# JFS-E-C Standard (Sector: E/L) [Requirements for Organizations]

Ver. 2.2

Japan Food Safety Management Association September 15, 2017

### 1. Introduction

### 1.1 JFS-C Standard

The JFS-C Standard (hereinafter referred to as "this Standard") is a standard developed by the Japan Food Safety Management Association (JFSM) and is intended to assist organizations to establish, operate and improve its management systems for manufacturing safe food products. In addition, this Standard can also be utilized to have the system of the organization (\*1) evaluated by external agencies including Certification Bodies. This Standard is utilized by organizations that endeavor to realize a food safety management system applicable worldwide.

(\*1) "Organization" refers to a business entity to whom the requirements of this Standard apply. In the manufacturing sector, it refers to business operator, group or individual who manufactures food products.

### 1.2 Scope of Application

This Standard applies to the "food manufacturing sector (E)" and to the "manufacturing sector of chemical products (including biochemical products) (L)" as follows:

Food Manufacturing Sector (E)

- El Processing of perishable animal products;
- Ell Processing of perishable plant products;
- EIII Processing of perishable animal and plant products (mixed products);
- EIV Processing of ambient stable products.

Manufacturing Sector of Chemical Products (including biochemical products) (L)

Production of chemical products (including biochemical products).
 (Production of additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids).
 "Chemical products (including biochemical products)" herein refer to those related to food.

### 1.3 Structure of this Standard

This Standard consists of three elements, namely, Food Safety Management Systems (FSM), Hazard Analysis and Critical Point Control (HACCP), and Good Manufacturing Practice (GMP).

This Standard only specifies common requirements for the manufacturing sector, and does not cover individual hygiene requirements for each product. Organizations shall use information appropriate for the organization (e.g. laws and regulations on food safety, standards specified by the relevant industry group, "General Principles of Food Hygiene Code of Practices" by the Codex Alimentarius Commission (\*2), specific code of conduct), in addition to the requirements stipulated in this Standard. Furthermore, organizations are advised to refer to JFS Standards Interpretation of the Requirements and JFSM Guidelines.

### (\*2) Codex Alimentarius Commission

"RECOMMENDED INTERNATIONAL CODE OF PRACTICES" GENERAL PRINCIPLES OF FOOD HYGIENE" developed and provided by Codex Alimentarius Commission for specific industry as CAC/RCP series.

### 1.4 Exclusion from Application of Requirements

All the requirements in this Standard shall be applied in principle. However, in case any of the requirements in this Standard is not able to apply for reasons arising from the business scale, business form and so on of an organization, the organization shall provide a document which indicates proof of non-applicability with explanations demonstrating the proper maintenance of food safety management.

### 1.5 Continuous Improvement

Organizations are required to fulfill requirements for organizations, make continuous improvement to the organization's food safety management, and to maintain and improve the level of the food safety management. Therefore, requirements for organizations are formulated on the basis of repeating Plan-Do-Check-Act (PDCA) cycles.

Each requirement for organizations specified by the Scheme is closely linked to one another in a PDCA cycle. Additionally, a PDCA cycle exists within each requirement. Organizations are required to understand the whole image of requirements and comply each individual requirement.

Requirements for organizations in PDCA cycle are summarized in the figure on the following page:

### **FSM Plan** 1 Food Safety Management Systems 7 Resource Management **General Requirements** 8 Document and Record Control 2 Food Safety Policy 9 Specification Control of Purchased or 3 Food Safety Manual **Provided Items and Services** 4 Top Management Responsibility 10 Procedures and Instructions 14 Product Release 5 Active Top Management Commitment 15 Purchasing 16 Supplier Performance Act 17 Outsourcing 12 Nonconformity Control 18 Complaint Handling 13 Corrective Action 19 Utilization of Suggestions for 28 Food Safety Management System Updating Improvement from Workers 20 Serious Incident Management Check Control of Measuring and Monitoring 6 Management Review 22 Food Defense 11 Internal Audit 23 Product Labeling 27 Verification Activities and Results Analysis 24 Traceability 25 Analysis of Input Materials Do 26 Food fraud prevention measures 29 Allergen Management 30 Environmental Monitoring for Food Manufacturing

### HACCP, GMP

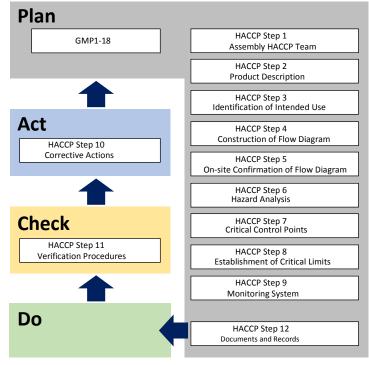


Figure: Structure of this Standard from the PDCA point of view

(Reference) Category is as shown in the table below:

# **Category List of JFS Standard Sectors**

The categories below are used in this JFS Standard.

