Establishing an EMP in Your Facility: What to Consider

Introduction

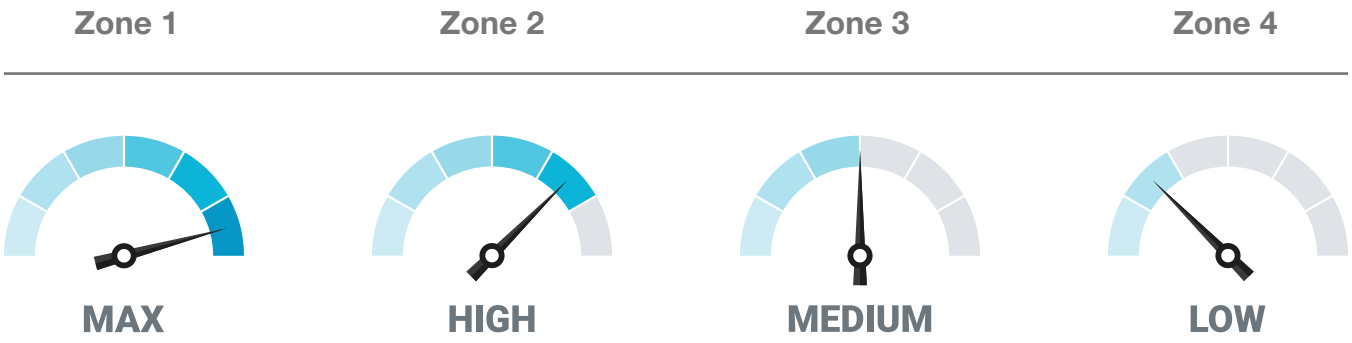
As part of the Food Safety Modernization Act (FSMA), food companies need to implement an effective environmental monitoring program (EMP) to minimize food safety risks by testing the food processing environment for microbial contamination and allergen cross-contact. Preventive control measures are now the norm and are included in the Good Manufacturing Practices (GMPs) which state that "All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food."

These requirements include sanitation verification activities and validation of allergen cleaning. Environmental monitoring activities are highly recommended as part of this process to verify the control of environmental pathogens and potential allergens. While the FDA has not established acceptable threshold limits for allergen residue, it is highly recommended that manufacturers perform validation to ensure cleaning procedures can adequately remove allergen residues.

Developing an EMP

All this means that it is important to have an effective EMP in place to meet all these guidelines. Developing an EMP requires consideration of specific in-plant factors, some unique to each facility. The first step to consider is what team will evaluate the facility's operation to help identify potential areas of risk and concern. These are specific to the facility and can include such factors as food types produced (plant vs. animal, wet vs. dry processing, etc.) and the expertise of the personnel. This team will then identify the regulatory requirements they must adhere to and what the EMP can easily address. The team will then identify the list of potential pathogens and allergens to control and monitor. Often, this requires contacting an experienced consultant for guidance. Next, the team must map out the facility areas and surfaces to be sampled. It is vital to select a variety of surfaces throughout the equipment and facility to sample to ensure the manufacturing environment remains as clean as possible. Typically, the facility is mapped out into four zones – zone 1 being the highest risk areas to zone 4 being the lowest risk areas. It is critical that, for each zone, a science-based environmental testing and verification program is established to effectively monitor all zones in the facility for overall hygiene quality. This involves establishing what type of testing will be performed for each swabbed site and when. Closely tied to this is the development of steps to take in case of a positive test, including the process for pulling the contaminated product, how to prevent it from entering commerce, and corrective actions to minimize recurrence of the issue. It is critical to understand what equipment or surface tested positive and why, if possible. Lastly, the team must select a qualified laboratory that uses accepted testing methodology so there is confidence that testing results are reliable and protect both the consumer and the facility's product and brand.

When testing for contaminants, both food and non-food surfaces are swabbed to identify the presence of pathogenic bacteria, indicator organisms, or allergens. In addition, raw materials and finished products can also be tested for these contaminants. Indicator organism testing is often used to evaluate the risk of pathogen presence and provides more rapid time to results.



