Environmental Monitoring Self-Assessment in Preparation for FSMA

Many years have passed since the Food Safety Modernization Act (FSMA) was signed into law, and the rules affecting food processors are finally imminent. With the focus shift from reaction to prevention, food processors carry even greater responsibility for the prevention of adulteration in facilities and final products. FSMA verbiage cites preventive controls that may include sanitation procedures, environmental monitoring of pathogen controls, allergen control, supply chain programs and current Good Manufacturing Practices (cGMPs), among others. Within the Hazard Analysis and Risk-Based Preventive Controls section of the rules, FSMA states the facility will be responsible for monitoring the effectiveness of the aforementioned preventive controls to verify that the controls are adequately addressing identified hazards by implementing corrective actions when needed. Objectively assessing the hazards in the processing environment and immediately acting to prevent contamination is a prudent exercise for any food processor.

Objective assessment of Hazards

Have you identified hazards associated with the environment in which you process your products?

Hazards relating to the manufacturing environment may include adulteration of products from the environment (bacteria, food residues), allergen cross-contamination, etc. The FDA has taken an approach similar to the Hazard Analysis Critical Control Point (HACCP) system, adopted by the food industry for the identification, evaluation and control of food safety hazards. The FSMA rules advance and strengthen those safeguards.

Have you analyzed the risks associated with those hazards?

The probability and severity of the risk will determine the depth and breadth of the preventive controls and verification monitoring program. For aged facilities with older equipment, the risk probability is higher than for new facilities with hygienically designed equipment.

Do you have preventive controls in place to address those identified hazards from the environment?

Environmental monitoring is not a control but a verification of controls such as hygienic design, employee hygiene, cGMPs and Sanitation Standard Operating Procedures (SSOPs). cGMPs and SSOPs are fundamental requirements of a solid food safety program.

How will you validate and then verify the control?

Perform validation when anything changes in the process such as new equipment, cleaning materials, etc. Validate initially, verify regularly. Verification requirements ask, “Are controls being performed as your food safety plan specifies?” You can verify controls by record-keeping, document review, internal auditing or observation.

How will you monitor the effectiveness of controls?

When designing an environmental monitoring program, there are many questions FSMA has not specifically answered, but has been challenged by industry to address. However, the preventive controls rules require that a facility verify that hazards are being controlled and take corrective action to prevent contamination; examples are product testing and environmental monitoring. Hygiena® is often asked how to set up and run a thorough environmental monitoring program.

Recommendations to Consider

What should you test for?

Don't limit your environmental monitoring program to pathogens only! A proactive strategy is to locate potential niches for pathogenic growth and detect areas of potential harborage. Remember, the best defense is a good offense. A robust food safety environmental monitoring program typically includes ATP sanitation monitoring, protein surface testing (allergen screening), environmental allergen test kits and microorganism testing.

Hygiena offers several innovative solutions. First, EnSURE® Touch is a handheld, easy-to-use monitoring system that, when paired with UltraSnap®, tests for ATP levels and identifies potential microorganism contamination. Also available are lateral flow allergen test kits, AlerTox® Sticks, and protein surface testing kits that do not require any instrumentation, allowing easy implementation.

Where will you test?

In addition to manufacturing lines where products directly contact surfaces, samples should also be taken from the environment. Refer to zones, considering risks and facility design to determine control points. If you're not finding key indicator organisms, including Listeria or Salmonella, in the areas you're testing, look elsewhere. Corrective actions should always be in place and well documented for any positive findings. Options for pathogen testing include InSite® for indicator organism detection and MicroSnap® for same-day microbial contamination detection.

How often should you test/how much?

Depending on the test being performed, environmental samples should be taken after sanitation, before start-up and during processing. Software tools like Hygiena's SureTrend® offers robust sampling plan management and unifies all testing data in one central location, regardless of test type and instrument. The software also generates shareable reports, including corrective action reports, which are essential for FSMA documentation and audits. Depending on your manufacturing schedule, volumes and changeover frequency, microorganism testing may be daily or weekly. Now that environmental test kits are so economical and much easier to use, bringing microbiological testing in-house is reasonable.

How fast can you get results?

With novel developments in microorganism testing like the MicroSnap® line from Hygiena, results are available in 8 hours or less. Many formats are AOAC-RI validated methods for products and environmental samples with results in 6–8 hours, including enrichment. This technology is evolving to include 4–5-hour tests designed specifically for surface detection.

What will you do with all the data?

Another facet of FSMA is the record-keeping requirement. Software tools compatible with monitoring systems, like Hygiena's SureTrend, store environmental monitoring test results for trending and long-term analysis. SureTrend also offers the added advantage of storing all your testing data in one location for easy review and trending analysis. The software also produces sharable reports, including corrective action reports useful for FSMA documentation and audits.

For reliable, easy-to-use and affordable environmental monitoring tools, visit https://www.hygiena.com.