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FOOD SAFETY MANAGEMENT SYSTEM MANUAL

(Meeting the requirements of FSSC 22000 Version 5.1)

This manual Contains ISO 22000 FSMS requirements and also additional requirements as per FSSC 22000

COMPANY NAME
Address

Disclaimer:

The Quality Manual, Procedures, Work Instructions, Records etc are prepared to the best of our judgement and for the guidance of the users. Please note that these are prepared keeping in view the general requirements of the particular standard. The user is advised to look at his processes, products, services, customer requirements, legal and food safety regulatory requirements etc while drafting his quality manual and other related documents. The requirements are under constant revision and the user is advised to go through the standards updates etc all the time.

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PREFACE

1. Manual details the food safety management activities of ABC, which is located at -----.
2. It is prepared in line with requirements of FSSC 22000 version 5.1, and ISO 22000 FSMS - requirements. The controls of pre-requisite programs as per ISO/TS22002 part 1, 2009 requirements and FSSC additional requirements..
3. It is prepared, and controlled by under signed, who is presently holding additional responsibility of FSTL (Food safety Team leader)
4. A food safety Team is appointed to co-ordinate planning, implementation and monitoring food safety related activities.
5. The issue and control of these manual and associated procedures will be by FSTL. It is mandatory for all departments/sections to follow the requirements strictly. No part of this manual shall be copied or issued without written permission of FSTL.

CEO

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TERMS AND DEFINITIONS

TERM	DEFINITION
Acceptable Level	Level of a food safety hazard not to be exceeded in the end product provided by the organization
Action Criterion	Measurable or observable specification for the monitoring of an OPRP
Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled
Competence	ability to apply knowledge and skills to achieve intended results
Conformity	Fulfillment of a <i>requirement</i>
Contamination	Introduction or occurrence of a contaminant including a food safety hazard in a product or processing environment
Continual Improvement	Recurring activity to enhance <i>performance</i>
Control Measure	Action or activity that is essential to prevent a significant food safety hazard or reduce it to an acceptable level
Correction	Action to eliminate a detected <i>nonconformity</i>
Corrective Action	Action to eliminate the cause of a nonconformity and to prevent recurrence
Critical Control Point (CCP)	Step in the process at which control measure are applied to prevent or reduce a significant food safety hazard to an Acceptable level, and defined critical limit(s) and measurement enable the application of corrections
Critical Limit	measurable value which separates acceptability from unacceptability

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Documented Information	Information required to be controlled and maintained by an organization and the medium on which it is contained
Effectiveness	Extent to which planned activities are realized and planned results achieved
End Product	Product that will undergo no further processing or transformation by the organization
Feed	Single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to food-producing animals
Flow Diagram	Schematic and systematic presentation of the sequence and interactions of steps in the process
Food	Substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances (ingredients) used only as drugs
Animal Food	Single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to non-food-producing animals
Food Chain	Sequence of the stages in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption
Food Safety	Assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use

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Food Safety Hazard	biological, chemical or physical agent in food with the potential to cause an adverse health effect
Interested Party (preferred term)/ Stakeholder	Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity
Lot	Defined quantity of a product produced and/or processed and/or packaged essentially under the same conditions
Management System	Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives
Measurement	Process to determine a value
Monitoring	Determining the status of a system, a process (3.36) or an activity
Nonconformity	Non-fulfilment of a requirement
Objective	Result to be achieved
Operational Prerequisite Programme (OPRP)	Control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level and where action criterion and measurement or observation enable effective control of the process and/or product
Organization	Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives
Outsource	Make an arrangement where an external organization performs part of an organization's function or process
Performance	Measurable result
Policy	Intentions and direction of an organization as formally expressed by its top management
Prerequisite Programme /PRP	Basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food

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	safety
Process	Set of interrelated or interacting activities which transforms inputs to outputs
Product	Output that is a result of a process
Requirement	Need or expectation that is stated, generally implied or obligatory
Risk	Effect of uncertainty
Significant Food Safety Hazard	Food safety hazard identified through the hazard assessment, which needs to be controlled by control measures
Top Management	Person or group of people who directs and controls an organization at the highest level
Traceability	Ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution
Update	Immediate and/or planned activity to ensure application of the most recent information
Validation	Food safety> obtaining evidence that a control measure (or combination of control measures) will be capable of effectively controlling the significant food safety hazard
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

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ABBREVIATIONS

BIS	Bureau of Indian Standards
C & F	Clearing and Forwarding
CFT	Cross Functional Team
CP	Common Procedures
DOC	Document
GR	Goods Receipt
IS	Indian Standard
ISO	International Organization for Standardization
MA	Management Assistant
FSTL	Food Safety Team Leader
MRV	Material Receipt Voucher
NCR	Non Conformity Report
OP	Operating Procedures
PROD	Production
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
QP	Quality Policy
SH	Section Head
SI	Section In-charge
WI	Work Instruction
MRL	Maximum Residue Level

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References:

- FSSC 22000 Scheme Version 5.1 Standard
- ISO 22000:2018- Food Safety Management Systems (Standard can be purchased from www.iso.org).
- ISO/TS 22002:2009- Part1- PRP – Food Manufacturing
- .Food Safety and Standard Act -2006, Rules and Regulations 2011
- Joint FAO/WHO Codex Alimentarius Commission
- Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application

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FSMS PURPOSE AND SCOPE

PURPOSE

FSMS manual purpose is:

1. To describe overall food safety system activities of ABC.
2. To achieve compliance to legal, food safety and customer specific requirements
3. To achieve consistency and continual improvement in all the activities through well-documented system.
4. To form the basis for evaluation of system for carrying out further improvements.
5. To be used as a tool to help new personnel to understand policy, procedures and methodology practiced within the organization.

SCOPE

FSMS Scope of Certification

Manufacture, Packing and supply of Vegetable Pickles.

This manual covers the following activities as applicable to the unit.

- Production covering blending, packing and despatch
- Quality Control covering incoming, in-process and final inspection
- Maintenance and PRP aspects
- Stores covering receipts, storage & issue of pickles and packing materials

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The products under production are pickles packed in various pack sizes. .

ISO 22000:2018
Requirements

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4. ORGANIZATION

4.1 THE ORGANIZATION UNDERSTANDING AND ITS CONTEXT

The organisation has determined the external and internal issues that are relevant to its purpose and its strategic direction, that affect its ability to achieve the intended results of FSMS. In this context, ABC has considered positive and negative factors or conditions.

The external issues include statutory, regulatory requirements, technological, competitiveness, , certifications, suppliers, contractors, cyber security and food fraud, food defence and contamination etc. The internal issues include performance of ABC infrastructure, food safety culture, human resources , work environment, etc.

Information on the above determined external and internal issues is maintained with CEO and monitored and reviewed in management reviews.

Ref: Annexure 1A - External & Internal issues, interested parties

4.2 Understanding the needs and expectations of interested parties

To ensure that ABC has the ability to consistently provide products and services that meet applicable statutory, regulatory and customer requirements with regard to food safety, the company has determined:

- a) Interested parties that are relevant to the FSMS;

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- b) Relevant requirements of the interested parties of the FSMS.

Information related to above is maintained with FSTL and is reviewed in management review meetings.

Ref: Annexure 1A - External & Internal issues, interested parties

4.3 SCOPE OF THE FOOD SAFETY MANAGEMENT SYSTEM

ABC has determined the boundaries and applicability of the FSMS to establish its scope. Scope of FSMS is given below and it covers all the products and services, processes and production site that are included in the FSMS. The scope shall include the activities, processes, products or services that can have an influence on the food safety of its end products.

When determining the scope, ABC has considered:

- a) The external and internal issues as determined under 4.1;
- b) The requirements of relevant interested as determined under 4.2

The scope of FSMS is given as under:

Manufacture, Packing and supply of Vegetable Pickles.

Quality manual covers the activities carried out by the following sections and applicable only to unit.

- Production , Packing and Dispatch
- Quality Control covering incoming, in-process and final inspection
- Maintenance and GMP/PRP aspects
- Stores covering receipts, storage & issue of pickles, and packing materials

4.4 Food Safety Management System

ABC has established implemented, maintained, updated and continually improve the FSMS, including the processes needed and their interactions, in accordance with the requirements of ISO 22000:2018.