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EMP Regulations & Requirements

As part of the development of the EMP, per 21 CFR Part 117 Subpart C Section 130 (2), the EM evaluation must consider the following issues, which affect food safety for the intended consumer and play an important role in minimizing contamination risk:

- Food formulation
- Condition, function, and design of the facility and equipment
- Raw materials and other ingredients
- Transportation practices
- Manufacturing/processing procedures
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene
- Temporal (e.g., weather-related) factors that can affect the nature of some hazards (e.g., level of toxins)

Once finalized, the documented EMP should list the target pathogens, indicator microorganisms, spoilage organisms and allergens, the location of sampling sites, the frequency of sampling and testing, when the samples should be taken, the sampling and analytical methods, and the name of the certified laboratory that will perform the testing. Corrective action procedures should also be included to address any positive test results and all records should be fully documented and stored for later access and analysis. Samples may be taken on a daily, weekly or monthly basis, (depending on the risks and the facility's budget) and should focus on the primary pathogen control area. Samples must be refrigerated and analyzed promptly. In addition, all sample information must be clearly documented – when it was taken, from where, by whom, and how the sample was handled.

All of this information must be clearly written into EMP SOPs which include the following:

- Sampling frequency
- When, where, how, and duration of sampling
- Data coding and recording procedures
- Sample numbers, sizes, and volumes
- Specific sampling and analysis validated protocols
- Monitoring of incubators and use of equipment
- Handling and shipping of samples
- Established alert and action levels and appropriate response to deviations from these levels

Zone Establishment

As for zones to consider within a facility, each area is divided into zones that refer to the location of sampling points based upon their proximity to food contact surfaces and what impact they may have on these locations. As mentioned above, there are typically four defined zones.

Zone 1

Includes all surfaces that come in direct contact with the food product — Work tables, utensils (peelers, slicers), pumps, belts, conveyers, hoppers, packing stations, employee hands, storage silos, racks and bulk containers.

Typically, zone 1 is tested for Aerobic Plate Count, indicator organisms (such as EB), or ATP. It is not generally tested for pathogens. Testing for pathogens is only done in extreme circumstances. If zone 1 tests positive for a pathogen, production must halt immediately, and the most likely outcome is that products produced in that zone will be recalled. The facility must also have a detailed corrective action procedure in place for identifying and removing the cause of the contamination. Typically, Zone 1 testing for pathogens occurs when investigating a root cause, opening of a new production line, or when a “positive” is found in adjacent zones or in product.

Zone 2

Includes nonfood areas of contact that are directly adjacent to Zone 1 and could have high impact on the safety of the food product – Framework of zone 1 equipment, drip shields, railings, areas above and below the production line, maintenance tools, ancillary equipment such as compressors and heat exchangers), chill units and aprons/tables. Zones 2 – 4 are typically tested for pathogens.

Zone 3

Includes nonfood areas of contact that are not close to or adjacent to Zone 1 but still could be in the production room — Walls, floors, ceilings, drains, sinks, footbaths, handling units (forklifts), hoses, phones, finished product storage areas.

Zone 4

Includes areas located remotely from food production and processing (i.e., outside the processing area)— Maintenance rooms, lockers/break rooms, refrigerators, doors, office areas, warehouse areas, sanitation wash rooms and loading docks.

Zones 2 to 4 are routinely monitored by many facilities to prevent product contamination and often include specific tests for Listeria and Salmonella. Zone 2 usually has the greatest potential to spread pathogens to Zone 1. Carefully monitored sanitation and verification processes can help mitigate risk of product contamination and minimize/control the levels of pathogens present. With regards to the frequency of sampling, there are no set rules and standards. Often, testing in zones 2 to 4 is done weekly, while ATP monitoring testing is done in zone 1 before a line is released for production. However, different facilities must establish best practices based on their custom needs based on product type, processing conditions, and plant layout.

Sampling Sites

Areas can be sampled in several ways: contact plates, swabs and wipes, direct surface agar plating or rinsing and vacuum collection. No matter what process is used, there are basic protocols to follow. First, work outward from zone 1 to zone 4. Be sure your hands are clean and wear gloves for sampling. Be sure to submit a negative control swab for comparison and transport samples at temperatures under 8 °C and ensure testing occurs within 48 hours of collection or refrigerate samples. It is also critical to establish the proper cadence for testing and the number of samples to collect per zone. Two of the most common weaknesses in EMPs is the lack of sufficient samples, either per sampling event or from not sampling often enough. Not taking sufficient samples frequently enough defeats the purpose of an EMP and puts your product at risk. The second weakness to avoid is not having an action plan for positive results and following it – this is an expectation that must be implemented or auditors will intervene.

