



Food Safety Testing and FSMA, GFSI, and Brand Protection

*Understanding the Role of Environmental,
Raw Material and Finished Product Testing*

**June 2016, by The Acheson Group, TAG
Sponsored by Neogen**



Table of Contents

What You'll Learn From this Paper	3
The Role of Testing.....	3
Testing as a Preventive Measure	4
Statistics	5
Methods.....	5
Test and Hold	6
Environmental Testing	6
Testing: Will FDA Require it as Part of the Final Preventive Controls Rule?.....	7
Testing and Monitoring.....	7
Now is the Time to Act.....	8
Testing Requirements in GFSI	8
Summary	9
About Our Paper Sponsor – Neogen.....	10
Foodborne Pathogens.....	10
General Microbiology	10
Natural Toxins (including mycotoxins).....	10
Food Allergens	10
Sanitation	10
About The Acheson Group, TAG	10

For more information on Leavitt Partners contact:

Lindsay Nix; Lindsay.Nix@AchesonGroup.com; (406) 471 5240
[//achesongroup.com/](http://achesongroup.com/)

For more information on Neogen contact:

Gerry Broski; gbroski@neogen.com; 800-234-5333 x 2361
foodsafety@neogen.com

What You'll Learn From this Paper

A number of established and proposed global food safety regulations and initiatives seek to both protect consumers, and provide guidance to the food industry on how to best produce the safest possible products. These regulations and initiatives address all aspects of safe food production, processing, and delivery every step of the way to the consumer.

Food companies can protect their consumers, and the integrity of their brands, by ensuring that they are performing the safest possible practices in their operations. A critical component of verifying the safety of their practices is testing. Testing serves multiple purposes in the food industry. This introductory paper provides an overview of the various aspects of microbial testing, including the testing of raw materials, finished products, or a facility's production environment, with a tilt toward discussing pathogen testing. Subsequent papers will focus on using testing to verify allergen controls, and testing as a means to verify sanitation. This paper is designed to:

- Provide the basic background information for:
 - Raw material testing
 - Finished product testing
 - Environmental pathogen monitoring
- Illustrate the extent to which FDA has required (and not required) these different types of testing as part of the final FSMA Preventive Controls Rule
- Explain how testing is addressed within GFSI schemes
- Describe the considerations when determining the best way to include testing in your food safety program

The Role of Testing

It is generally recognized that you cannot test every single product, or test every inch of a facility, and therefore, there is debate around whether testing serves a preventive purpose by “catching” contaminated ingredients before they are used or finished product before it goes into distribution, or serves as a verification tool that systems in place are working. Clearly, relying solely on product testing to assure food safety in the absence of an overall food safety management system is not a good plan; however, testing does play an important role in verifying that food safety controls are working and in some circumstances can even serve as a preventive measure. When it comes to pathogen detection, the main types of testing that occur in a food environment are:

- Raw material testing
 - This can verify the information (such as a certificate of analysis (COA)) provided by a supplier
 - Testing serves a food safety role if the ingredient or product lacks a “kill step”
 -

- Finished product testing
 - If the finished product lacks a kill step, statistically valid testing of finished products can be used as a food safety measure
 - Finished product testing can verify that the food safety system is functioning properly and can help define the scope of a problem
- Environmental testing
 - This can provide rapid verification of sanitation standard operating procedures using ATP tests (detecting the presence of organic material) or in some cases, visual inspection
 - As a more direct food safety measure, facilities can test directly for environmental pathogens such as *Listeria* and *Salmonella* spp. or indicator organisms.

Testing as a Preventive Measure

Ideally, the controls in place throughout the supply chain would be adequate to protect food from contamination. However, there are some instances where testing has been shown to be the most effective measure to promote food safety. For example, the US FDA and Health Canada performed a joint risk-assessment of *Listeria monocytogenes* in soft ripened cheese (such as Camembert). When this style of cheese is made from raw milk, the risk assessment showed that testing the finished cheese product was the practice most effective at reducing the amount of contaminated cheese reaching the marketplace. Without testing, the risk of listeriosis in susceptible populations was 100 times higher for raw milk cheese rather than cheese made from pasteurized milk. However, if each bulk tank (raw ingredient) was tested for *Listeria*, then raw milk cheeses were “only” three times more risky. The greatest reduction in risk resulted from testing composite samples from the finished cheese product, which reduced risk to levels below that of pasteurization.¹). Other examples of testing being used as preventive controls are the mandatory testing of peanuts for aflatoxin and bulk milk for antibiotics.

Testing composite samples from the finished (raw milk) cheese product...reduced the risk (of listeriosis) to levels below that of pasteurization

Testing the production environment for environmental pathogens is clearly a mechanism to verify the effectiveness of sanitation procedures, but if a pathogen is found close to or on product contact surfaces, then the identification of pathogens allows a facility to address them, thus proactively protecting the food from contamination.

1

<http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM338618.pdf>

Statistics

As companies are considering testing, questions that often comes up are, “How often do I need to test?” and “How many samples do I need to take?”

