Objective :

To establish a procedure to ensure that the environment in which products are processed does not pose a risk of contamination to the product.

Scope

Environmental microbiological monitoring for specific pathogens within the processing environment.

Responsibility

QA Manager/ Technician are responsible for coordinating the activities

Procedure :

Pathogens enters the plant/ facility from the following sources such as
Equipment, raw materials, vehicles, ingredients, processing aides, packing materials pest, workers, visitors etc. Once inside the facility they persist in niches and move through the facility through dust, traffic flow.

A risk assessment using FMEA is performed to assess the level of contamination at various stages in the plant and take appropriate mitigation/ control measures to ensure that the final product is safe for consumption.

The risk assessment, mitigation plan and its control measures are defined in Annexure 1.

a) An Environmental Monitoring Team is constituted to coordinate the activities of EMP as given below:

Name of Person	Designation	Role
		EMP coordinator
		Member
		Member
		Member
		Member

The pathogens under the scope of EMP are :

a) Listeria
b) Salmonella
c) Coliforms
d) Staphylococcus
e) TPC
f) Yeast and mould

Zoning the plant/ facility based on risk:

Zone 1 - Product contact surfaces such as employee hands, utensils, working tables, Inner surface of final tank, Inner surface of Pipe/hose through which oil flows for filling etc.

Zone 2 – Non product contact surfaces close to the product such as exterior of the equipment, equipment housing , etc

Zone 3 – Walls , floor, drains, phones, etc

Zone 4 – Locker room, loading dock, Pallets, Waste bins.

Sample collection for zones

Zone	Sample site	Target organism	Minimum frequency	Method	Testing
1	Employee hands, utensils, working tables, Inner surface of final tank, Inner surface of Pipe/hose through which oil flows for filling etc.	Coliforms TPC Staphylococcus	Quarterly	Indicator organisms	Outside lab
2	exterior of the equipment, equipment housing , etc	Salmonella Coliforms	Once in Six Months	Swabs	Outside lab
3	Walls Floor Drains Phones Doors	Salmonella Coliforms	Yearly	Swabs	Outside lab
4	Loading dock Waste bins Pallets	Salmonella Coliforms	yearly	Swabs	Outside lab
5	Air (Finished product packing area)	TPC	Once in Six Months	Air plates	Outside lab

Acceptance criteria

Target organism	Acceptance limit Zone wise	Cfu/ Sq. Cm
Salmonella	Zone 2, 3,4	Absent
Coli forms	Zone 1& 2 Zone 3& 4	< 10 <1000
TPC	Zone 1 Air sample	<100 <100
Staphylococcus	Zone 1	<100

Corrective actions:

The test results are documented and corrective actions are taken when the monitoring results indicate a failure to meet the control limit. This includes actions such as:

a) Cease production and quarantine the affected area (if Zone1)
b) Break down the line for inspection , swabbing and cleaning (zone 1 & 2)
c) Thorough cleaning of the site.
d) Increase the frequency of cleaning
e) modification of the equipment
f) Re inforce training etc

Review the effectiveness of Environmental Monitoring Programme:

The company reviews the environmental monitoring programme annually or whenever there is

- Changes in processing conditions, process flow
- New development in scientific information
- Product failure (products with positive test results)
- Consistently negative results

Reference
Nil
Records
Swab test reports