MERIEUX NutriSciences

ENVIRONMENTAL MONITORING PROGRAMS:

A COMPREHENSIVE GUIDE FOR THE PET FOOD INDUSTRY

The Ultimate Goal of the Environmental Monitoring Program

The goal of a well-designed Environmental Monitoring Program (EMP) is to provide an efficient proactive risk reduction tool to protect products from environmental contamination. The pet food industry has found that an aggressive approach, often called "seek and destroy" is necessary. The EMP is not meant to be a checklist but a road map to controlling pathogens in pet food manufacturing sites.

A well-designed EMP needs to be much more than just a schedule for routine monitoring. It must also include in-depth investigational sampling when the routine program indicates a problem, and corrective action that attacks the root cause and provides lasting future protection. It should also be designed to find pathogens when they are still far away from the finished product, allowing correction before the product is contaminated.

EMP can be used as a verification of the effectiveness of sanitation, sanitary design, employee practices and other Good Manufacturing Practices (GMP). It is also used to monitor the environment for transient pathogens and to find or predict harborage sites or growth niches in the facility and equipment.

EMP needs to be customized for every facility and product type, it should be risk based, and be built to consider pathogen finding as a win, because these findings can illuminate issues that can be corrected to reduce the overall risk.

Notable Recall due to Poor EMP

An in-depth look at an outbreak of *Salmonella* in 2012 linked to dry dog food production.

49 cases of *Salmonella* Infantis in US and Canada with more than 10 cases hospitalized.

30,000 tons of product implicated

FDA investigation found:

- Post-extruder additions (fat and digest) not tested or controlled
- No hand wash stations or sanitizer where people handled product
- Conveyor paddles damaged and had product build-up (post-extrusion)
- Non-cleanable surfaces in close proximity to finished product (post-extrusion)

Risk Assessments

Risk assessments should be conducted using a multidisciplinary team approach. This would be a cross-functional team that can provide valuable information as to site selection, frequency and implementation solutions for the development of an EMP.

The risk assessment team should consider all aspects of the pet food manufacturing process, including:

- Validated pathogen reduction steps
- Ingredients
- Packaging materials
- Equipment
- Rework
- Personnel

These team members should include a representative from:

- Maintenance / Sanitation
- Quality Assurance
- Quality Control
- Production
- Engineering

Any unusual event that has occurred or will occur should be considered as to what impact it will have on the environment with respect to pathogen contamination.

The team should interview as many employees as needed to gain a comprehensive picture of all potential risks.

Trade associations, published literature, government guidance, and expert consultants can be used to expand the scope of the risk assessment and improve its effectiveness.

Risk Assessment Considerations: Pet Food Connected to Human

Direct

- GFSI found in a study that 30% of people making under $30,000 year supplement their diet with pet food
- The risk of infants and toddlers eating from a pet's bowl
- People may handle pet food, then handle human food

Indirect

- Pets can harbor and shed *Salmonella* with and without showing any symptoms

Not just *Salmonella* anymore

- Recalls performed for pet food or treats have been linked to *Listeria monocytogenes*

Where to Sample

A well-designed EMP will include samples from various areas throughout the production process. The simplest way to organize your sampling program is through the use of zones.

Multiple sampling sites from each zone should be determined before you begin taking samples based on your specific facility design and processes. If the final number of sampling sites in a zone exceeds number that is practical to sample within a single sampling session, you can rotate sites to increase coverage in a particular zone.