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5. LEADERSHIP

5.1 Leadership and Commitment

Top Management is commitment to the food safety management system by:

- a) ensuring that the food safety policy and the objectives of the FSMS are established and are compatible with the strategic direction of the organization;
- b) ensuring the integration of the FSMS requirements into the organization's business processes;
- c) ensuring that the resources such as finance/ infrastructure/ human resources etc needed for the FSMS are available;
- d) communicating the importance of effective food safety management and conforming to the FSMS requirements, applicable statutory and regulatory requirements, and mutually agreed customer requirements related to food safety;
- e) ensuring that the FSMS is evaluated and maintained to achieve its intended result(s)
- f) directing and supporting persons to contribute to the effectiveness of the FSMS;
- g) promoting continual improvement;

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- h) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.2 Policy

5.2.1 Establishing the food safety policy

CEO has adopted the food safety policy, which is appropriate to the purpose and context of ABC. It includes a commitment to satisfy the applicable requirements and continual improvement of the FSMS. It provides a framework for setting and reviewing objectives.

The food safety policy is maintained as documented information and is made available to customers, suppliers and contractors through ABC website. To ensure its understanding, it is communicated to all concerned personnel through training programmes, displays and distribution.

Food Safety Policy

ABC is committed to manufacture and supply high quality and safe products consistently, which meet customer requirements, statutory and regulatory norms and delight our customers & consumers always.

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The Management is committed to create excellent food safety culture in the organization, create competency related to food safety and improve continuously the FSMS in order to provide best value to our customers, employees and the society.

MD

5.3 Organizational roles, responsibilities and authorities

Organization chart (Annexure 02) of the company depicts all the posts in the organization. For all the posts, the responsibilities and authorities have been defined in the form of Job Description and the roles are assigned and communicated to all concerned.

CEO has assigned the responsibility and authority to HODs & Food safety for the following:

- ensure that the FSMS conforms to the requirements of this standard;
- reporting on the performance of the FSMS to top management;
- appointing the food safety team and the food safety team leader;
- food safety team with defined responsibility and authority to initiate and document action(s).

5.3.2 Food Safety Team Leader:

----- has been appointed as the Food Safety Team Leader
FSTL Will be responsible for:

- ensuring the FSMS is established, implemented, maintained and updated;

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- b) managing and organizing the work of the food safety team;
- c) ensuring relevant training and competencies for the food safety team being provided;
- d) reporting to top management on the effectiveness and suitability of the FSMS.

All persons shall have the responsibility to report problem(s) with regards to the FSMS to identified person(s).

The food safety team members and their responsibilities are shown in Annexure 02.

RESPONSIBILITY AND AUTHORITY

The responsibility and authority of personnel, who manage, perform and verify the work affecting quality and productivity to meet the objectives are identified as listed below.

Food Safety Team Leader- (FSTL)

Top management appointed ----- as team leader to ensure that all the processes required for the FSMS are established, implemented and maintained.

The team leader irrespective of other responsibilities and authorities shall have full responsibility and authority for:

Ensuring that the FSMS is established, implemented and maintained in accordance with requirements of ISO 22000:2018.

Organizing the identification and recording of non-compliance in the system through Internal Audits.

Initiating, recommending, coordinating and/ or providing solutions through designated channels.

Identification, procurement, updating and issuing copies of applicable regulatory requirement, standards & codes

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Liaison with external agencies, including certifying bodies, on matters related to Food Safety Management System.

To ensure that all the associated persons are aware of the customer requirements.

To ensure timely action of reporting to the top management about the performance of the FSMS and the improvement needed if any.

Ensuring all reviews are organized as per documented plan and minutes are maintained and feed backs are encouraged as outlined in the procedure and monitors the actions there on.

Organizing and maintaining records of all activities related ISO 22000:2018 Internal audit, Management review meeting, Food safety team meeting etc.

Ref: Annexure 02 – Organizational Chart

Ref: Annexure 03 – Food safety Team.

6. PLANNING

6.1 Actions to address risks and opportunities

When planning for the food safety management system, ABC has considered the issues referred to in 4.1 and the requirements referred to in 4.2 and 4.3 and determined the risks and opportunities that need to be addressed to:

- Give assurance that the FSMS can achieve its intended results;
- Enhance desirable effects;
- Prevent, or reduce, undesired effects;
- Achieve continual improvement.

To address these risks and opportunities, ABC takes actions by establishing control measures (record / review mechanism) and identifying improvement areas. These are integrated with process activities and implemented accordingly. The effectiveness of above actions are evaluated in management reviews.

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The action to address risks and opportunities are depended on:

- a) the impact on food safety requirements;
- b) the conformity of food products and services to customers;
- c) Requirements of interested parties in the food chain.

Ref: - Risk & Opportunities - Annexure I-B

6.2 Objectives of the food safety management system and planning to achieve them

In line with the management's commitment expressed in the organization's Food Safety Policy, measurable objectives are established at relevant functions and levels needed for FSMS.

While establishing food safety objectives, applicable food safety requirements, including statutory, regulatory and customer requirements are taken into account.

These are communicated to all concerned personnel and monitored by MD/FSTL and updated accordingly.

The food safety objectives for various Functions are given at Annexure - 4

ABC establishes a planning mechanism determining the following to achieve food safety objectives.

- a) What will be done;
- b) What resources will be required;

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- c) Who will be responsible;
- d) When it will completed;
- e) How the results will be evaluated.

6.3 Planning of changes

When ABC determines the need for changes to the FSMS, the changes are carried out in a planned manner considering the following:

- a) The purpose of the changes and their potential consequences;
- b) Continued integrity of the FSMS;
- c) The availability of resources to effectively implementing changes;
- d) The allocation or reallocation of responsibilities and authorities.

Ref: Annexure 04 – Food safety Objectives

7. SUPPORT

7.1 Resources

ABC determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the FSMS considering the following:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers

7.1.2 People

ABC has determined and provides the persons necessary for the effective implementation of its FSMS and for the operation and control of its processes.

Where the assistance of external experts is used for the development, implementation, operation or assessment of the FSMS, evidence of agreement or contracts defining the

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competency, responsibility and authority of external experts. Records of such information are maintained.

7.1.3 Infrastructure

Infrastructure requirements are determined by CEO to ensure conformity to the requirements of FSMS. Infrastructure to include:

- Land, buildings and required utilities;
- Machinery, equipment, including hardware and software;
- Transportation;
- Information and communication technology.

7.1.4 Work environment

Work environment necessary to achieve conformity to the requirements of FSMS are determined by CEO and provided accordingly.

The work environment includes:

Social (non-discriminatory, Calm)

Psychological (Stress reducing, emotionally protective)

Physical (such as noise, temperature, humidity, lighting, air flow, hygiene)

7.1.5 Externally developed elements of the FSMS

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When ABC establishes, maintains, updates and continually improves its FSMS by using externally developed elements of a FSMS, including PRPs, the hazard analysis and the hazard control plan, the unit will ensure that the provided elements are:

- a) developed in conformance with requirements of this standard;
- b) applicable to the unit, processes and products;
- c) specifically adapted to the processes and products of the organization by the food safety team;
- d) implemented, maintained and updated as required by this document;
- e) records are maintained.

7.1.6 Control of externally provided processes, products or services

ABC has established a procedure for evaluation, selection, monitoring of performance and re- evaluation of external providers of processes, products and/or services; The suppliers or services providers are given communication of requirements. Also ensured that externally provided processes, products or services do not adversely affect the organization's ability to consistently meet the requirements of the FSMS.

The records evaluation, re-evaluation is maintained.

7.2 Competence

Competence requirements for various positions are determined by the CEO and the competence of the existing personnel is evaluated annually by CEO vis-à-vis the requirements as determined. The competence of external providers working under the control that effects the performance of FSMS have been identified in the respective work orders.

It is ensured that these persons, including the food safety team and those responsible for the operation of the hazard control plan, are competent on the basis of appropriate

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education, training and/or experience, Competence requirements for the food safety team is documented and maintained.

Ensured that the food safety team has a combination of multi-disciplinary knowledge and experience in developing and implementing the FSMS.

Training needs are identified once in a year or as and when required by CEO based on inputs from HODs and Trainings are conducted and effectiveness of the training being evaluated. The records of training are maintained.

7.3 Awareness

It is ensured that all relevant persons working under the control of the company including employees of ABC are aware of:

- a) The Food safety Policy;
- b) Relevant food safety Objectives;
- c) Their contribution to the effectiveness of FSMS, including the benefits of improved performance;
- d) The implications of not conforming with the requirements of FSMS.

7.4 Communication

ABC has determined the internal and external communications relevant to FSMS, including:

- a) On what it will communicate;
- b) When to communicate;
- c) With whom to communicate;
- d) How to communicate;
- e) Who communicates?