The "food manufacturing sector (E)" refers to EI-EIV.

The "manufacturing sector of chemical products (including biochemical products) (L)" refers to L.

Code	Category	Code	Category
Al	Farming of Animals for Meat/ Milk/ Eggs/ Honey	F	Production of feed
AII	Farming of Fish and Seafood	G	Catering
BI	Farming of Plants (other than grains and pulses)	Н	Retail / Wholesale
BII	Farming of Grains and Pulses	1	Provision of Food Safety Services
С	Animal Conversion	J	Provision of Storage and Distribution Services
D	Pre-process handling of plant products, nuts and grain	К	Manufacture of Food Processing Equipment
EI	Processing of perishable animal products		Production of Chemical Products (including
EII	Processing of perishable plant products		Biochemical Products) (Additives, Vitamins, Minerals, Bio-cultures, Flavorings, Enzymes
EIII	Processing of perishable animal and plant		and Processing aids)
LIII	products (mixed products)		Production of Food Packaging
EIV	Processing of ambient stable products	N	Food Broker / Agent

Cited from GFSI Benchmarking Requirements

# 2. Specific Requirements (Standard)

# 2.1 Food safety management systems (FSM)

Number	Clause Name	Requirements
FSM 1	Food Safety Management Systems General Requirements	The organization shall document, implement and maintain the elements of the organization's Food Safety Management Systems. Additionally, the organization shall continuously improve the organization's Food Safety Management Systems properly adapting to changes in the surrounding social environment. The food safety management systems shall:  a) clarify the scope of application of the food safety management systems, b) comply with laws and regulations related to food safety in the country of manufacture and the country of destination. c) identify the processes needed for the food safety management systems, d) determine the sequence and interaction of these processes, e) determine the criteria and methods required to ensure the effective operation and control of these processes, f) continue and maintain the operation and monitoring of these processes, ensure the availability of resources and information necessary to support the operation and monitoring of these processes, g) measure, monitor and analyze these processes and implement actions necessary to achieve planned results and continuous improvement. h) include a procedure for verification of the food safety management system to confirm that the system continues to be effective. Updating of a food safety management system shall be planned and conducted. On updating, considerations shall be given to maintain the
FSM 2	Food Safety Policy	integrity of the food safety management system.  The top management shall have a clear, concise and documented food safety policy statement and objectives specifying the extent of the organization's commitment to meet the safety needs of its products. The top management shall ensure the organization to establish measurable objectives consistent with the organization's food safety policy, formulate plans to achieve the objectives, monitor the progresses against the objectives, and to update the objectives as necessary.
FSM 3	Food Safety Manual	The organization shall have a documented Food Safety Manual having a scope appropriate for the range of business activities to be covered, including documented procedures and specific references to them and describing the interaction of the related process steps.

Number	Clause Name	Requirements
FSM 4	Тор	The top management shall establish a clear organizational structure
	Management	which unambiguously defines and documents the job functions,
	Responsibility	responsibilities, directing and reporting structure and information
		sharing of at least the workers whose activities affect food safety.
		The top management shall appoint person(s) responsible for the
		operation of the organization's food safety management system.
FSM 5	Тор	The top management shall provide evidence of the commitment to
	Management	establish, implement, maintain and improve the food safety
E014.0	Commitment	management system.
FSM 6	Management	The top management shall review the verification of the food safety
	Review	management system and HACCP Plan, at planned intervals, to ensure
		the continuing conformity, suitability and effectiveness.
		HACCP Plan shall be reviewed also in the event of any change that impacts food safety. Such a review shall evaluate the need for
		changes to the entire food safety management system, including the
		food safety policy and food safety objectives.
FSM 7	Resource	The top management shall determine and provide, in a timely manner,
1 OW 7	Management	the qualified resources (including suitably qualified personnel) needed
	Managomone	to implement, maintain and improve the food safety management
		system.
FSM 8	Document	The organization shall prepare documents and keep records to
	and Record	demonstrate that the organization's operations and activities comply
	Control	with the requirements of this Standard.
		The organization shall have a written procedure to control and maintain
		the documents and records and make the documents and records
		readily accessible when needed.
		The retention period of the documents and records shall be set
		complying with, if any, the regulatory and customer requirements.
FSM 9	Specification	For all inputs to the process, such as items and services (including raw
	Control of	materials and ingredients, utilities and services (e.g. electricity, water,
	Purchased or	transport, maintenance)) that are purchased or provided and have an
	Provided	effect on the safety of final product, the organization shall ensure that
	Items and	documented specifications are prepared, maintained, securely retained
FSM 10	Services Procedures	and readily accessible when needed.  The organization shall design the products and production processes
FSIVI 10	and	taking into account all relevant safety requirements. The organization
	Instructions	shall establish, implement and maintain documented procedures and
	instructions	instructions for all processes and operations having an effect on food
		safety.
FSM 11	Internal Audit	The organization shall plan and implement internal audits for the
		activities covering all the scope of the food safety management system,
		including HACCP Plan, Food Defense Plan and Food Fraud Prevention
		Plan.
		The results of internal audits and corrective actions shall be recorded.
		The organization shall specify the competence required for internal
		auditors and provide training.

