**Company Name Document Reference:**

**Program Document**

**Document Type: Hygienic Zoning**/**Environmental Monitoring Page: 1 of 3**

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**Hygienic Zoning (Barrier Control)**

Hygienic zoning in the production facility is important to minimize potential environmental pathogen cross-contamination. To outline the potential risk a plant “traffic flow” diagram should be mapped out showing a overview of the raw material and RTE areas depicting foot traffic, fork lift traffic, trash compactor, and pressurized air flow. Procedures shall than be developed to outline the protocol that employees follow to mitigate risk of cross contamination

All packaging and processing areas (Zone 3) are monitored from other processes (Zone 4 areas) including receiving and storage areas to mitigate cross contamination.

The primary personnel access points is equipped with foot mats, hands free wash sinks, soap, hands free towels and hand sanitizer. Personnel are trained and monitored in the application of personal hygiene (GMP’s) in zone 3 areas. GMP training includes hand washing requirements, uniform requirements.

Access or transfer points between Zone 3 and Zone 4 areas other than main personnel access point are protected by hand sanitizers and foot mats.

Areas in which zone 3 processes are conducted are only serviced by staff dedicated to that function, meaning that for an employee to transfer from a (Zone 4) to (Zone 3) area the relevant criteria needs to be met including barrier control and GMP’s.

**Environmental Monitoring Program**

|  |  |  |  |
| --- | --- | --- | --- |
| Area | Pathogen/Indicator | Target | Action Limit |
| Zone 1  Product Contact | Coliform, Yeast and Mold, ATP, and or Protein swab | <10  0 RLU Stainless Steel, <100 RLU Plastic, Rubber | >100  >100 |
| Zone 2  Environmental | Listeria | Negative | Positive |
| Zone 3  Environmental | Listeria  Salmonella | Negative  Negative | Positive  Positive |
| Zone 4  Environmental | Listeria  Salmonella | Negative  Negative | Positive  Positive |

**Recommended Frequency and Number of Samples:**

**Frequency**: Weekly

**# of swabs**: dependent upon size of facility, past history, product risk assessment, processing conditions etc.

As a note composite swab may be taken but do not recommend more than 5 per test, if a positive result is returned each location will than need to be sampled individually.

**Zone Definition**

Z-1: Product Contact Surfaces, i.e., utensil, conveyor, people, etc.

Z-2: Non-Product Contact Surfaces (near Zone 1), i.e., guides, control panels, aprons, etc.

Z-3: Other Locations within RTE/High Hygiene processing areas, i.e., table legs, floors, processing drains, etc.

Z-4: Areas Outside of Processing Rooms, i.e., doorways, walls, drains (non- processing)

* Perform more environmental tests in Zone 2, 3 or 4 to prevent food contamination on Zone 1. (Recommend 50% zone 2, 40% zone 3 and 10% zone 4) What percentage of swabs should be zone 1? All these numbers add to 100% currently?

**Corrective Actions**

For Zone 1 swabs, the swab site shall be cleaned and sanitized and re-swabbed. Sanitation personnel are notified to pay special attention to the area and update cleaning frequencies and procedures if required.

For Zone 2 to 4, the area cleaned and is re-swabbed until 3 consecutive results are negative. If two consecutive swabs are positive, vector swabbing is done to determine the root cause. Cleaning procedures need to be updated if required. Corrective criteria shall be documented.

Trending: It is best practice to use a map of your facility and display where all the environmental positive results and coliform counts are arising in a given year. Review these findings on a yearly basis at minimum and determine if there are any trends.

**Comprehensive investigation should include:**

1. Vector swabbing – collecting a minimum of 3 samples around the area to help develop hypothesis of the source.
2. Equipment review

Good Sanitary Design?

Any harborage points?

1. Review Food Safety Plan for execution flaws and modify accordingly
2. Test areas upstream from where positive was in the production area
3. Check maintenance records for modifications or repairs to major equipment
4. Interview and observe sanitation, maintenance, and production personnel for potential modifications to procedures
5. Review Traffic flow patterns, equipment layout, GMP adherence. Correct flaws and findings in the above. Document all corrections, corrective actions and observations.

Responsibility and Methods

The Operations Manager is responsible for the management of the environmental monitoring program and training of qualified individuals to deploy the program.

The methods for swabbing and submission are outlined in the swab training materials.

Environmental samples are submitted to an external accredited laboratory. Results are trended.

The environmental trend analysis is used to monitor the effectiveness of the barrier controls.

A sampling schedule is prepared that outlines all the sites to be swabbed. Some random sites are swabbed on a regular basis.

Reference: Environmental Monitoring Program Records/Trends

Traffic Flow map

Control of Listeria Monocytogenes (Guidance for the U.S. Dairy Industry) Innovation Center for U.S. Dairy

Addendum I and II

**END**