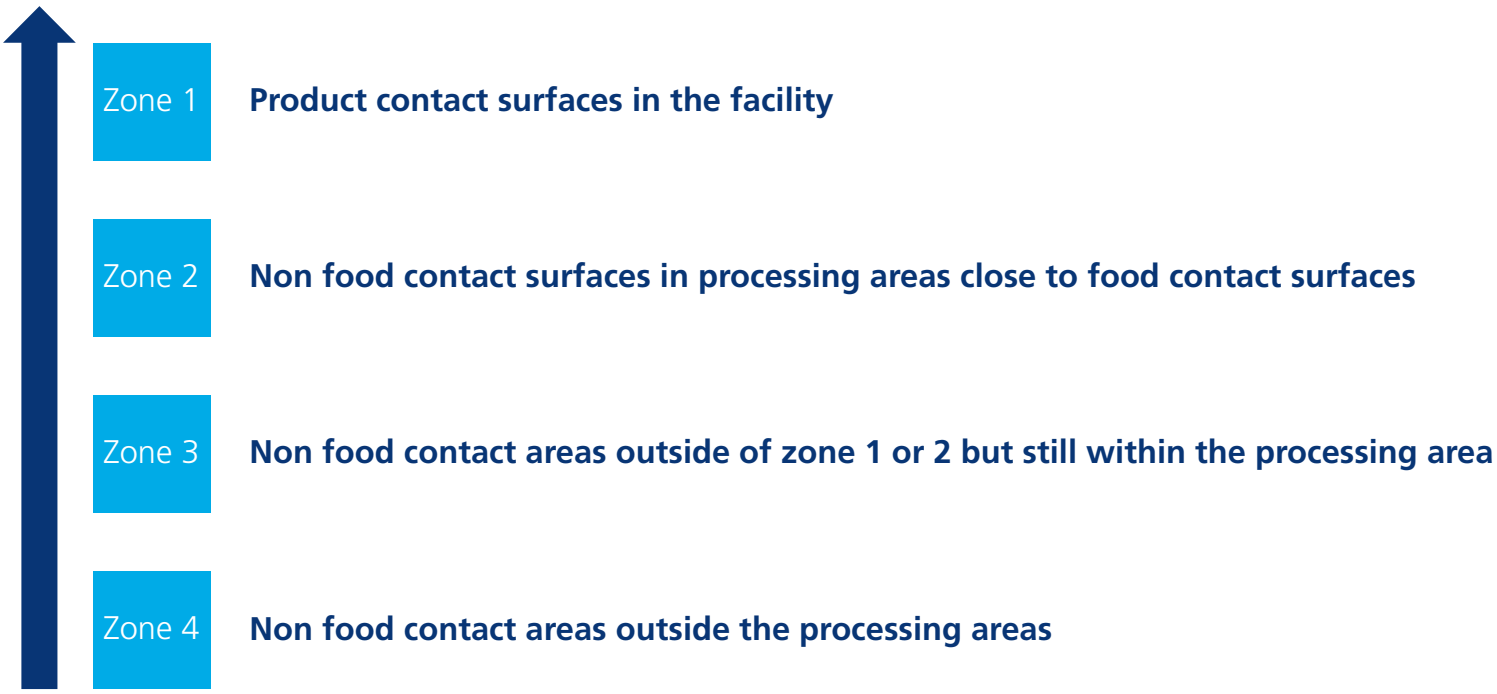
A risk-based EMP targets the highest risk area for the most sampling. This high-risk area is typically the area after a pathogen kill or reduction step, and before product is sealed in its final packaging.

High Risk Zone Example

In a pet food manufacturing operation, where *Salmonella* is the primary environmental pathogen of concern, the highest risk area would be from the area from where exposed product exits the extrutor, then cools until it is sealed in the package.

Zones 1 – 3 sites in this area should be identified, with a heavy emphasis on sampling zone 2 and 3 sites, with fewer but still very important samples pulled from Zone 1 sites.

An Efficient EMP



Zone Action Items Summary

Zone	Locations	Tests	Frequency of Testing	Minimum # of Samples
Zone 1	Tables, conveyor belts, buckets, fillers, hoppers, utensils, employee hands and gloves, items and surfaces directly over or in close proximity to direct food contact surfaces such as lights fixtures and piping, compressed air lines, and water filters.	Pathogens and indicator bacteria (product dependent)	Weekly	Dependant on line complexity
Zone 2	Equipment frames, drip shields and pans, control panels and buttons, overhead fixtures and piping not directly over or in close proximity to food contact surfaces, computer screens, maintenance tools.	Pathogens and indicator bacteria	Weekly	10 to 15
Zone 3	Floors, walls, ceilings, drains, hoses, cleaning equipment including brooms and brushes, air handling units, condensate drip pans, carts, pallets, forklifts, trash cans, foot baths, sink area including soap and towel dispensers.	Pathogens and indicator bacteria (product dependent)	Weekly	Dependant on line complexity
Zone 4	Bathrooms, locker rooms, cafeteria and break rooms, office rooms, hallways, warehouse, loading docks, maintenance shop, storage areas.	Indicator bacteria	Monthly	NA

10 Basic Steps on How to Sample

1. Label sample bags using a separate code for each sampling site
2. Wash, dry, and sanitize hands
3. Aseptically glove hands
4. Aseptically remove sponge or sampling tool
5. Swab area with sponge using steady pressure
6. Aseptically replace sponge in bag and seal
7. Sanitize sampling site
8. Wash hands and replace gloves between sampling sites
9. Do a negative control by aseptically removing a sponge and replacing back into the bag and seal. Code this bag similar to other samples
10. Within 24 hours send samples to the laboratory in a clean container with ice packs such that sample temperature does not exceed 45˚F

LEARN EVERYTHING YOU NEED TO KNOW ABOUT SURFACE SAMPLING IN OUR

EMP SWAB INSTRUCTIONS GUIDE

See the Guide

Sampling Schemes

Sampling schemes should be defined according to the objectives. We distinguish 3 levels of sampling plans that need to be initially formalized in your quality system:

Level 1: Standard Sampling Plan

The standard sampling plan objective is to detect, with the highest sensitivity, any loss of process control regarding potential pathogen contamination in the environment.