The above is captured in the form of communication matrix'

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7.4.2 External communication

Company has established, implemented and maintained a documented procedure to ensure that sufficient information on issues concerning food safety is available throughout the food chain. This includes communication with:

- a) External providers and contractors,
- b) Customers in relation to product information such as intended use, specific storage requirements and, as appropriate, shelf life.
- c) Enquiries, contracts or order – handling of customer feedback including customer complaints are handled by Marketing Dept. Enquiries and orders are handled by Marketing Department.
- d) Statutory and regulatory authorities, such as FSSAI authorities, IS standards, and Other organizations such as service providers that have an impact on, the effectiveness or updating of the FSMS

It is ensured that information on food safety aspects of the Unit's products that may be relevant to other organizations in the food chain is communicated. This applies especially to know food safety hazards that need to be controlled by the supplier in the food chain. Records of communication are maintained.

FSTL is authorized and have responsibility and authority for external communication.

Information obtained through external communication is included as input to system updating and management review.

7.4.3 Internal communication

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The Unit has established, implemented and maintained effective arrangements for communicating with personnel on issues having an impact on food safety. This is done by the following methods:

- a) Inter office communications
- b) By news letters
- c) Telephonic communication
- d) Meetings
- e) Electronic mails
- f) Briefings etc.

In order to maintain the effectiveness of the food safety management system, the company has ensured that the food safety team is informed in a timely manner of changes especially the following aspects:

- a) products or new products;
- b) raw materials, ingredients and services;
- c) production systems and equipment;
- d) production premises, location of equipment and surrounding environment;
- e) cleaning and sanitation programs;
- f) packaging, storage and distribution systems;
- g) competencies and/or allocation of responsibilities and authorizations;
- h) applicable statutory and regulatory requirements;
- i) knowledge regarding food safety hazards and control measures;
- j) customer, sector and other requirements that the organization observes;
- k) relevant enquiries and communications from external interested parties;
- l) complaints and alerts indicating food safety hazards associated with the end product;
- m) Other conditions that have an impact on food safety.

The food safety team ensures that the information is included in updating FSMS and reported to MRM.

7.5 Documented information

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ABC has determined the documented information required by FSSC 22000, information determined for the effectiveness of FSMS and food safety requirements required by statutory authorities and customers.

The documented information maintained for the purpose of establishing FSSC 22000 is given under Section : below:

- a) Food Safety Policy
- b) Food safety Objectives
- c) FSMS Manual
- d) GMP/PRP Manual
- e) SOPs
- f) Work instructions
- g) Records
- h) Risks & Opportunities bases on organization context.
- i) Hazard analysis work sheet
- j) Hazard Control Plan (CCP/OPRP control plan)
- k) Product specifications
- l) Statutory and regulatory requirements
- m) Equipment Manuals

Documented information retained by for the purpose of providing evidence of result achieved (records) is available with the concerned Department in soft copy / hard copy in any or combination of the following:

- a) Files
- b) Registers
- c) Log books
- d) Meeting minutes
- e) Emails

7.5.2 Creating and updating

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When creating the documented information mentioned under 7.5.1, it is ensured that these are:

- a) Provided with appropriate identification and description which include title, date, prepared & approved and reference number / code.
- b) Format and media (Hard copy or electronic)
- c) Reviewed and approved, whereas necessary, for suitability and adequacy.

The documented information is maintained and retained in English language in hard copy / soft copy as suitable.

7.5.3 Control of documented information

Documented information is controlled to ensure;

- a) It is available and suitable for use, when and when it is needed;
- b) It is adequately protected.

While control of documented information maintained and retained by ABC, the following are considered, as applicable;

- a) Distribution, access, retrieval and use;
- b) Storage and preservation, including preservation of legibility;
- c) Control of changes (revision/issue);
- d) Retention and disposition.

Documented information of external origin for the planning and operation of the FSMS is determined by FSTL. These are identified and controlled by the FSTL.

It is ensured by FSTL/HODs that the documented information retained (records) as evidence of conformity is protected from unintended alterations.

Reference:

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Ref: Procedure for Document control
Ref: Procedure for Control of records
Ref: Procedure for training

8. OPERATIONS

8.1 Operational planning and control

All processes involved in realization of safe product are planned, implemented, controlled, maintained and updated to ensure requirements of realization of safe product are determined as part of risks and opportunities by:

- a) establishing criteria for the processes;
- b) implementing control of the processes in accordance with the criteria;
- c) keeping documented information to the extent necessary to demonstrate that the

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processes have been carried out as planned.

The company controls planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Control over Outsourced processes

Activities outsourced and the type & extent of controls adopted.

Sr. no	Activities and processes	Type and extent of control
1	Calibration Generator Maintenance Transportation Maintenance of Computer UPS. Repair / rewinding of motors Overhauling of Constanta machine	Suppliers / service providers are evaluated and selected as per purchase procedures. Purchase requirements are communicated as per purchase order / agreement. End of the year / agreement the service provider performance is reevaluated and then the contract is renewed. All other controls / responsibilities are carried out by the service provider
2	Testing of MRL , Analysis of ambient air, stack emission, , noise levels, swab tests - equipment & personnel , testing as per for physical, chemical and biological parameters and water potability.	The test lab is selected either based on NABL/FSSAI approval/ customer approval/statutory recommendation. The test requirements and samples are either forwarded or collected by them and the results / certificates are received and verified. All other controls / responsibilities are carried out by the test house. In case of any complaint on the test results it is taken up with test house directly.
3	Pest control	The selection of the pest control agency is based on statutory requirements, assessment and evaluation of their expertise, market reputation and the client list. The terms & conditions, service requirements are communicated through an annual agreement. The pest control inputs, equipment and manpower are provided by the agency and during their visit their activities

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	are monitored by one of the food safety team member. Any complaints are also resolved during this visit.
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8.2 Prerequisite programs (PRPs)

ABC has established, implemented, maintained and updated PRP(s) to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment.

It is ensured that PRPs are:

- Appropriate to company and its context with regard to food safety;
- Appropriate for the operation and the nature of the products being manufactured and/or handled;

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- Implemented across the entire production system, covering all product lines.
- Approved by the food safety team.

While selecting and establishing PRPs, ABC ensured the following:

- applicable statutory, regulatory and mutually agreed customer requirements
- ISO/TS 22002 Part 1:2009 – Manufacturing
- CAC/RCP 1-1969, Rev. 5- 2020

The company has considered the following aspects while establishing PRPs.

- Construction, lay-out of buildings and associated utilities;
- Lay-out of premises, including zoning, workspace and employee facilities;
- Supplies of air, water, energy and other utilities;
- Pest control, waste and sewage disposal and supporting services;
- The suitability of equipment and its accessibility for cleaning and maintenance;
- Supplier approval and assurance processes (e.g. raw materials, ingredients, chemicals and packaging);
- Reception of incoming materials, storage, dispatch, transportation and handling of products
- Measures for the prevention of cross contamination;
- Cleaning and disinfecting;
- Personal hygiene and employee facilities
- Rework
- Product information/consumer awareness
- Product recall
- Warehousing
- others, as appropriate.

Ref: GMP/ PRP Manual

8.3 Traceability system

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Documented procedure has been established for traceability to identify incoming materials from suppliers to the first stage distribution of the end products.

This includes

- a) relation of lots of received materials, ingredients and intermediate products to the end products;
- b) reworking of materials/products;
- c) distribution of the end product.

It is ensured that applicable statutory, regulatory and customer requirements are identified. Records of traceability is retained for the shelf life period and periodic mock drill (once in six months) are conducted to test the effectiveness of the traceability system.

Ref: Procedure for Traceability

8.4 Emergency preparedness and response

ABC has established documented procedure to respond to potential emergency situations such as natural calamities, bioterrorism, public health emergencies such as viral diseases or incidents such as vehicle accidents etc that can have an impact on food safety which are relevant to the role of the organization in the food chain.

Handling of emergencies and incidents

An Emergency Response Team (ERT) is constituted to respond to actual emergency situations and incidents by:

- Ensuring applicable statutory and regulatory requirements are identified;
- Communicating internally;
- Communicating externally (e.g. suppliers, customers, appropriate authorities, media);

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- Take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident and the potential food safety impact;
- Mock drill conducted periodically to test procedures,
- Review and, where necessary, update the documented information after the occurrence of any incident, emergency situation or tests.

Ref: Procedure for Emergencies and Incident handling procedure

8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

All relevant information such as the origin of the raw materials, ingredients, packing materials etc required to conduct the hazard analysis are collected, maintained.

The preliminary information/data for conducting hazard analysis is collected by food safety team from the following sources:

- applicable statutory, regulatory and customer requirements;
- the organization's products, processes and equipment;
- food safety hazards relevant to the FSMS.
- Any other information as relevant to FSMS

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials

Documented specifications are established for all raw materials/ packing Materials and ingredients indicating the aspects given below:

- biological, chemical and physical characteristics;
- composition of formulated ingredients, including additives and processing aids;
- source (e.g. animal, mineral or vegetable);
- place of origin (location/country);
- method of production;
- method of packaging and delivery;

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- g) storage conditions and shelf life;
- h) preparation and/or handling before use or processing;
- i) acceptance criteria related to food safety or specifications of purchased materials and ingredients appropriate to their intended use.