Number	Clause Name	Requirements
FSM 12	Nonconformity	The organization shall establish effective procedures to ensure that any
	Control	product, which does not conform to food safety requirements, is clearly
		identified, controlled, discarded, modified, reprocessed and/or corrected
		to prevent unintended use or delivery.
		These procedures shall be defined in a documented procedure that is
		securely retained and readily accessible when needed.
FSM 13	Corrective	The organization shall establish procedures for the determination and
	Action	implementation of corrective action in the event of any nonconformities
		relating to food safety.
		In case of deviance or violation, the organization shall identify the root
		cause, take measures to prevent recurrence, and review the
<b>501444</b>		effectiveness for the series of corrective actions.
FSM 14	Product	The organization shall prepare and implement appropriate product
=014.4=	Release	release procedures.
FSM 15	Purchasing	The organization shall control purchasing processes to ensure that all
		externally sourced raw materials, ingredients and services (including
		packaging materials) which have an effect on food safety, conform to
		requirements.
		In case of emergency, such as natural disaster, purchasing from non-
		approved suppliers is allowed. Under such situation, in order to ensure food safety, the organization shall assess the non-approved supplier
		facility and verify the conformity of the products to the given
		specification.
FSM 16	Supplier	The organization shall establish, implement and maintain procedures for
I GIVI 10	Performance	the evaluation, approval and continued monitoring of suppliers, which
	Chomianec	have an effect on food safety. The results of evaluations and
		investigations, and follow up actions shall be recorded.
FSM 17	Outsourcing	The organization shall, where the organization chooses to outsource
		any process that may affect food safety, shall ensure control over such
		processes.
		Control of such outsourced processes shall be identified, documented
		and monitored as a part of food safety management system.
		In case of emergency, such as natural disaster, purchasing from non-
		approved service provider is allowed. Under such situation, in order to
		ensure food safety, the organization shall assess the non-approved
		service provider facility, as necessary, and verify the conformity of the
		products to the given specification.
FSM 18	Complaint	The organization shall establish, implement and maintain an effective
	Handling	system for the management of complaints and complaint data to
		properly control and correct defects in food safety activities.
FSM 19	Utilization of	The organization shall establish and implement a system to properly
	Suggestions	utilize suggestions from workers to improve food safety.
	for	
	Improvement	
	from Workers	

FSM 20 Serious Incident Incident Management Management Management Procedure shall be regularly tested for all products it supplies and planning for product withdrawal and product recall as required. The effectiveness of the incident management procedure shall be verified at least once a year, and the results shall be recorded.	
Management procedure shall be regularly tested for all products it supplies and planning for product withdrawal and product recall as required. The effectiveness of the incident management procedure shall be	cover
planning for product withdrawal and product recall as required.  The effectiveness of the incident management procedure shall be	cover
The effectiveness of the incident management procedure shall be	
verified at least once a year, and the results shall be recorded.	
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FSM 21 Control of The organization shall identify the methods for measurement of	1
Measuring parameters critical to ensure food safety, identify the measuring are	na
and monitoring devices required, and carry out calibration of these	ional
Monitoring measuring and monitoring devices by a method traceable to a nati	onai,
Devices international or equivalent standard.	d
FSM 22 Food Defense The organization shall establish a documented assessment proced	
to identify threats of food defense and prioritize food defense measurement and record the result.	suies,
The organization shall develop a documented plan that specifies the	he
measures the organization implements to mitigate the identified th	
of food defense.	icats
The plan (Food Defense Plan) shall cover GMP and shall be	
incorporated into the food safety management system.	
FSM 23 Product The organization shall ensure that all product bears or is accompa	nied
Labeling by information to enable the safe handling, display, storage, prepa	
and use of the product including allergens in the food supply chain	
consumer.	
The finished product shall be labelled according to the applicable f	ood
regulations in the intended country of sale.	
Procedures to ensure the correct information on the product shall	be
established and implemented.	
FSM 24 Traceability The organization shall establish, implement and maintain appropri	ate
procedures and systems to ensure:	
a) identification of any outsourced raw materials and ingredier	nts
(including packaging materials), products, services and	
outsourced processes;	
b) product identification that includes, as a minimum, the name	e and
location of the producer;	in
c) identification of batches, partially processed products, work progress, products being reprocessed, reworks, finished	""
products, and packaging materials throughout the production	'n
process;	""
d) records of purchaser and delivery destination for all product	te
supplied.	
The procedures and systems shall be verified at least once a year	. and
the results shall be recorded.	,
FSM 25 Analysis of The organization shall establish and implement a system to ensure	e
Input analysis of input raw materials and ingredients (including water) th	
Materials have an effect on food safety. The inspection shall be conducted	
compliance with ISO 17025 or equivalent standards.	