Initially, sampling must be done at high levels (25-50 swabs/zone/day for a month). Following this, sampling can be reduced to weekly or even monthly in zone 4. Over time, this data will be used to establish and refine baselines and review action levels. It is best to collect and review six to twelve months of data to identify trends and determine the ideal baseline and action levels. Of course, these values will vary for each facility and each zone. The baselines can then be used to define trends based on products, facilities, sanitizer changes, maintenance changes, and other possible sources of fluctuation. Any noted deviations can be identified and addressed immediately. Corrective actions will need to be put into place to bring values back to baseline levels and verify processes are staying in control. Often, monitoring for indicator organisms is done to measure how controlled the EMP is and that all SSOPs are being executed properly.

Environmental monitoring program and sampling plan

Sampling Sites	Where to sample?	Frequency of testing	What to look for
Zone 1	**Product contact site:** racks, conveyors, utensils, work tables, packing stations	Weekly	Total plate count, coliforms, yeast and molds, *enterobacteriaceae*
Zone 2	**Adjacent to Zone 1:** equipment framework, maintenance tools, drip shields, housings	Weekly	Total plate count, coliforms, yeast and molds, *enterobacteriaceae, Listeria* spp., and *Salmonella* spp.
Zone 3	**Further from Zone 1:** wall, floors, ceilings, sinks, hoses, drains, forklifts, finished product storage areas	Weekly	Total plate count, coliforms, yeast and molds, *Listeria* spp., and *Salmonella* spp.
Zone 4	**Outside the process area:** maintenance rooms, break rooms, warehouse areas, loading docks	Monthly	Total plate count, coliforms, yeast and molds, *enterobacteriaceae, Listeria* spp., and *Salmonella* spp.

It is recommended that food manufacturing facilities customize their EMPs after careful evaluation of microbial risks associated with their products and in compliance with the regulatory guidance/standards. The sampling frequency, type of indicator microorganism, and number of samples per zone can be modified after reviewing the results and assessing the effectiveness of corrective actions.

Not taking sufficient samples frequently enough defeats the purpose of an EMP and puts your product at risk.

Use of Indicator Organisms

Why use indicator organism testing? Indicator organisms are typically present in food or the environment and are not pathogenic. Therefore, they can be used to assess the cleaning and sanitation processes in place within a facility. Generally, zone 1 is routinely tested for indicator organisms while other zones may be tested for both indicators and pathogens. Indicator organisms are chosen and added to an EMP for the following reasons:

- Indicator organisms are less expensive and save time compared to pathogens.
- Low level presence of pathogens limits the practicality of performing pathogen testing.
- Indicator organisms are often present in high numbers, so easily enumerated.
- Indicator organisms have similar growth properties and requirements as pathogens, so easy to propagate under normal environmental conditions.
- Indicator organisms are non-pathogenic, so they pose no risk to containments facilities/labs that analyze samples.

While not a substitute for pathogen testing, they can help trend the maintenance of proper cleaning within facility zones and quickly identify potential issues. This allows for pinpointing the source of potential contamination so thorough cleaning can be done and the site retested to ensure all potential pathogens have been removed. Examples of some of the indicator microorganisms that can be used to monitor hygienic conditions are total aerobic plate count, total coliforms, fecal coliforms, and *Enterococcus* spp. of fecal origin.