While developing the product characteristics, FSSAI requirements, Customer requirements are considered.

8.5.1.3 End products Characteristics

Documented product characteristics are established for all end products indicating the aspects given below:

- a) product name or similar identification;
- b) composition;
- c) biological, chemical and physical characteristics relevant for food safety;
- d) intended shelf life and storage conditions;
- e) packaging;
- f) labeling relating to food safety and/or instructions for handling, preparation and intended use
- g) method of distribution and delivery.

While developing the product characteristics, FSSAI requirements, Customer Requirements are considered.

8.5.1.4. Intended use

The intended use, including reasonably expected handling of the end product and any unintended use but reasonably expected mishandling and misuse of the end

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product, are considered and are documented in product description to conduct the hazard analysis.

8.5.1.5 Description of processes and Flow diagrams

Preparation of the flow diagrams

Flow diagrams are prepared by food safety team considering the processes involved for the products or process categories covered by the food safety management system

Flow diagrams are prepared in detail include the following:

- a) the sequence and interaction of the steps in the operation;
- b) any outsourced processes;
- c) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
- d) where reworking and recycling take place;
- e) where end products, intermediate products, by-products and waste are released or removed.

Flow diagrams for products: Refer Annexure 7

On-site confirmation of flow diagrams

After preparation of the flow diagrams, the food safety team verifies its accuracy by checking it with on- site process steps and record for the same is maintained. This will be done annually or any change in the process by way of addition equipment, process change, new product.

Description of processes and process environment

For each process line, the food safety team prepares a documented description, detailing the information to conduct the hazard analysis such as:

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- a) the layout of premises, including food and non-food handling areas;
- b) processing equipment and contact materials, processing aids and flow of materials;
- c) existing PRPs, process parameters, control measures (if any) and/or the strictness with which they are applied, or procedures that can influence food safety;
- d) statutory and regulatory authorities or customers that can impact the choice and the strictness of the control measures.

Ref: Annex 05 – Raw material specifications

Ref: Annex 06 – End Product specifications

8.5.2 Hazard analysis

Food safety team conducts a hazard analysis to determine which hazards to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required.

Hazard identification and determination of acceptable levels

Food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities are identified and recorded. The identification is based on:

- a) the preliminary information and data collection from inputs.
- b) experience,
- c) Internal and external information including, to the extent possible historical, epidemiological, scientific data.
- d) information from the food chain on food safety hazards that may be relevance for the safety of the end products, intermediate products and the food at consumption.

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e) statutory, regulatory and customer requirements

The steps from the (raw material, processing and distribution) at which each food safety hazard can introduced are indicated.

When identifying the hazards, consideration is given to

- a) The stages preceding and following in the food chain;
- b) All steps in the flow diagram;
- c) The process equipment, utilities/services, process environment and persons.

For each of the food safety hazard identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data.

When determining acceptable levels, the Food safety team ensures that:

- a) ensure that applicable statutory, regulatory and customer requirements are identified;
- b) consider the intended use of end products;
- c) consider any other relevant information

8.5.2.3 Hazard assessment

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A hazard assessment is conducted to determine, for each food safety hazard identified its prevention or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met.

Each food safety hazard is evaluated according to the flowing parameters:

- likelihood of its occurrence in the end product prior to application of control measures;
- Severity of its adverse health effects in relation to the intended use.

A hazard assessment criterion is as follows:

Likelihood of occurrence prior to application of control measure		Severity of its adverse health effect on intended use	
Most likely (daily)	4	Hospitalization	4
Likely (Weekly)	3	Illness	3
Least likely (Monthly)	2	Medication	2
Negligible(Six months)	1	Inconvenience	1

Severity	4	8	12	16
	3	6	9	12
	2	4	6	8
	1	2	3	4
	Likelihood			

Calculation for identification of significant food safety hazard:

Likelihood factor X Severity factor = Significant food safety hazard

The total multiplied score of 9 and above will be considered as significant food safety hazard and these hazards are further evaluated to categorize the control measures such as CCP or OPRP determination based on decision tree under section 8.5.2.4.

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Ref: Procedure for Hazard analysis

8.5.2.3 Selection and categorization of control measure(s)

Based on the hazard assessment an appropriate combination of control measures is selected which is capable of preventing, eliminating or reducing these significant food safety hazards to defined acceptable levels.

The control measures selected are categorized as

1. Operational PRP – (OPRP)
2. Critical Control Point – (CCP)

The categorization is carried out using a systematic approach that includes assessments with regards to the following:

- a) the likelihood of failure of its functioning;
- b) the severity of the consequence in the case of failure of its functioning:
 - 1) the effect on identified significant food safety hazards;
 - 2) the location in relation to other control measure(s);
 - 3) whether it is specifically established and applied to reduce the hazards to an acceptable level;
 - 4) Whether it is a single measure or is part of combination of control measure(s).

For each control measure, the systematic approach includes an assessment of the feasibility of:

- a) establishing measurable critical limits and/or measurable/observable action criteria;
- b) monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;
- c) applying timely corrections in case of failure.

The criteria for categorization of the control measures is described in the procedure

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For hazard assessment and CCP/OPRP determination procedure

8.5.3 Validation of control measure(s) and combinations of control measures

The food safety team validates the control measure identified for the significant food safety hazard and is done on the following conditions:

- Prior to implementation of control measures for Hazard control plan
- Any change in the machinery or layout or product.

When the result of validation shows that the control measures are not capable of achieving the intended control, the food safety team will modify and re-assess the control measure(s) and/or combination of control measures.

Each of the hazard control plan is validated by food safety team prior to implementation and records are maintained.

The initial validation is done by the food safety team and subsequent validation is done in once in a year basis or any change in the process line will be done by food safety team members of production and quality.

Ref: Procedure for Hazard analysis

8.5.4 Hazard control plan (HACCP /OPRP Plan)

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ABC has documented, established, implemented and maintained a hazard control plan (HACCP/OPRP Plan . The hazard control plan includes the following information for each control measure at each CCP : or OPRP

- a) food safety hazard(s) to be controlled at the CCP/OPRP
- b) critical limit(s) at CCP or active criteria for OPRP;
- c) monitoring procedure(s);
- d) correction(s) to be made if critical limits or action criteria are not met;
- e) responsibilities and authorities;
- f) records of monitoring.

Ref: Annexure 8 – Hazard Control Plan- Annexure 8A

8.5.4.2 Determination of critical limits and action criteria

For each of the CCP and action criteria for OPRP , critical limit is specified and the rationale for establishing the critical limit based on scientific data, statutory specification etc will be documented. Critical will be measurable and conformance with critical limits will ensure that the acceptable level is not exceeded.

For each of the CCP identified, action criteria will be established and the action criteria for OPRP measurable or observable. Conformance with action criteria will contribute to the assurance that the acceptable level is not exceeded.

Ref: Initial Validation Report – CCP

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8.5.4.3 Monitoring systems at CCPs and for OPRPs

The monitoring system, for each CCP and for each OPRP, consists of documented information, including:

- a) measurements or observations that provide results within an adequate time frame;
- b) monitoring methods or devices used;
- c) applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations
- d) monitoring frequency;
- e) monitoring results;
- f) responsibility and authority related to monitoring;
- g) Responsibility and authority related to evaluation of monitoring results.

8.5.4.4 Actions when critical limits or action criteria are not met

HACCP Plan & OPRP Plan specifies the corrections and corrective actions to be taken when critical limits or action criterion are not met and will ensure that actions are taken as specified below:

- a) the potentially unsafe products are not released,
- b) the cause of nonconformity is identified;
- c) the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria;
- d) Recurrence is prevented.

Organization shall make corrections in accordance with 8.9.2 and corrective actions in accordance with 8.9.3

8.5.4.5 Implementation of the hazard control plan

The Hazard control plan will be implemented and corresponding records are maintained. The hazard control plans (CCP/OPRP), and retain evidence of the implementation as documented information.

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8.6 Updating the information specifying the PRPs and the hazard control plan

After implementation and establishment of hazard control plan, operational PRPs and/or the HACCP plan the company verifies and updates the following information once in six months:

- a) characteristics of raw materials, ingredients and product-contact materials;
- b) characteristics of end products;
- c) intended use;
- d) flow diagrams and descriptions of processes and process environment.

8.7 Control of monitoring and measuring

The company ensures that the monitoring and measuring methods and equipment are adequate to for monitoring and measuring activities related to PRPs and hazard control plan.

