Environmental Monitoring Programs

ΓΚΙΩΝΗΣ ΝΊΚΟΣ

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FOOD SAFETY:TOP PRIORITY

- Food processing environment plays an important role
- Microorganisms can enter food processing environment through different routes
- Good Hygienic Practice is critical to achieve food safety (ICMSF)
- Each year foodborne illness outbreaks affect millions of people & kill thousands in the US

ICMSF: International Commission on Microbiological Specifications for Foods

WHY DO WE NEED AN EMP?

- Foodborne illness outbreaks often result from poor hygiene practices
- Post-lethality recontamination remains a serious concern
- It is critical to monitor hygienic environment
- To achieve this we need an EMP

WHY DO WE NEED AN EMP?

- EMP measures the overall effectiveness of:
  - Sanitary design
  - Personnel practices
  - Operational methods
- Verifies cleaning and sanitizing procedures are adequate
- Assesses the risks posed by pathogen of concern
- Acts as an early warning tool

WHEN IS AN EMP DEFINITELY NECESSARY?

- A facility, as appropriate to the facility, the food, and the nature of

the preventive control, must conduct environmental monitoring

and product testing if:

  - Ready-to-eat (RTE) food product is exposed to the environment before it is packaged
  - Packaged food does not receive a treatment that would significantly minimize an environmental pathogen

WHICH ARE THE LEGISLATION REQUIREMENTS?

- Food business operators manufacturing **ready-to-eat foods, which may pose a Listeria monocytogenes** risk for public health, shall **sample the processing areas and equipment** for Listeria monocytogenes as part of their sampling scheme.
- Food business operators manufacturing **dried infant formulae or dried foods for special medical purposes** intended for infants below six months which pose an **Enterobacter sakazakii risk** shall monitor the **processing areas and equipment** for Enterobacteriaceae as part of their sampling scheme.
- Commission Regulation 2073/2005

DESIGNING AN EMP

1. EMP Team
2. Zoning Concept
3. Indicator Bacteria
4. Sampling & Frequency
5. Labelling & Shipping
6. Baseline Target
7. Verification
8. Product Testing
9. Corrective Actions
10. Documentation

STEP 1: CREATE AN EMP TEAM

- Bring together individuals familiar with the operation to form an "EMP team"
- Choose a "team leader"
- Examples of team include:
  - Plant quality manager
  - Plant or corporate microbiologist
  - Line supervisors or operators
  - Sanitation supervisors or workers
  - Plant engineer

STEP 1: CREATE AN EMP TEAM

- Walk through the plant to identify areas where the product may be vulnerable to contamination
- Using facility map, mark the hygienic zones
- Identify specific sampling sites

STEP 2: UTILIZE THE ZONING CONCEPT

- To identify sampling points, the best practice is to use the zoning concept
- Based on the sanitary zoning concept, the facility operations are divided into four zones

STEP 2: UTILIZE THE ZONING CONCEPT

Zone 1

- All direct food contact surfaces in the plant (blenders, conveyors,utensils, work tables, etc.)
- Zone 1 is the most sensitive to contamination
- It is recommended not to swab for pathogens in zone 1 environment
- Total percentage of testing from zone 1 is normally 10-20%

STEP 2: UTILIZE THE ZONING CONCEPT

Zone 2

- Non-food contact areas in the plant that are closely adjacent to food contact surfaces (equipment frame, maintenance tools, drip shields, chain-guard housings, etc.)
- Area in which environmental contamination is most likely to affect the safety of the product
- Total percentage of testing from zone 2 is normally 40-50%

STEP 2: UTILIZE THE ZONING CONCEPT

Zone 3

- Non-food contact surfaces that are not close to zone 1 surfaces (walls, floors, drains, ceilings, pallets, etc.)
- If zone 3 is contaminated with a pathogen, it could lead to contamination of zone 2
- Total percentage of testing from zone 3 would be around 30-40%

STEP 2: UTILIZE THE ZONING CONCEPT

Zone 4

- Refers to the areas remote from the product processing areas (employee break area, office area, maintenance room, etc.)
- If zone 4 is not maintained in a good hygienic condition, it can lead to cross-contamination of zones 3, 2, and 1
- Percentage of testing from zone 4 will be <10%

STEP 3: INDICATOR BACTERIA/MICROORGANISM

Why indicator microorganisms?

