FOOD Quality
Farm to Fork Quality Assurance

The Palltronic Aquawit System

Raising the Bar on *Integrity Testing*

BY KATHLEEN BERRY

FOOD PROCESSORS TODAY MUST BE PROACTIVE in protecting the consumer by preventing food contamination at all costs. The expeditious elimination of any process deficiencies is critical to a manufacturer's integrity and must be resolved before it leads to consumer complaints and illnesses or costly product recalls. Integrity testing of food production processes is a growing, but still underutilized safety method and can be a critical component in any food safety initiative.

The reasons for the underutilization of integrity testing are simple: The tests require an investment of both time and money – an investment that many companies, especially small ones, are not always willing to make. But as any company that has had a product recall can tell you, food contamination can result in even more devastating costs.

There are two basic but extremely important reasons to integrity test in the food industry: One, to satisfy HACCP requirements to safeguard food, and two to maintain food quality, consumer acceptance and brand equity.

The ABCs of HACCP

HACCP is a food safety initiative that has rapidly gained acceptance in the food industry. Developed almost 30 years ago as a food safety program for astronauts, HACCP governs process control points where physical, chemical or microbial contaminants could cause safety issues in food production. The original focus of HAACP was to prevent hazards that could cause foodborne illnesses by applying science-based controls, and the current initiative adheres to and has built on that goal.

New challenges to the U.S. food supply have prompted the FDA to consider adopting a HACCP-based food safety system on a wider scale. One of the driving factors is the increasing number of new food pathogens. For example, between the early 1970s and late 1980s, bacteria not previously recognized as important causes of foodborne illness — such as *E. coli* and *Salmonella* — became more widespread.

Preventing problems from occurring is the main goal underlying any HACCP system. A HACCP initiative means that the critical points in the manufacturing process, where an upset could cause food safety issues, need to be analyzed, identified, monitored and, most importantly, corrected and documented. Examples of where filters are responsible for microbial quality which could affect food safety are sterile air filters in aseptic processes, sterile liquid filters prior to bottling, especially for low-acid foods, and filters involved in ensuring microbial quality in low-acid foods.

Any place where there's a filter responsible for a required amount of contaminant removal, the absence of which would cause food safety issues, is a critical control point regulated by HACCP. Those filters would need to be identified in the process, and integrity testing would need to be carried out to verify their integrity. Filter integrity should be verified after shipping, steaming, use and reuse.

Integrity testing can also be used in non-HACCP regulated manufacturing. In these cases, its use verifies filter integrity, the failure of which could cause reduction in process yield, food spoilage, food quality degradation or other quality issues, which do not necessarily result in safety concerns, but do result in product recalls, brand damage or consumer dissatisfaction. For example, if a filter were used to remove particles that cause haze in a food product, its failure would not cause food safety issues, but could cause a negative visual effect of the product and along with it a reduced consumer acceptance.

Typical Practice

It has often been the case, in practice, that no integrity testing is done at all. In these cases, there is no way to pinpoint whether sterility problems or reductions in process yields are due to the filters or other factors. Also, the proactive correction of problems before they occur isn't possible.

For example, sterile air vent filters on dairy culture tanks should be designed to keep out rogue microorganisms from the surrounding air in order to allow controlled fermentation to occur within the tank. The degree to which such rogue microorganisms truly affect the fermentation is sometimes hard to pinpoint, but any concerns can easily be eliminated by the monitored use and integrity verification of the sterile filters.

Another practice is the use of manually designed methods in place of integrity testers. These methods are subject to operator error, or results may be influenced by fluctuations in the surrounding environment; temperature, air flow conditions, etc. At the very least, simple integrity testing using a purpose-designed integrity tester should be used to replace these manual methods. For example, an integrity testing device using simple pressure hold test principles on a liquid membrane filter will yield accurate and reproducible results every time, with a print-out to document test results.

Aerosol penetration tests are also used to determine sterile air filter integrity, but such tests are not correlated with liquid bacterial challenge testing.

Rules of Integrity Testing

Six key features must be considered for a sensitive, accurate and correlated integrity test for membrane filters used to sterilize gases and liquids used in food manufacturing. Tests must

be non-destructive and non-contaminating, reliable and reproducible, objective, fully correlated with liquid bacterial challenge testing and practical and easy to use.

In the past, three different tests have been commonly used for sterile air filters:

1) Aerosol penetration test: A measurement of the penetration of aerosolized particles (such as NaCl), droplets of oil (such as di-octyl phthalate or DOP), or other mineral/vegetable oils.

2) Bubble Point Test: A measurement of the gas pressure required to achieve liquid displacement from a wetted membrane.

3) Diffusive Flow Test: A measurement of diffusive air or nitrogen flow through a membrane wetted with an appropriate liquid

For hydrophobic membrane filter cartridges, the diffusive flow test has been the most commonly used because of its high sensitivity and correlation to liquid bacterial challenge, the "worst case" condition.

To perform this test, it is necessary to wet the filter membrane completely with an alcohol solution. For an in situ integrity test of a hydrophobic membrane air filter, the wetting agent has to be introduced into the filter system and, after the test; this fluid must be removed to restore airflow through the filter membrane. The potential flammability of the alcohol solutions must also be considered, and in some applications it is necessary to validate the complete removal of the solvent mixture to avoid contamination of the product.

For these reasons integrity testing of hydrophobic filters in situ has not been widely used and off-line testing has been more common. The increasing industry demand and growing regulatory requirement for in situ integrity testing of sterilizing air filters has led to the development of water-based tests.

The Water Intrusion Test

A water intrusion test (WIT) addresses these issues. As with traditional solvent-based tests, water-based tests can be correlated to 100-percent bacterial retention in gas streams. Since upstream water-based tests are non-contaminating, don't require downstream manipulations, use a non-flammable test liquid and eliminate the need to use alcohol, they provide an excellent alternative to solvent-based tests. A water-based integrity test also maintains downstream sterility throughout the test, which is especially important since filters are an integral part of downstream processing. Water-based integrity tests are practical, validated tests and have become a very viable option for in situ integrity testing of sterile air filters.

The Seven Principles of HACCP

- Analyze biological, chemical, and physical hazards
- Identify critical control points including cooking, cooling, packaging and metal detection points
- Establish preventive measures with critical limits for each control point
- Establish procedures to monitor the critical control points
- Establish corrective actions to be taken when monitoring shows that a critical limit has not been met
- Establish procedures to verify that the system is working properly
- Establish effective recordkeeping to document the HACCP system

Conclusions

Assuring the integrity and function of filters in critical food manufacturing processes has become an increasing concern of the FDA, USDA and international regulatory authorities. To help overcome the challenges of testing in place, a fully automated integrity testing system can confirm hydrophobic membrane filter integrity by performing a WIT on filter assemblies in place. Direct measurement of upstream flow is the ideal method for determining water intrusion flow rates as it avoids the use of upstream volume determination and flow calculation which are necessary with pressure decay instruments.

When implementing integrity testing, the ideal approach is to incorporate it into a total fluid management initiative to ensure consistency and quality of your filtration requirements throughout every phase of the food manufacturing process.

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Filter Integrity Test Regimen vs. "At-Risk" Material for large-scale food manufacturers

TEST FREQUENCY	MONETARY VALUE OF AT RISK MATERIAL
Daily or Weekly	Thousands
Monthly	Hundreds of thousands
Quarterly or Yearly	Millions

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