The monitoring and measuring equipment used shall be:

- a) calibrated or verified at specified intervals prior to use;
- b) adjusted or re-adjusted as necessary;
- c) identified to enable the calibration status to be determined;
- d) Safe safeguarded from adjustments that would invalidate the measurement results
- e) protected from damage and deterioration

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8.8 Verification related to PRPs and the hazard control plan

8.8.1 Verification

Verification includes verification of FSM systems and records, review of documentation and product disposition, verification to confirm the efficacy of the FSMS plan, verification of procedures and records.

Verification of the FSMS system is carried out once in six months by Food safety team.

This includes:

- a) the PRP(s) are implemented and effective
- b) the hazard control plans are implemented and effective
- c) hazard levels are within identified acceptable levels
- d) input to hazard analysis is continually updated,
- e) other actions determined by the organization are implemented and effective

The verification results are recorded and are communicated to the food safety team.

8.8.2 Analysis of results of verification activities

The food safety team shall conduct analysis of the results of verification that will be used as an input to the performance evaluation of the FSMS.

Ref: Procedure for Verification and validation

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8.9 Control of product and process nonconformities

The Food Safety team ensures that data derived from the monitoring of OPRPs and at CCPs are evaluated by designated persons as per procedure of control of non-conforming product who are competent and have the authority to initiate corrections and corrective actions.

8.9.2 Corrections

A documented procedure has been established and maintained for identification and dealing with non-conforming products. The products where critical limits for CCP(s) are exceeded or there is a loss of control of operational PRP(s), such products affected are identified and controlled with regard to their use and release.

Procedure for control of non-conforming products includes:

- Method of identification, assessment and correction for affected products to ensure their proper handling;
- Arrangements for review of the corrections carried out.

When critical limits at CCPs are not met, affected products are identified and handled as potentially unsafe products.

Where action criteria for an OPRP are not met, the following are carried out:

- determination of the consequences of that failure with respect to food safety;
- determination of the cause(s) of failure;
- identification of the affected products and handling as potentially

unsafe products.

Documented information is retained on corrections made on non-

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conforming products and processes including the nature of non-conformity ,causes of failure and consequences as a result of non conformance.

Records of action taken are maintained.

8.9.3 Corrective actions

The data derived from the monitoring of Critical limits (CCPS) and action criteria for OPRPs are not met the Food safety team to intimate corrective actions.

Documented procedure has been establish and maintained describing appropriate actions to identify and eliminate the cause detected nonconformities, to prevent recurrence, and to bring the process or system back in to control after nonconformity is encountered. These actions include

- a) reviewing nonconformities (including customer complaints),regulatory inspections
- b) reviewing the trends in monitoring results that may indicate development towards loss of control,
- c) determining the root cause(s) of nonconformities,
- d) evaluating the need for action to ensure that nonconformities do not recur,
- e) determining and implementing the actions needed,
- f) recording the results of corrective action taken, and
- g) Verifying the corrective action taken to ensure that they are effective.

Records of corrective actions are maintained.

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8.9.4 Handling of potentially unsafe products

The company takes effective actions to prevent potentially unsafe products from entering the food chain unless it is possible to ensure that:

- the food safety hazard(s) of concern are reduced to the acceptable levels,
- the food safety hazard(s) of concern is reduced to identified acceptable levels prior to entering into the food chain,
- the products still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

All lots/ batch of products that may are affected by a nonconforming situation are held under control until they are evaluated.

If products that have left the control of the company are subsequently determine to be unsafe, the products are recalled immediately and the concerned interested parties are intimated.

The details of control of the products and recall of the products are maintained.

8.9.4.2 Evaluation for release

The nonconforming products are released as safe when only on the following conditions:

- evidence other than the monitoring system demonstrates that the control measures have been effective;
- evidence shows that the combined effect of the control measures for that particular product complies with the performance intended.

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- c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of products complies with the identified acceptable levels for the food safety hazard(s) concerned.

Records of evaluation for release of products are maintained.

8.9.4.3 Disposition of nonconforming products

The non-conforming products are disposed by any of the following methods:

- a) reprocessing or further processing within or outside the company to ensure that the food safety hazard is eliminated or reduced to the acceptable levels;
- b) redirected for other use as long as food safety in the food chain is not affected
- c) destruction and/or disposal as waste.

Ref: Procedure for Control of Non-conformance and corrective action

8.9.5 Withdrawal/recall

Documented procedure has been established to facilitate the timely withdrawal/recall of lots of end products, which have been identified, as unsafe by Food safety team along with the marketing team is responsible for initiating actions for withdrawal/recall.

This includes

- 1) notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),

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- 2) handling of withdrawn/recalled products as well as affected lots of the products still in stock, and
- 3) the sequence of actions to be taken.

products that are withdrawn/recalled are held under supervision until they are destroyed, used for purposes other than originally intended, determine to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.

Causes, extent and result of a withdrawal/recall are recorded and reported to top management as input to the management review

Mock recall will be conducted at least once in a six months to verify the effectiveness of system.

9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

The food safety team, HODs and MD determine the aspects/ processes of FSMS to be monitored and measured.

The frequency of monitoring, measurement, analysis and evaluation of the system Is done as defined in the respective procedures.

The results of monitoring and measurements are analyzed and evaluated by the food safety team or by authorized person.

The records of monitoring, analysis and evaluations are maintained.

The effectiveness of the action is reviewed in MRM

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9.1.2 Analysis and evaluation

The food safety team analyses and evaluates appropriate data or information from monitoring and measurement including result of verification activities related to PRPs, CCP/OPRP Plans including the results of the internal audits and external audits.

The analysis is carried out in order:

- a) to conform that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the organization,
- b) to identify the need for updating or improving the food safety management system,
- c) to identify trends which indicates a higher incidence of potentially unsafe products,
- d) to establish information for planning of the internal audit programme concerning the status and importance of areas to be audited, and
- e) to provide evidence that any corrections and corrective actions that have taken are effective.

The results of the analysis are recorded and reported, to top management as input to the management review.

It is also be used as an input for updating the food safety management system.

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9.2 Internal audit

Documented procedure has been established to conduct internal audits at planned intervals (Once in 6 months) to provide information on whether the quality management system:

- a) Conforms to :
 - 1) The organization's own requirements for its FSMS;
 - 2) The requirements of this International Standards;
- b) Is effectively implemented and maintained.

An audit program (Plan & Schedule) is planned based on the importance of the processes concerned, changes affecting the organization, and the results of previous audits. The audit criteria, scope, frequency and methods and other details of conducting Internal Audit are defined in the process or in the documented information retained (internal audit plan, schedule, check list, NCRs).

- Auditors are selected and conduct audits to ensure objectivity and the impartiality of the audit process;
- It is ensured that the results of the audits are reported to the food safety team and relevant management;
- Records are maintained as evidence of the implementation of the audit programme and the audit results;
- Make the necessary correction and take the necessary corrective action within the agreed time frame;
- Determine if the FSMS meets the intent of the food safety policy and objectives of the FSMS

Ref: Procedure for Internal audit

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9.3 Management review

To ensure the continuing suitability, adequacy and effectiveness of food safety management system, management review is conducted by Unit Head at least once in six months.

Management review input

The management review is conducted based on the following inputs / agenda

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the FSMS, including changes in the organization and its context;
- c) information on the performance and the effectiveness of the FSMS, including trends in:
 - 1) result(s) of system updating activities;
 - 2) monitoring and measurement results;
 - 3) analysis of the results of verification activities related to PRPs and the hazard control plan
 - 4) nonconformities and corrective actions;
 - 5) audit results (internal and external);
 - 6) inspections (e.g. regulatory, customer);
 - 7) the performance of external providers;
 - 8) the review of risks and opportunities and of the effectiveness of actions taken to address them
 - 9) the extent to which objectives of the FSMS have been met;
- d) the adequacy of resources;
- e) any emergency situation, incident or withdrawal/recall that occurred;
- f) relevant information obtained through external and internal communication, including requests and complaints from interested parties;
- g) Opportunities for continual improvement.

Management review output

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The outputs of the management review in the form of minutes include decisions and actions related to:

- a) Decisions and actions related to continual improvement Opportunities;
- b) Any need for changes to the food safety management system (Policy & Objectives);
- c) Resource needs.

Company retains documented information as evidence of the results of management reviews.

10. IMPROVEMENT

10.1 Nonconformity and corrective action

In case of occurrence of non-conformity, including any complaints arising, ABC takes action to control and correct it and/or deals with the consequences.

Subsequently, ABC evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

- a) reviewing and analysing the nonconformity;
- b) determining the causes of the nonconformity;
- c) determining the similar nonconformities exists, or could potentially occur;

Based on the above, actions are implemented as needed and review the effectiveness of corrective action taken.