Level of Detection

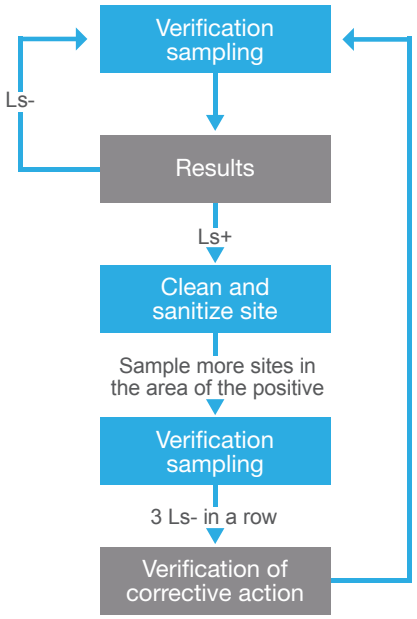
In addition to testing for the presence of indicator organisms, it is often critical to understand the level of contamination. This may be important in situations where pathogens are present in very low levels as regulations often allow these levels of some organisms in food products (example, the FDA allows *E. coli* in tree nuts at <0.36/gram). In addition, zone 1 data can be used to evaluate sanitation programs – as levels can be quantified in CFUs post-cleaning and compared to acceptable limits. Also, some facilities process carcasses where a positive on one carcass is much different than contamination across multiple carcasses. The former allows isolation of the issue to a restricted zone while the latter risks discarding an entire processing line of meat. There are also requirements for quantifying levels on *Listeria* in RTE food products, and Quantitation also aids in root cause determination and understanding how well sanitation efforts are working in any given zone or facility.

Quantitative Results

Two options commonly used for quantitative testing are most probable number (MPN) and direct plating. Other methods offering quantitation include PCR but are not used as often. MPN is a traditional enrichment-based analysis where a series of dilutions are performed from a single sample homogenate. Tests are often done in triplicate to ensure accurate results. While very sensitive, this testing method is very resource intensive and expensive but works for detecting low levels of common pathogens such as *Salmonella, E. coli* O157:H7, and *Listeria* monocytogenes. Direct plating, on the other hand, involves homogenizing a sample in diluent and then removing a small volume for plating. This method, while relatively inexpensive, has a higher limit of detection so is not suitable for detection low levels of pathogens. However, it can easily be used for indicator organism testing or for detecting rapidly growing pathogens such as *Campylobacter, S. aureus, C. perfringens,* or *B. cereus*. PCR (and other rapid methods) have many advantages including increased sensitivity and speed of detection, and identification of microorganisms from numerous and varied sample matrices. Compared with MPN and direct plating, the detection time required for the assay can be reduced from days or weeks to hours. In addition, these methods are particularly applicable to target organisms expected to be present in low numbers.

Documentation

No matter what results are obtained or what method is used, documentation is essential. First, testing methods must be validated; and sensitivity, sensitivity and limit of detection data documented to ensure consistent, accurate and reliable results. Additional record keeping includes having written, detailed procedures and methods for EMP; training records; pre-operation inspection logs and all collected data from swabbing, plating and monitoring including date, location, and person conducting the testing. All information must be easily accessible, legible, dated and signed, and available for review upon request. In addition, any corrective action records and hold/release records must be documented and retained for future audits or reference. There must be evidence of immediate actions upon identification of pathogens.



Summary

Implementing an effective EMP ensures each facility has an “early warning system” for the detection of potential issues in the food manufacture and processing systems. In addition, it can measure the performance of the overall food safety program, using data-based information to demonstrate the cleanliness of the facility. It ensures sanitary design, personnel practices, and operational methods are in control and validated. It shows regulators, auditors, and customers that you are committed to food safety and in protecting the brand being produced.

Product Solutions

Throughout the development and implementation of an EMP, there are many steps where rapid, accurate, validated testing is essential to maximizing the food safety program. Hygiena® offers solutions for each step in the process.

Once a facility is ready and an EMP created, each zone can be cleaned and swabbed to determine the presence of either indicator organism or pathogens. One validated test to consider is the **UltraSnap®** surface ATP testing device. When paired with the **EnSURE® Touch** system, not only can it rapidly determine if areas pass for "clean" (10 seconds), it can also help you map out testing locations within the facility and send data to a cloud-based software, **SureTrend® Cloud**, for review, analysis, and trending. Some advantages of this system are EnSURE Touch is certified by AOAC-RI's *Performance Tested Method*℠ program, demonstrating the system's sensitivity, reliability and robust operation. In addition, the relationship between the ATP levels and the RLU are linear, making it easy to interpret and compare results from multiple testing sites. (For additional information on ATP testing as part of an EMP, please refer to our Guide to ATP Hygiene Monitoring).