In order to have statistically valid results—meaning results that you can have a defined degree of confidence in—one must use a statistically valid sampling plan. It’s

Finding a positive without a statistically valid plan is akin to finding a needle in a haystack.

recommended that companies consult with statisticians to determine how many samples need to be taken. For environmental monitoring, there are also software programs that help identify the locations that should be tested on a rotating schedule.

Although a statistically valid sampling plan may show that numerous tests need to be conducted, haphazardly sampling products should be viewed as a waste of resources since contamination is seldom homogenous, and finding a positive without a statistically valid plan is akin to finding a needle in a haystack.

How do you know what is statistically valid? If companies don’t have a statistician on staff, they can consult a few handy references that lay out the relationship between the number of samples taken, the “true” level of contamination, and the likelihood that testing a given number of samples will give the “right” result, meaning that contaminated lots will be discovered. Military Standard 105 is a common reference and there are some online calculators that can guide users through the process of developing statistically valid plans.

Methods

Resources can also be wasted if an inappropriate method is used. Whether testing raw materials or finished products, method selection is critical to ensure that the test is not impacted by any inhibitors or other components of the food product. Additionally, it can be very difficult to isolate bacteria from foods (e.g., some food matrices interfere with detection techniques). Similarly, the sanitizers used in processing plants can have an inhibitory effect and may prevent the detection of some pathogens. For best results, companies should use testing methods that have been demonstrated to work under comparable circumstances, or similar environments.

For the detection of pathogens, the “gold standard” for testing is a culture-based method. However, the time it takes for bacteria to grow can be very protracted and there are now numerous methods that can produce results more quickly. However, virtually all methods require an “enrichment step” so that the bacteria can grow to levels which can be detected. Methods may be validated or tested by independent scientific groups such as AOAC and AFNOR for robustness.

Rapid methods have been developed because of a growing need for shortened time to results, and ease of use. The difficulty in performing culture-based pathogen detection protocols can be eliminated with

some rapid pathogen detection methods. Rapid methods have also incorporated new technologies such as isothermal DNA amplification, which increases sensitivity and specificity and reduces the likelihood of false positives and false negatives.

Rapid pathogen detection allows interventions and corrective actions to be taken days ahead of time. Faster results can mean that the number of implicated lots or amount of product is greatly reduced in the event of a contamination. Companies can be alerted to a problem more quickly, and can react faster. Easier-to-use methods improve lab efficiencies and also improve throughput, and reduce warehouse space requirements and associated costs.

Many companies will make decisions on product release based on “presumptive” tests, meaning that a “presumptive positive” result often leads to an alternate disposition of the product such as further processing or disposal— practices which result in waste and inefficiency if they are inaccurate. This is part of the reason that test manufacturers and the organizations that validate methods focus on “false positive” and “false negative” rates. While there is increased confidence that “presumptive positives” are truly positive, it is still important to pursue confirmatory testing, ideally identifying the “fingerprint” of pathogens. This allows more focused investigation into the root cause of contamination, and fingerprinting (e.g., genotyping) can help identify trends and patterns.

Test and Hold

In addition to determining the correct number of samples to take and the appropriate method to use, a challenge that is often expressed relates to “test and hold” requirements. It is undesirable to test a product (whether raw material or finished product), use the ingredient or release the finished product into distribution, and then subsequently learn that the product tested positive for a contaminant. Therefore, most product testing is done using a “test and hold” process, meaning that the product being tested cannot be released until test results are obtained. While the idea is straightforward, this means that facilities must have room to store products that are on “hold”. For fresh or finished products in particular, this may begin to cut into the product’s shelf life, but the alternative would be to release the product into distribution and potentially need to recall the product. As noted above, the more rapid the method, the more quickly decisions can be made regarding product that is being held under a “test and hold” protocol.

Environmental Testing

As noted previously, food safety systems strive to minimize contamination in finished products. For certain types of products, particularly ready-to-eat products, it is critical that environmental pathogens are controlled so that they do not contaminate the product. For these types of products, perhaps the greatest use of testing lies in environmental pathogen monitoring. Additional details on environmental testing and other aspects of sanitation verification will be provided in a subsequent paper, but it is such a hot topic that any paper on testing would be remiss not to address it.

Environmental pathogens may be introduced by raw materials, ingredients, people, pests, or objects (like equipment or transportation vehicles). Testing for these pathogens, generally *Salmonella* and *Listeria*, can be used not only to verify that sanitation controls are working, but can also help to refine the frequency and intensity of cleaning and sanitation. A well-designed environmental monitoring program can be used to identify hotspots, check the validity of food safety programs, and indicate trends: control, trending out of control (early warning), or requiring corrective action.

If environmental testing detects an environmental pathogen or indicator organism on a product contact surface, then the facility may consider conducting end-product testing to determine if the product was contaminated.

Testing: Does the FDA Require it as Part of the Final Preventive Controls Rule?

The major provision of the final rule describes product testing and environmental monitoring listed as possible verification activities, but, like other preventive controls management components in general, they are only required as appropriate to the food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system. In many cases, neither product testing nor environmental monitoring will be appropriate. For example, there would be little to no benefit to product testing or environmental monitoring in facilities that pack or hold produce raw agricultural commodities that are rarely consumed raw, such as potatoes.