You need to identify the most relevant sampling points according to your risk assessment, and review historical data (historical positivity can help select the relevant points). When a full list of the relevant sampling points are defined you can define the frequency of sampling.

Level 2: Reinforced Sampling Plan

The reinforced sampling plan objective is to reinforce the standard sampling plan when a risk factor appears. If a risk factor appears, sampling should be performed to check if the risk factor was exposed to contamination.

Example

If construction or new equipment is introduced, the frequency of sampling in the area should be reinforced and repeated until effective validation of maintained hygiene is achieved.

Such reinforced sampling plans should be predefined according to the most probable risk factors linked to the facility and the process.

Level 3: Investigational Sampling Plan

The investigational sampling plan objective is to identify the root cause of a contamination. For example - a positive pathogen result on the final product or on pet food contact surfaces.

In this case, the most efficient approach is to systematically sample the full reinforced sampling plan in an enlarged perimeter.

Example

When a zone 2 sample reveals a positive, an investigation should lead to:

- Sampling Zone 3+4 to discover where it came from
- Sampling Zone 2+1 to understand any consequences on zone 2 and 1 with repetitions

The team should consider all process data to identify specific risks and carefully review all results globally to better prescribe specific samplings where needed to demonstrate the contamination route (vectoring).

The key is the repetition of sampling for root cause analysis followed by sampling for corrective action validation.

INVESTIGATION
Equipment Sampling

Equipment sampling, requiring special investigations, is typically conducted during downtime or during sanitation shift. It usually occurs on third-shift or a weekend to limit operational downtime.

Equipment disassembly is needed to properly determine the possible root cause of product contamination. Contaminants are often found located deep within the equipment and can be the result of improper equipment design and/or lack of deep cleaning. The tear down of equipment during an investigation needs to be very granular - down to literally nuts, bolts, and washers. These areas provide excellent harborage areas for environmental pathogens like *Listeria monocytogenes* and *Salmonella*.

Normal and routine sanitation practices may not reach as deep into the equipment as the pet food, water, and pathogens. Deep cleans should be conducted by the plant at a set frequency.

Equipment modifications to better accommodate production schedules are good, however, they must be reviewed by the EMP team so that product will not be compromised in any way. Modifications made for operational efficiency can create an unintentional potential pathogen growth niche.

INVESTIGATION
Traffic Patterns

Traffic Patterns should be considered during an investigation as they may show some interesting scenarios.

This is where a team approach becomes important. Understanding where and how people, ingredients, tools, forklifts, contractors etc. move around and through a pet food production area is imperative to understanding and ultimately solving any findings.

Example: Roof Access

Determining how roofs are accessed can point to a root cause for how an environmental pathogen may gain entry into the facility, and finally into the production lines.

Questions to investigate for roof access:

- Who has access to the roof?
- Are shoes changed prior to entering and exiting the roof and if so, how?
- Are environmental samples taken at the roof access points and how often?
- Are coverings for uniforms worn when working on the roof?
- Do these people have free access to areas where exposed product, packaging, ingredients may become contaminated?
- Are other mitigation strategies implemented that prevent such product contaminations?
- Are potentially contaminated equipment or roofing materials carried back through the plant or bagged and dropped from the roof to the ground?

These are just very brief examples of the types of questions and approaches that an investigator needs to be comfortable with asking when on site and investigating.

It is also important to ask questions about any unusual occurrences or activities that may have happened prior to a contamination event. For example, were there any construction or repair activity, new employees, a big increase in production, storms, power outages, pest findings, roof leaks, or anything else outside of normal operations?

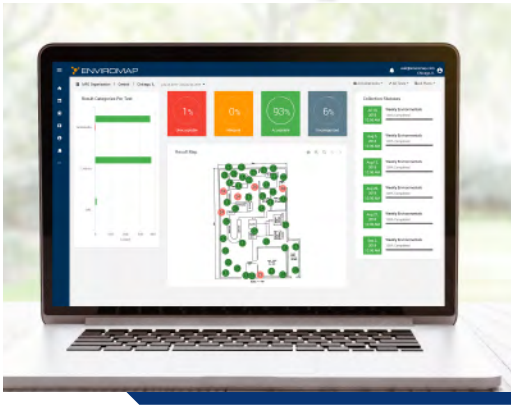
Data Management and Trend Analysis

Data generated must be accurate and reliable. At least once per year, there should be a thorough review of how the swab data is collected, stored, and analyzed.