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Based on the above actions, updates risks and opportunities, if necessary and makes changes to its FSMS, if necessary.

Company retains documented information as evidence of 'the nature of the nonconformities' and 'any subsequent actions taken'.

10.2 Continual improvement

ABC is committed to continually improve the suitability, adequacy and effectiveness of the food safety management system.

The effectiveness of continual improvement of FSMS is done by using the following aspects:

- Internal and external communications
- Management review
- Internal audit
- Analysis of results of verification activities
- Validation of control measures
- Corrective action
- Updating FSMS.

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10.3 Update of the FSMS

ABC ensures that the FSMS is continually updated.

To achieve this, the food safety team evaluates the FSMS at planned intervals. The team considers the need to review the hazard analysis, the established hazard control plan and the established PRPs. The updating activities are based on:

- a) input from communication, external as well as internal
- b) input from other information concerning the suitability, adequacy and effectiveness of the FSMS;
- c) output from the analysis of results of verification activities
- d) output from management review

System updating activities are retained as documented information and reported as

Inputs to the management review.

Ref: Procedure for Corrective action.

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2.5 - FSSC 22000 ADDITIONAL REQUIREMENTS

2.5.1 MANAGEMENT OF SERVICES AND PURCHASED MATERIALS

- a) ABC ensures that the external/internal laboratory analysis services are used for the verification and/or validation of food safety, are conducted by a competent laboratory that has the capability to produce precise and repeatable test results using validated test methods and best practices (such as successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards such as ISO 17025).
- b) ABC has established a documented procedure (-----) for procurement in emergency situations to ensure products still conform to the specifications. The evaluation of these suppliers will be done as per the established parameters as specified in the procedure.
- c) Not applicable
- d) ABC has established a process for review the product specifications (Raw materials/ Ingredients/ Packing materials/ Final products) by FS team to ensure continued compliance with food safety/legal and customer requirements.

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2.5.2 PRODUCT LABELLING

In addition to clause 8.5.1.3 of ISO 22000:2018, ABC, ensures that finished products are labeled according to all applicable food safety (including allergens) statutory and regulatory requirements in the country of intended sale.

Where product is unlabeled, all relevant product information will be made available by way of packing slips or other methods to ensure safe use of the food by the customer or consumer.

2.5.3 FOOD DEFENSE

THREAT ASSESSMENT

ABC has a documented procedure in place to:

- Conducted a threat assessment to identify and assess potential threats using Food Defense Checklist
- Developed and implemented mitigation measures for significant threats.

FOOD DEFENSE PLAN

- ABC has a documented food defense plan specifying the mitigation measures covering the processes and products within the FSMS scope of the organization.
- The food defense plan is supported by the organization's FSMS.
- The plan complies with applicable legislation and be kept up-to-date.

Ref- Food Defense Checklist

2.5.4 FOOD FRAUD MITIGATION

VULNERABILITY ASSESSMENT

ABC has established a documented procedure to:

- Conducted a food fraud vulnerability assessment to identify and assess potential vulnerabilities using checklist;

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- b) Developed and implemented mitigation measures for significant vulnerabilities.

PLAN

- a) ABC has established a documented food fraud mitigation plan specifying the mitigation measures covering the processes and products within the FSMS scope of the unit.
- b) The food fraud mitigation plan is supported by the organization's FSMS.
- c) The plan complies with the applicable legislation and be kept up-to-date.

2.5.5 LOGO USE

- a) ABC uses the FSSC 22000 logo only for marketing activities such as organization's printed matter, website and another promotional material.
- b) In case of using the logo ABC complies with the following specifications:

Use of the logo in black and white is permitted when all other text and images are in black and white.

- c) ABC is not using the FSSC 22000 logo, any statement or make reference to its certified status on:
 - i. a product;
 - ii. its labelling;
 - iii. its packaging (primary, secondary or any other form);
 - iv. in any other manner that implies FSSC 22000 approves a product, process or service.

2.5.6 MANAGEMENT OF ALLERGENS

The products of ABC are not having any allergens and as such this is not applicable.

2.5.7 ENVIRONMENTAL MONITORING

ABC has in place:

- a) Risk-based environmental monitoring program;

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- b) Documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment and this includes, the evaluation of microbiological and allergen controls present;
- c) Data of the monitoring activities including regular trend analysis.

2.5.8 FORMULATION OF PRODUCTS

Not applicable

2.5.9 TRANSPORT AND DELIVERY

Not applicable

2.5.10 STORAGE AND WAREHOUSING

ABC has established, implemented and maintained a procedure for storage of products which follows stock rotation by way of FIFO/FEFO.

2.5.11 HAZARD CONTROL AND MEASURES TO PREVENTING CROSS CONTAMINATION

- a) Not applicable
- b) Not applicable

2.5.12 PRP VERIFICATION

ABC has established, implemented and maintained a documented routine (monthly) Site inspection/ PRP check to verify that the site (Internal/ External) production environment And processing equipment are maintained in suitable condition to ensure food safety.
(PRP Checklist)

2.5.13 PRODUCT DEVELOPMENT

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ABC has established, implemented and maintained a documented for product design and development procedure for new products and changes to product or manufacturing processes to ensure safe and legal products are produced.

This shall include the following:

- a) Evaluation of the impact of the change on the FSMS taking into account any new foodsafety hazards (incl. allergens) introduced and updating the hazard analysis accordingly,
- b) Consideration of the impact on the process flow for the new product and existing products and processes,
- c) Resource and training needs,
- d) Equipment and maintenance requirements,
- e) The need to conduct production and shelf-life trials to validate product formulation and processes are capable of producing a safe product and meet customer requirements.

2.5.14 HEALTH STATUS

Not applicable

2.5.15 REQUIREMENTS FOR ORGANIZATIONS WITH MULTI-SITE CERTIFICATION

Not applicable

Reference

Food defense procedure
Food Defense Plan
Food Fraud procedure
Food fraud mitigation plan
Environmental monitoring procedure.
Product design and development procedure
Site Inspection/PRP Checklist

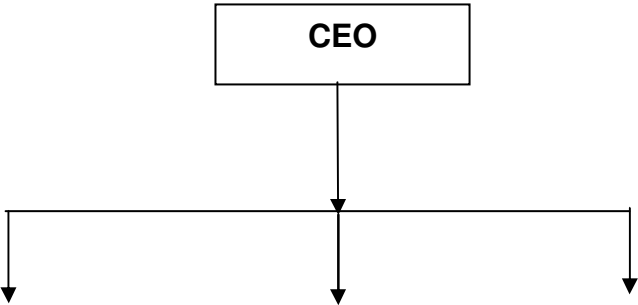
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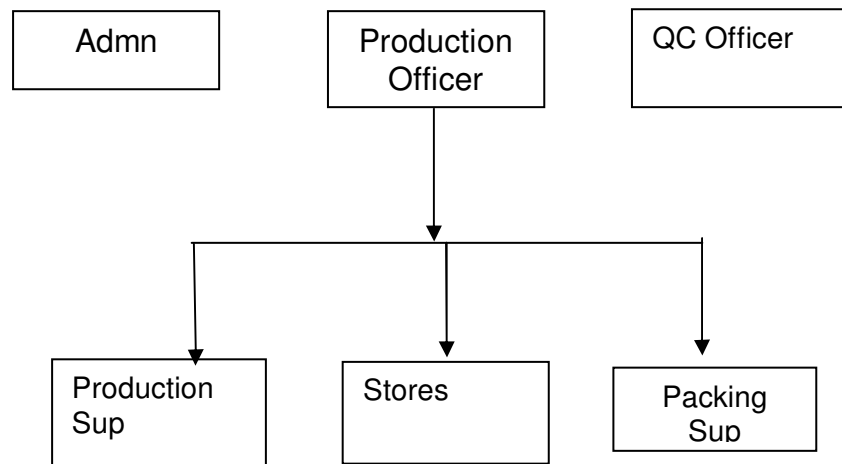
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Annexures

Organization Chart - Annexure 1



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Responsibilities & Authorities

Annexure 02A

CEO

RESPONSIBILITIES

Organize personnel for the various functions, assign duties and responsibilities to them and supervises their performances.

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Maintain relation with all external regulatory and government departments and controls records of regulatory and legal requirements

Plan and executive company growth

Decision making role involves high level decision about policy and strategy.

Communicates with Management and Employees

PRODUCTION MANAGER

RESPONSIBILITIES

Planning appropriate strategies and actions plans for production in co-ordination with the CEO

Planning production plan and production schedule

*Coordinating activities with other operational and functional employees working in different departments for streamlining production

* Monitoring continuously the availability of all the requisite resources for production and supply of quality-finished product.