For example, environmental monitoring would be required to verify effectiveness of sanitation controls when an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen because such environmental monitoring is appropriate to the facility (one manufacturing RTE foods), the food (an RTE food exposed to the environment), and the nature of the preventive control (sanitation controls). Foods such as peanut butter, soft cheeses, dried dairy products for use in RTE foods, and roasted nuts are among the products for which manufacturing operations would need to have an environmental monitoring program when such foods are exposed to the environment.

Testing and Monitoring

Based on your hazard analysis and identification of preventive controls, it may very well be that facilities will be using testing as part of their food safety plans. Although FDA isn't requiring every food safety plan to include elements of testing, this does not mean that testing won't be appropriate under some circumstances.

Supplier verification is not proposed to be required as part of all food safety plans, but for certain types of products (especially those that lack a kill step). The final preventive control rule has a section that requires companies to have a supply chain control program and raw material testing could be a component of this.

FDA identifies two elements of sanitation that are currently part of cGMPs that could be used as preventive controls (sanitation of product contact surfaces and sanitation to prevent cross contamination and cross contact). Testing can be used to verify that sanitation is being conducted according to the food safety plan. So while FDA is not requiring environmental monitoring across the board, if a facility identifies a sanitation control as necessary to address environmental pathogens, then environmental pathogen testing is an obvious way to make sure that sanitation is being conducted in a way that addresses these pathogens. If sanitation is determined to be a preventive control in the food safety plan, then it will need to be validated and verified. Testing can play a role for validation and verification.

There are several methods that can be used to demonstrate adequate cleaning and sanitation. For the purpose of an FDA Food Safety Plan, the focus is really on pathogens, and making sure that pathogens are not in the finished product. Therefore, an environmental monitoring program used to verify sanitation and other environmental controls must seek out pathogens. Generally testing for sanitation is considered part of cGMPs and for the most part, is not expected to be considered in a food safety plan.

Now is The Time to Act

The clock is ticking for large companies who must have the food safety plan in place for each facility by September 19th 2016. Each food facility should ask itself the following questions:

- Are you producing a ready-to-eat product that could become contaminated with an environmental pathogen such as *L. monocytogenes* or *Salmonella*?
- Does the product support the growth of pathogens (environmental or otherwise)?
- Are you adding ingredients to finished products after a kill step?
- Are you producing products that don't have a kill step?
- Will the product be consumed by a population that is at high risk for foodborne illness (e.g., children, elderly individuals, or immunocompromised individuals)? Does this include known and foreseeable uses of my product?
- Have you considered economically motivated adulteration of the ingredients in your product that can cause a food safety issue (introduction of a pathogen)?

Testing Requirements in GFSI

Increasingly, GFSI has become a major force within much of the food industry. GFSI set forth a guidance document outlining expectations of food safety management systems and different audit schemes have been benchmarked against the GFSI standard. There are numerous facets to GFSI, and testing fits into several of them. Some of the audit schemes call out testing opportunities more specifically than others.

British Retail Consortium (BRC) specifically mentions testing more frequently than several of the other schemes. There is a general requirement that there be a “scheduled program of testing covering products and the processing environment.” More focused applications of testing are referenced in other parts of the scheme.

Another GFSI benchmarked scheme, Safe Quality Food (SQF), requires that environmental monitoring be conducted for high risk foods, including documenting the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling. BRC speaks to cleaning more broadly, stating that microbiological testing can help define an acceptable level of cleaning.

Although finished product testing is not required, SQF does require that facilities establish a process to release product, and testing could play a role in this. Similarly, BRC requires that if there is a process to release product, it be followed.

SQF, BRC, and FSSC 22000 note testing as an option to verify the conformity of raw materials. FSSC 22000 also mentions testing in the context of verification planning, noting that testing can be used to verify the overall effect of prerequisite programs, operational PRPs and elements within the HACCP plan, and generally to make sure that hazard levels are within identified acceptable levels.

Summary

While testing cannot guarantee the safety of a product, it is definitely an important component of a comprehensive food safety management system. Whether motivated by regulation, customer requirements (such as providing COAs or being certified to a GFSI audit scheme), or simply brand protection, the three types of testing, raw material, environmental, and finished product, each have a role to play. The effort and resources expended on each type of testing are highly dependent on the product being produced and the process used.

The establishment of allergen control programs, sanitation monitoring programs, environmental monitoring programs, and product testing all help to validate food safety programs, processes and procedures and verify that controls are working as planned. This paper focused on testing as a means to verify microbial food safety, whether it's testing of food (raw materials and/or finished product) or the production environment. Testing should be considered as food safety plans are developed, particularly when processes lack a “kill step” and/or when there is a reasonable risk of post-process contamination.

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%.

Natural Toxins (including mycotoxins)

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

About The Acheson Group (TAG)

The Acheson Group (TAG) brings clients practical food safety solutions. Food companies today worry about operational efficiency and risk control, brand reputation and complying with regulations.

TAG 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.

Our team is comprised of noted industry leaders with global experience in food safety and defense.

Our clients span farm to fork and include technology companies looking to assist all sectors of the food industry.