- High number and easy to enumerate
- Positive indicator means possible contamination and a risk of foodborne disease
- Total aerobic plate count, total coliforms, E. coli biotype I counts, fecal coliforms, and Enterococcus spp. of fecal origin (NACMCF)

NACMCF: National Advisory Committee on Microbiological Criteria For Foods

STEP 3: INDICATOR BACTERIA/MICROORGANISM

Examples:

- Wet processes/environments
  - Pathogen of concern: Listeria monocytogenes
  - Indicator: Listeria spp.
- Dry products & processes
  - Pathogen of concern: Salmonella
  - Indicators: Enterobacteriaceae

STEP 4: SAMPLING & SAMPLING FREQUENCIES

- Cover all potential sites within a defined period of time (e.g., one month)

- Test both FCS and non-FCS sites at each sampling time
  - Example: Smallest processors collect samples from at least 5 sites of FCS and 5 sites of non-FCS on each production line (FDA 2017)

FCS: Food Contact Surface

TIMING/FREQUENCY FOR COLLECTING ENVIRONMENTAL SAMPLES

- Several hours into production or preferably just prior to cleanup (FDA 2017)
- Do not take swab samples too close to the time when surfaces have been sanitized

TIMING/FREQUENCY FOR COLLECTING ENVIRONMENTAL SAMPLES

- Frequency of routine sampling should be based on risk
  - RTE foods that do not support growth of Lm: Lowest frequency (e.g., monthly)
  - RTE foods that support growth of Lm: Highest frequency (e.g., weekly)

EMP SAMPLING TOOLS/TECHNIQUES

- Tools/techniques

  - Swab (Sponge-stick)
  - Air sampling
  - Petri plate/RODAC plates, Petrifilm
  - Water/liquid samples
  - ATP Bio luminescence, etc.

(RODAC = Replicate Organism Detection And Counting)

STEP 5: LABELING AND SHIPPING

- Date, time, and shift sample taken
- Location
- Product size
- Testing requested
- Date submitted to laboratory
  - Transport samples < 4°C
  - Test ≤ 48 hours

LABORATORY TESTING OF SWAB SAMPLES

- Analyze samples in-house or at an outside laboratory
- Implement a scientifically valid EMP (FDA 2017)
- Sampling methods and the analytical testing of samples should be consistent with:
  - FDA's Bacteriological Analytical Manual (BAM)
  - ICMSF
  - American Public Health Association (APHA)

STEP 6: ESTABLISHING A BASELINE/TARGET

- Use historical results (e.g., previous year data) and regulatory guidelines to establish a baseline
- E.g., A site may test <50 cfu for a year with two spike readings, then 50 cfu would be set as baseline. *Example below (for demonstration only, it is not a recommendation):*

Indicator	Action Levels	Before Sanitation	After Sanitation
APC or TPC	Target	< 100	< 10
	Acceptable	< 500	< 100
	Un - acceptable	> 500	> 100
Total Coliforms	Target	< 10	< 10
	Acceptable	< 100	< 50
	Un - acceptable	> 100	> 50

Indicators in environmental samples indicate a deviation of sanitary standards

STEP 7: PRODUCT TESTING

- Product testing is a verification activity

- Finished product testing as sole means of controlling microbiological hazards is not a good strategy

STEP 8: CORRECTIVE ACTIONS FOR POSITIVE RESULTS

- Reassemble your team
- Initiate root cause investigation
- Use team's findings to improve operations such as:
  - Increase cleaning and sanitation frequencies
  - Repairs
  - Employee traffic patterns
  - Increase the swab frequencies
  - Verify the effectiveness
  - Monitor

CORRECTIVE ACTIONS - ZONE I

- Product should always be placed on hold if zone 1 *Salmonella* testing is to be done
- Quarantine the suspect area and limit access to that area
- Break down the line from the initial positive site on for visual inspection, additional vector sponge/swab sampling, and cleaning and sanitation activities
- Conduct vector sampling in zones 1, 2, and 3 around the area of the initial positive result prior to cleaning. Precaution should be taken not to spread contamination to other areas of the plant
- Thoroughly clean and sanitize the line and surrounding area using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments
- Conduct pre-operational inspections on the line equipment and area prior to start-up and take additional vector samples of the area prior to start-up. It is highly advisable not to start-up the line until all vector sampling results are obtained (if the line is started prior to obtaining all vector sampling results, then product must be put on hold until negative results are obtained)