*Ensuring inspection and test functions at appropriate stages

*Controlling that non-conforming product are either packed or dispatched from the factory.

*Laying down Quality Plans for inspection as per the customer requirements

*Controlling storage and identification of all materials, where preservation and protection from damage.

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QUALITY CONTROL Officer

RESPONSIBILITIES

- *Assisting Production Department in ascertaining the quality at various stages of production and give feedback for improvement.
- *Carrying out sample testing and maintained relevant records.
- *Identifying and sourcing of appropriate inspection equipment of required accuracy.
- *Ensuring calibration of all instruments and maintain calibration records.
- *Authorized to approve Quality of products
- *Authorized to release finished goods.

Administrator

RESPONSIBILITIES

- * Reporting to CEO all legal, financial control, company accounts and security functions.
- *Maintaining relation with all external regulatory and government departments and controls records of regulatory and legal requirements.
- * Maintain all employee related records
- * Conduct Medical examination report of food handlers annually.
- * Organize training for staff and keep records.
- * Day to day administration of the plant

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Food safety Objectives

Annexure 04

Top Management Level

SI.No	Objectives	Measurable target
1	Compliance to all applicable statutory/ regulatory requirements	100%
2	Providing resources on time	100%
3	Product recall/ withdrawal	Nil

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Quality Assurance

SI.No	Objectives	Measurable target
1	Conducting testing of products as per quality plan	100%
2	To ensure that all products are released with the acceptance criteria limits.	100%
3	Customer complaints related to food safety shall not exceed 3 per year	3 per year

Production

SI.No	Objectives	Measurable target
1	To reduce the re-processing/ re-packing of the products	2 drums/1000
3	To monitor and minimize the Pest infestation in the plant.	No incidence of pest

Food safety Team

SI.No	Objectives	Measurable target
1	To complete all verification activities within 5 days of the scheduled date.	100%
2	No breaches of hygiene practices (not wearing scalp covering, jewelry violations etc) are allowed in the high risk production department per month	100%

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RM- Specification

Annexure -05

Raw materials used are:

Fresh fruits and Vegetables, dry ingredients like red chilly, turmeric, coriander etc, vegetable oil and salt.

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Sl. No	Name of the Product	Ingredients
01	Mango Pickle (in oil)	Brined Mango slices, water, Chilly powder Gingerly oil, mustard powder, salt, acetic acid, Turmeric powder, Fenugreek powder, Asafetida, Sodium benzoate, water
02	Tender Mango pickle(in Oil)	Brined mango, Water, Chilly powder, Gingili oil, Mustard paste, Salt, Acetic acid, Asafetida, Turmeric powder, Sodium benzoate,
03	Garlic Pickle (in oil)	Water, Brined and fried Garlic, Gingili oil, Chilly powder, Salt, Mustard powder, Sugar, Ginger paste, Garlic paste, Tamarind, Green chilly, Acetic acid, Pepper powder, Turmeric powder ,Fenugreek powder, Mustard, Curry leaves, Asafetida ,Sodium benzoate,
04	Ginger Pickle (in oil)	Water, Brined and fried Ginger, Gingili oil, Chilly powder, Salt, Green chilly, Onion, Tamarind, Acetic acid, Fried Coconut ,Mustard powder, Turmeric powder, Fenugreek powder, Cardamom, Mustard, Curry Leaves, Asafetida, Sodium benzoate, Sugar,

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5	Mixed Vegetable Pickle (in oil)	Water, Brined Carrot, Garlic, Papaya, Mango, Tomato, Chilly powder Garlic paste, Brinjal, Gingili oil, Ginger, Ginger paste, Green chilly, Pineapple, Mustard powder, Tamarind, Sugar, Salt, Acetic Acid, Curry leaves, Fenugreek powder, Turmeric powder, Asafetida, Pepper powder, Sodium benzoate, Cumin, Fennel,
07	Bitter guard (Pickle in oil)	Water, Brined and fried Bitter gourd, ,Onion, Gingili oil, Chilly powder ,Garlic, Ginger, Tamarind, Green Chilly ,Mustard powder, Acetic acid, Sugar, Fenugreek powder, Turmeric powder, Curry leaves, Asafetida, Mustard ,Sodium benzoate, Spices.
08	Gooseberry pickle(in oil)	Brined Gooseberry, Water, Gingili oil ,Chilly powder, Ginger, Salt, Garlic, Mustard powder, Acetic acid, Green chilly, Fenugreek powder, Turmeric powder, Asafetida, Mustard, Sodium benzoate,
09	Green chilly pickle (in oil)	Brined green chilly, Bhaji chilly, Water, Gingili oil, Garlic, Salt, Ginger, Mustard powder, Tamarind, Acetic acid, Fenugreek

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		powder, Turmeric powder, Mustard, Curry leaves, Asafetida, sodium Benzoate.
10	Kadumango pickle (in oil)	Brined mango slices, Gingili oil, Green chilly, Garlic, Turmeric powder, Acetic Acid, Fenugreek, Asafetida, Mustard, Curry leaves,

1 1	Hot & sweet lime Pickle (in oil)	Brined lime, Water, sugar, Dates, Gingili oil, Garlic, Ginger, Chilly powder, Green chilly, Grapes, Acetic acid, fenugreek, turmeric, cardamom, Mustard, curry leaves, Asafetida, Sodium Benzoate.
1 2	Pineapple pickle (in Oil)	Water, Pineapple, Gingili oil, Chilly powder, Green chilly, Onion, Garlic, Tamarind, sugar, Acetic acid, Mustard powder, Ginger , Turmeric powder, Fenugreek powder, Cardamom, Mustard, Sodium Benzoate
1 3	Dates Pickle (in oil)	Dates, Water, Chilly powder, Gingili oil, Salt, Ginger, Garlic, Mustard powder, Green chilly, Acetic acid, Turmeric powder, Curry leaves, Mustard, Cumin, Fennel, Cardamom, Sodium Benzoate.
1	Tomato Pickle (in oil)	Tomato, Water, Gingili oil, Chilly powder, Garlic, ginger, salt,

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4		sugar, Mustard powder, fenugreek powder, Curry leaves, Asafetida, Mustard, Turmeric powder, Sodium Benzoate, Pepper powder, cumin, Fennel
1	White lime pickle (in oil)	Lime, Bhaji chilly, Garlic, Green chilly, Gingili oil, Ginger,
5		fenugreek powder, Acetic Acid, Mustard, Sodium Benzoate, Asafetida.

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Annexure 06

Final Product Specifications

1. Pickles

Pickles are salted fruit and vegetable product containing spices and acidulants like citric acid or glacial acetic acid (a class II preservative) categorizing the product as acidified medium acid food. Pickles are added with minimum 8 percentage of vegetable oil, which act as additional preservation medium.

Product Characteristics

Salt content -	Minimum 9%
PH -	Less than 3.7
Acidity -	Min. 1.5%
Acidulants -	Acetic acid
Heat treatment -	Not applicable
Aw -	Not applicable

Microbiological Characteristics

Salmonella -	Absent
TPC -	10000 CFU
E.Coli -	Absent
Yeast & Molds-	100 CFU- Max

Packing &Storage conditions

Pickles are packed in pre-washed glass bottles and laminated flexible pouches further packed in corrugated boxes. The product can be stored at ambient temperature as the storage is not critical the label is not provided with any storage instructions.