In addition, a review of the lab procedures, technician competencies, and types of swabs, sponges, and tools used for the EMP program should be done by a subject matter expert.

The company is depending on the data generated to make sound decisions, and proper attention and review are needed during this entire process.

The success of the EMP is efficient data management to allow for real-time actions in case of a positive result, and relevant long term improvement. In order to have relevant interpretation you need reliable information.



Each sampling point should be very carefully defined and registered. Circumstances of sampling should also be well documented. A list of key information to be mentioned:

- Room
- Equipment
- Surface
- Zoning area (1, 2, 3, 4…)
- Day
- Hour
- Status of the surface (after cleaning, in process)
- Status of the equipment: (stopped, dismantled)
- Specific risk factor (after maintenance intervention)
- Who did the sampling and how the sampling was done (swabbing with a sponge)

Efficient data management will need short term actions in case of a postivie result, including application of mitigation plans with reinforced or investigational sampling plans with communication to all actors for the corrective action plans (sanitation, maintenance, operation, QA/QC, etc.).

In order to evaluate a gradual loss of control or recurrence of contaminations, a systematic trend analysis is necessary.

Classical tools to be used are Statistical Process Control, with moving windows approached preferably with quantitative data such as enterobacteriaceae monitoring in dry process areas, or prevalence calculations for qualitative data such as *Listeria* spp in zone 3.

Proper data management needs predefined target values and mitigation plans in case of nonconformities. In order to achieve efficient data management, a digital solution can be very useful to take care of the full set of sampling plans, from sampling and mitigation plans to data utilization and corrective actions.

Corrective Actions

In order to target the proper corrective actions, it's key to conduct an efficient root cause analysis by a cross-functional team to determine if the positive environmental samples are from a transient source or from a growth niche. All systems, processes and data should be reviewed. In certain cases, increasing investigational swabbing and expanding on the root cause assessment to the entire product stream path can be necessary. This may also include rewriting SOP, SSOP, policies, procedures, as well as pet food safety and HACCP plans.

As an example, the following page can serve as a partial checklist in conducting a root cause analysis in case of contamination

ROOT CAUSE ANALYSIS CHECKLIST

DATE _____

- [ ] Personnel changes, GMP violations, employee intervention
- [ ] Increase percentage rate around a certain area or equipment
- [ ] Repeat positives on sites that were positive before
- [ ] Supplier/Ingredient changes
- [ ] Equipment modifications
- [ ] New equipment
- [ ] Similar issues at another plant and root cause identified
- [ ] Construction activities
- [ ] Modifications or changes in sanitation practices, chemical used and usage
- [ ] Process changes
- [ ] Exceeding capacity of production
- [ ] Many pre-operational positive swab failures
- [ ] Surrounding plant location or environment
- [ ] Used equipment purchases
- [ ] Inability to perform deep cleaning activities when required
- [ ] Pest Infestation
- [ ] Improper sanitary design
- [ ] Roof leaks as well as roof access restriction to and from production.
- [ ] Traffic flow, employee, product, materials and contractor/ maintenance activities
- [ ] Drain directional flow and functionality
- [ ] New Limit access to area
- [ ] Re swab positive area and surroundings to determine if contamination is localized or spread
- [ ] Clean and sanitize all equipment, surfaces, and tools in area
- [ ] Conduct pre-operational inspection and re swab
- [ ] Do not restart operations until all tests are negative
- [ ] Document corrective actions and consider SOP to prevent re-occurrence
- [ ] Increase frequency of sampling from weekly to daily
- [ ] After 3 consecutive days of negative results normal sampling may resume
- [ ] If problem persists, consider removal of contaminated equipment and replace or redesign

TEAR HERE

Key Take-Aways

1. **A well-designed EMP can be a very effective tool for reducing the risk for environmental pathogen contamination.**

2. **The EMP needs to begin with a thorough risk assessment conducted by a multidisciplinary team.**

3. **The best, most predictive sites must be chosen for each production area of the facility for each of the sampling zones.**

4. **Data should be carefully generated, evaluated, and documented.**

5. **Proper investigation and corrective actions need to be planned before they are needed, and if needed, need to be aggressively pursued.**

When all these pieces of an EMP are in place and properly executed, product, reputation and public health will be protected from environmental pathogens.