improving time to results for sanitation monitoring allows for corrective action to remedy potential sanitation issues. If these actions are taken at 24 hours instead of 48 hours, a day's worth of production is produced under better conditions.

Adenosine Triphosphate (ATP)

Adenosine triphosphate (ATP) tests utilize ATP bioluminescence to determine the cleanliness of surfaces. ATP is a chemical compound found in all cells that are, or once were, alive, including bacteria, food debris, yeast and mold. The results of ATP tests do not always correlate to actual microbiological results, however, they simply provide an assessment of the presence of organic material – whether that be food residue, harmless microbes, or pathogens.

An advantage of ATP testing is its real-time, immediate results. Using ATP, the food manufacturer can get rapid verification that a surface is clean and sanitation standard operating procedures were effective. Or, if the tests show that ATP is detected on cleaned/sanitized surfaces, it can be an indication that the SSOPs need to be reassessed or that employee retraining may be needed. ATP is the only type of environmental assay that allows verification before an operation begins (i.e. “pre-operations”). Finding problems during a pre-operational verification can help prevent contamination and other problems before valuable product is added to the processing environment.

Overall, an ATP test provides value in ensuring that surfaces are clean and ready for use, because the better a surface is cleaned, and the more organic material removed, the lower the likelihood for environmental pathogens to remain on a surface.

APC and ATP

While APC and ATP can be stand-alone methods of environmental monitoring, with some facilities using only ATP testing for immediate results for real-time remediation, the two methods are generally used in tandem and complement one another.

APC measures the overall environment for microorganisms, general microflora, and variable organisms - anything that will grow in the presence of oxygen. ATP provides a measurement of organic substances on the surface – providing assurance that it is free of all food as well as bacteria. Thus, in concert, a facility can get a sense of overall cleanliness using ATP, and get more detailed information on the presence of microorganisms using APC.

Summary

A well-designed, regularly conducted Environmental Monitoring Program, utilizing a complement of best-fit testing methods, helps food facilities keep food products safe by ensuring that sanitation practices are effective and potential contaminants are being detected and destroyed before they can reach food contact surfaces and food products.

To ensure this, it is critical that environmental monitoring focus first on Zones 2 and 3 utilizing best-fit test methodologies. An environmental monitoring program is only as good as the depth of its procedures, thus the goal of any program should be to seek and destroy.

By implementing a thorough program, the food facility is reducing the risk to its product from cross-zone contamination. Additionally, utilizing rapid test methodologies enables faster detection to protect the brand through faster response to out-of-specification results – and even immediate remediation in some cases. The more immediate the remediation, the safer your product, your customer, and your brand.

About Our Paper Sponsor - Neogen

Neogen is a leader in developing and marketing diagnostic test kits that provide food safety solutions. Its products are unsurpassed in terms of ease of use, convenience and speed. Neogen's comprehensive line of rapid food safety diagnostics includes:

Foodborne Pathogens

Neogen provides multiple different pathogen detection systems. Neogen's revolutionary new ANSR™ system is the quickest and easiest testing method to definitively detect pathogen DNA in food and environmental samples — providing results in as little as 10 minutes. Reveal® 2.0 for pathogens are fast and easy immunological lateral flow devices, which can be used at nearly any facility.

General Microbiology

Neogen's Soleris® system rapidly detects microbial contamination by monitoring the color differences produced by changing pH or CO₂. Using Soleris, time to results for general microbiological assays are reduced by up to 60%. Neogen offers NEO-GRID® and ISO-GRID® disposable filter membrane system and culture media for rapid and easy enumeration of bacteria in liquids.

Natural Toxins (including mycotoxins)

Neogen's Reveal® Q+ fully quantitative lateral flow test for mycotoxins are quick and easy, with results in just minutes. Agri-Screen® and Veratox® mycotoxin tests kits provide screening and quantitative ELISA-based test for aflatoxin, DON, fumonisin, zearalenone, ochratoxin, and T-2/HT-2.

Food Allergens

Neogen offers food allergen test kits to detect almond, egg, gliadin (gluten), hazelnut, crustacea, total milk, mustard, peanut, sesame, shellfish, soy, and walnut residues. Neogen provides allergen test kits in multiple formats for validation, verification and finished product testing.

Sanitation

Neogen's AccuPoint® 2 sanitation monitoring system quickly and easily measures ATP collected from food contact surfaces or liquids as a verification of sanitation programs. Data Manager software allows for complete data traceability and data analysis.

About The Acheson Group

The Acheson Group brings clients practical food safety solutions. Food companies today worry about operational efficiency and risk control, brand reputation and complying with current and new regulations. Our holistic approach is designed to provide practical, cost-effective solutions to manage these current multi-faceted challenges using a variety of approaches outlined below. Food companies, and those that provide services to them, have no choice but to be focused on assessing and managing risk in a cost-conscious way. The Acheson Group brings a unique suite of services that provides deep industry expertise and a global perspective focused on assessing and managing operational risk, reputational risk and regulatory risk.