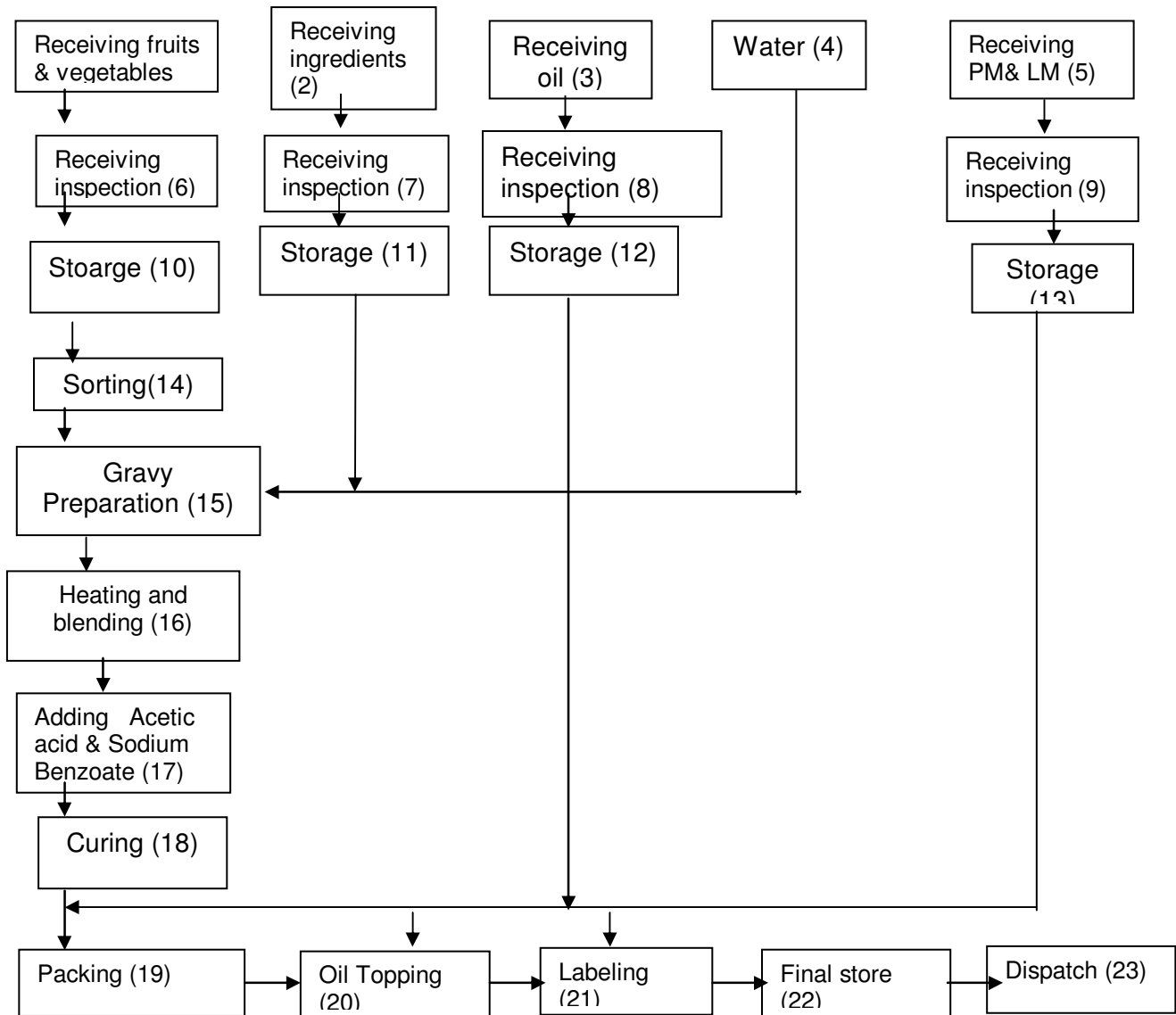
Shelf Life:

Eighteen months shelf life is declared on the label. The products consumed after the shelf life may have sensory deficits but any health hazard.

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FlowChart-1(Pickles)

Annexure -07



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HAZARD ANALYSIS WORK SHEET

Annexure 08

Process step	Hazard Type	Source or cause of hazard	Assessment				
			Likelihood	Severity	Risk	Control measure	Significant Hazard
1. & 6 Receiving fruits & vegetables	B—Y	Fruits & vegetables may be contaminated with pathogenic bacteria, yeast & mold	2	2	4	* Inspection of fruits and vegetables (visual inspection) * COA obtained from supplier	N
	C—Y	toxic chemicals,					
	P—Y	extraneous matters like stone, metal materials pieces, glass etc					
2. & 7 Receiving Ingredient	B—N	nil	2	2	4	* Receiving inspection as per quality plan. COA from supplier obtained for packed items	N
	C—N	nil					
	P—Y	Presence of foreign objects					
3. & 8 Receiving oil	B—N	Nil	1	3	3	* Physical analysis for foreign matter and sediments. * COA obtained from supplier	N
	C—Y	Chemical degradation and adulteration					
	P—Y	Foreign particles					
4. Water	B--Y	Presence of pathogenic Microorganisms	1	2	2	* Water drawn from the source is analysed once in a year for bacteriological chemical quality. * It is stored in a tank with covered	N
	C--Y	Dissolved heavy metals & organic chemicals					
	P--Y	Presence of foreign particles					
5. & 9 Receiving PM & LM	B-Y	Presence of Micro organisms	1	2	2	* Bottles are accepted only from approved suppliers. * Physical verification at	N
	C-N	Nil					

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	P--Y	Presence of dust & other foreign particles.				the time of receipt	
Process step	Hazard Type	Source or cause of hazard	Assessment				
			Likelihood	Severity	Risk	Control measure	
10.Storage of Semi processed pickles	B--Y	Presence of Microorganisms/ fungal growth	3	4	12	* Periodic verification for salinity . Add salt as required.	Y
	C--N	Nil					
	P--N						
11 - 13 .Storage of items	B--N	Nil	-	-	-	* Items pass the receiving inspection and are stored . These items are either packed or bottled .	N
	C--N	Nil					
	P--N	Nil.					
14. Sorting	B—N	Nil	2	2	4	* Ensure personnel hygiene * Usage of hygienic and SS grade trays for verification.	N
	C—N	Nil					
	P—Y	Presence of foreign particles					
15. Gravy preparation	B—Y	Nil	2	2	4	* Ensure personnel hygiene * water tested for portability	N
	C—N	Dissolved heavy metals & organic chemicals					
	P—N	Presence of foreign particles					
16.Heating & Blending	B-Y	Presence of Micro organisms	3	4	12	* Monitoring temperature * Adding spices as per recipe. * Ensure personnel hygiene.	Y
	C-N	Nil					
	P--Y	Extraneous contaminants from operators					
17. Adding Acetic acid/ Salt & Sodium Benzoate	B-Y	Insufficient mixing leads to microbial growth	3	4	12	* Ensure personnel hygiene. * Adding ingredients as per permitted limit.	Y
	C- N						
	P-N	Foreign particles					

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Process step	Hazard Type	Source or cause of hazard	Assessment				
			Likelihood	Severity	Risk	Control measure	Significant hazard
18. Curing	B—Y	Micro organisms	2	2	4	*Ensure the Operation procedure for temperature checking.	N
	C—N	nil					
	P—N	Nil					
19.Packing	B—N	Nil	2	1	2	*. Ensure personnel hygiene	N
	C—N	Nil					
	P—Y	Extraneous contaminants from operators					
20.oil topping	B—Y	Insufficient oil on the top could result in the microbial penetration.	3	4	12	* Filled bottles are cleaned and topped with sufficient oil. * Verified & analyzed by QC Dept.	Y
	C—N	Nil					
	P—N	Nil					
21, 22,23 .Labelling, Storage& Dispatch	B—N	Nil	1	1	1	After labeling the unit packs are stored at designated area.	N
	C—N	Nil					
	P—N	Nil					

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CCP/ OPRP Determination- Decision tree

Annexure 8A

Step Number & Process step	Significant Hazard	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Total Score	CCP/ OPRP	
10.Storage of Semi processed pickles	Presence of Microorganisms/ fungal growth	1	1	1	3	3	1	1	1	12	OPR P-1	
16.Heating & Bending	Presence of Microorganisms	3	3	1	3	3	3	3	3	22	CCP -1	
17. Adding Acetic acid/ Salt & Sodium Benzoate	Presence of Microorganisms	3	3	1	3	3	3	3	3	22	CCP -2	
20.oil topping	Insufficient oil on the top could result in the microbial penetration	3	3	1	3	3	3	3	3	22	CCP -3	

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OPRP Control Plan

Annexure 09

Step	Action Criteria	Monitoring				Corrective Action	Verification Procedure	Record
		Who	What	How	When			
10.Storage of Semi processed pickles OPRP-01	Verify the salinity level and add salt if required.	QC Person	Salinity level	Tasting	Every 3 months	Operator adjust The level of salt	Check the added Level of salt and frequency of addition	Salinity Register

HACCP Plan CCP-01

Step	Critical limit	Monitoring				Corrective Action	Verification Procedure	Record
		Who	What	How	When			
16.Heating & Blending CCP-01	60 °C Max.	QC Person	Temperature	Temperature Probe	Every batch	Heating upto the required temperature	Check the temperature log	Production report

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HACCP Plan (CCP 2 & 3)

Step	Critical limit	Monitoring				Corrective Action	Verification Procedure	Record
		Who	What	How	When			
17. Salt Acetic acid Sodium Benzoate 20.oil topping	*Salt- Minimum 9- 12% *Acetic acid-1.2-2% * 250ppm Oil-0.5cm unit (Bottle) Drained weight-60%	QC person	Acidity and Percentage of salt concentration SB level and oil level Drained weight	Testing Oil level by visual inspection	Every batch Oil level- After filling every unit	Operator adjust the quantity of salt , Acetic acid & oil	Checking the process and limits for acceptance limit	Production report