

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 an overview of the raw material and RTE areas depicting foot traffic, fork lift traffic, trash compactor, and pressurized air flow. Procedures shall then 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	Action Limit
Zone 1 Product Contact	Coliform, Yeast and Mold, ATP, and or Protein swab	>100 >100
Zone 2 Environmental	Listeria	Positive
Zone 3 Environmental	Listeria Salmonella	Positive Positive
Zone 4 Environmental	Listeria Salmonella	Positive Positive



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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 swabs may be taken but do not recommend more than 5 per test, if a positive result is returned each location will then 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)

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.

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Responsibility and Methods

The Operations Manager is responsible for the management of the environmental monitoring program. The packaging manager or other trained person is responsible for swabbing.

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

END

Date	Action	Approved By
	New Document	