Beyond ATP testing, Hygiena also offers other rapid tests which can be read on the EnSURE Touch luminometer. **SuperSnap®** devices detects extremely low levels of ATP so it can be used as an allergen cross-contamination prevention tools or when dealing with harsh samples. **MicroSnap®** devices detect and enumerate indicator organisms that may be present on any surface. MicroSnap tests are available for coliforms, *E. coli, Enterobacteriaceae* or total viable counts with results available the same shift.

SureTrend®

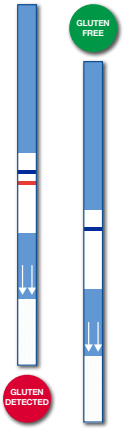
Clean & Rinse → Swab → Sanitize

Product Solutions

Hygiena also provides rapid allergen testing devices. **AlerTox® Sticks** can detect allergens in raw materials, final products and from surfaces. Tests are available for egg, peanut, crustacean, hazelnut, fish, beta-lactoglobulin, casein, total milk, almond, mustard seed, soy, and walnut. Highly sensitive results can be obtained in 10 minutes or less with no cross-reactivity. A related product, **GlutenTox® Sticks Plus** can detect gluten to 3 ppm (<20 ppm is considered "gluten free") with no cross-reactivity with soy, rice or corn. For quantification, **GlutenTox® Sticks Plus for Reader** can be used to determine the level of gluten in a product from 1 – 40 ppm when paired with the **Hygiena Cube Reader**. Other options for quantitative results include **AlerTox® ELISA** assays or **GlutenTox® ELISA** assays. AlerTox ELISA assays are available for a wide range of allergens (lupine, sesame, mustard, cashew, soy, walnut, peanut, hazelnut, almond, coconut, pistachio, macadamia, egg, lysozyme, ovalbumin, casein, milk, beta-lactoglobulin, crustacean and fish). GlutenTox ELISA tests have been validation for a wide range of hydrolyzed samples and food matrices, with no-cross reactivity and very low limits of detection and wide quantification ranges (up to 200 ppm of gluten) with results in 1.5 hours.

Hygiena also offers a variety of rapid pathogen tests. **InSite™ *Listeria*** is designed for all *Listeria* species while **InSite™ *L. mono* Glo** is specific for *Listeria* monocytogenes. **InSite™ *Salmonella*** detects the presence of *Salmonella* species. All these tests are self-contained, provide results in 24-48 hours and contain a chromogenic media formulation to make interpretation of results easy. No additional equipment is required – only an incubator.

AlerTox® Sticks



GlutenTox® Sticks

Hygiena Cube

Product Solutions

For more advanced testing, Hygiena offers the **BAX® System** for PCR testing for pathogens. Both standard and real-time PCR assays are available for a variety of organisms: *Salmonella, E. coli* (including *E. coli* O157:H7 and STEC), *Listeria* (including *L. mono*), and *Campylobacter, Shigella, Vibrio, Cronobacter, Staphylococcus,* and Yeast and Mold. Tests are extremely accurate and validated on a multitude of food matrices. In addition, Hygiena has pioneering real-time PCR Quantification with the **BAX® System SalQuant™** assay, providing yes or no results in as little as 13 hours and flexible protocols to meet any unique workflow needs.

An additional test that can be used to evaluate final product is Hygiena's **Innovate System**. Designed specifically for the dairy and beverage industries, the Innovate System allows manufacturers to rapidly confirm the quality of the final product. With actionable results in 30 minutes for up to 96 samples, the Innovate System helps reduce production cycle times, inventory requirements and warehouse space costs and provides earlier notification in the event of a contamination.

Conclusions

An effective EMP is essential to ensure food safety in any facility or manufacturing site. When implemented and controlled properly, it is essentially an "early warning system" for microbial contamination and can identify issues at any step in the manufacturing process.

From the time raw material enters a facility to the shipment of final product, Hygiena tests can help ensure food is safe for use in manufacture and for consumer consumption. Knowing results sooner reduces facility costs overall, meaning more profits for any manufacturer. In addition, accurate, rapid results mean less recalls, reducing costs further and strengthening the product's brand in the marketplace.