CORRECTIVE ACTIONS - ZONE I

- Increase the frequency of intensive sampling of the line and adjacent areas from weekly to daily (zones 1 – 3). After three consecutive days of negatives are obtained, the normal routine PEM sampling plan may be reinstituted
- The response team should make a careful decision on disposition of finished product that is put on hold as a result of a zone 1 positive Salmonella finding. All finished product from full microbiological clean-up/sanitation to full microbiological clean-up/sanitation must be addressed by the team. Product should be re-worked, if possible, or condemned according to all legal and regulatory statutes. It is not an acceptable practice to test lots of finished product for Salmonella in response to a confirmed zone 1 result for the purposes of releasing product.

CORRECTIVE ACTIONS - ZONE II

- Stop production and prepare the system for cleaning and sanitation
- Quarantine the suspect area and limit access to that area
- Break down the line from the initial positive site on for visual inspection, additional vector sponge/swab sampling, and cleaning and sanitation activities
- Conduct vector sampling in zones 2, and 3 around the area of the initial positive result prior to cleaning. Precaution should be taken not to spread contamination to other areas of the plant
- Thoroughly clean and sanitize the line and surrounding area using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments
- Conduct pre-operational inspections on the line equipment and area prior to start-up and take additional vector samples of the area prior to start-up. Do not restart the line until satisfactory vector swab results have been obtained.
- Increase the frequency of intensive sampling of the line and adjacent areas from weekly to daily (zones 2, 3). After three consecutive days of negatives are obtained, the normal routine PEM sampling plan may be reinstituted

CORRECTIVE ACTIONS - ZONE III

- The response team should make the decision whether or not to stop production based on the proximity of the initial positive site to product contact areas
- Quarantine the suspect area and limit access to that area, if feasible
- Visually inspect the area and conduct additional vector sponge/swab sampling prior to cleaning and sanitation activities
- Conduct vector sampling in zones 2, and 3 around the area of the initial positive result prior to cleaning (zone 2 sampling is done to ensure that contamination has not spread closer to open product areas). Precaution should be taken not to spread contamination to other areas of the plant
- Thoroughly clean and sanitize the area (at least a 50 foot radius, if possible) using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments (47, 49)
- Conduct pre-operational inspections on the line equipment and area prior to start-up and take additional vector samples of the area prior to start-up. Do not restart the line until satisfactory vector swab results have been obtained.
- Increase the frequency of intensive sampling of the line and adjacent areas from weekly to daily (zones 2, 3). After three consecutive days of negatives are obtained, the normal routine PEMsampling plan may be reinstituted

CORRECTIVE ACTIONS - ZONE IV

- A Salmonella positive finding in a zone 4 location does not implicate finished product, but it does provide information on non-production areas and the potential for spread of contamination throughout the facility
- Quarantine the suspect area and limit access to that area, if feasible
- Visually inspect the area and conduct additional vector sponge/swab sampling prior to cleaningand sanitation activities
- Conduct vector sampling in selected zone 3 areas adjacent to the location of the initial zone 4 positive location, if appropriate, and zone 4 sites around the area of the initial positive result prior to cleaning (selected zone 3 sampling is done to ensure that contamination has not spread closer to open product areas). Precaution should be taken not to spread contamination to other areas of the plant
- Thoroughly clean and sanitize the area (at least a 50 foot radius, if possible) using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments
- Take additional vector samples of the area after cleaning and sanitation to verify effectiveness of those procedures
- Increase the frequency of intensive sampling of the areas from monthly to daily (zone 4 and selected zone 3 areas adjacent to the location of the initial zone 4 positive). After three consecutive days of negatives are obtained, the normal routine PEM sampling plan may be reinstituted.

VECTOR SWABBING

- Taking additional samples around the initial positive site
- Typically, 10-15 additional swab samples are taken in a “star burst” pattern

STEP 9:VERIFICATION

Periodically verify your written environmental monitoring procedures by increased and intensive environmental sampling of the plant to assess whether the sampling sites are appropriate (FDA 2017)

STEP 10: DOCUMENTATION

If you haven't written it, then you haven’t done it!

SUMMARY

- EMP is specific to the individual food facility
- Number of swab samples and sampling frequency should be based on risk
- Choose the right indicator bacteria
- Verify EMP periodically
- Document all the procedures, results, and corrective actions
- Environmental monitoring and product testing are verification activities

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