Number	Clause Name	Requirements
FSM 26	Food Fraud Prevention	The organization shall establish a documented assessment procedure to identify the food fraud vulnerability such as potential falsification of product record, mislabeling and intentional dilution of product, and to prioritize food fraud mitigation measures, implement the procedure, and record the result.  The organization shall develop a documented plan that specifies the measures the organization implements to mitigate the identified threats of food fraud.  The plan (Food Fraud Mitigation Plan) shall cover GMP and shall be
FSM 27	Verification Activities and	incorporated into the food safety management system.  The organization shall verify the implementation status of FSM, GMP and HACCP, and analyze the results of verification activities. Results
	Result Analysis	of analysis and follow up activities shall be recorded. These results shall be reported to the top management at the management review.
FSM 28	Food Safety Management System Updating	The top management shall ensure continuous update of the organization's food safety management system. In order to achieve the continuous update, the organization shall review the organization's food safety management system at planned intervals, and record the result.  The organization shall report the system updating activities to the top management at the management review.
FSM 29	Allergen Management	The organization shall develop and implement an allergen management plan for all food manufacturing facilities.  The plan shall include a risk assessment of allergen cross-contamination and implemented control measures to reduce or eliminate the risk of cross-contamination.  All finished products intentionally or potentially containing allergenic materials shall be labelled according to the allergen labelling regulations in the country of manufacture and the country of destination.
FSM 30	Environmental Monitoring for Food Manufacturing	The organization shall develop and implement a risk-based environmental monitoring program which includes all high-care and high-risk areas.

# 2.2 Hazard Analysis and Critical Control Point (HACCP)

HACCP Step 1 Assembly  HACCP Product Step 2  Description  HACCP Product Step 2  Description  HACCP Product Description  HACCP Step 3  Identification of Intended Use HACCP Step 4  HACCP Construction of Flow Diagram HACCP Step 5  Confirmation of Flow Diagram HACCP Step 6  (Principle 1)  HACCP Critical Control Step 7  HACCP Step 8  HACCP Critical Control Step 9  HACCP Step 10  HACCP HAC		Clause Name	Requirements
HACCP Step 2 Description The document shall be described in written document. The document shall describe all product information necessary to conduct hazard analysis. Scope of the HACCP system shall be defined per product/product group and per process line/process-location.  HACCP Identification of Intended Use Construction of Step 3 Intended Use Construction of Flow Diagram HACCP Step 5 Confirmation of Flow Diagram HACCP Step 6 Confirmation of Flow Diagram HACCP Step 7 Corifical Control Principle 1)  HACCP Critical Control Principle 2)  HACCP Step 8 Critical Control Step 8 Critical Limits Principle 3)  HACCP Step 9 Corrective Actions Actions Actions Corrective Actions Actions Corrective Actions Actions Actions Actions Actions Actions Actions Accord Actions Actions Accord Ac	HACCP	HACCP Team	A HACCP team shall be assembled with competent staff.
Description   The document shall describe all product information necessary to conduct hazard analysis. Scope of the HACCP system shall be defined per product/product group and per process line/process-location. The intended use of product and target consumers shall be clearly described in written document. The flow diagram that covers all steps in the operation shall be clearly described in written document. The flow diagram that covers all steps in the operation shall be constructed. The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation. The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation. The flow diagram shall list all of the hazards that are reasonably likely to occur at each process steps, conduct an analysis, and identify any necessary measures to control them. Hazard shall include allergens where required.  HHACCP   Step 1   Critical Control Points (CCPs) shall be determined.  Critical Limits   Critical Control Points (CCPs) shall be determined.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation. The flow diagram shall list all of the hazards that are reasonably likely to occur at each process steps, conduct an analysis, and identify any necessary measures to control them. Hazard shall include allergens where required.  Critical Control Points (CCPs) shall be determined.  Critical Limits (Principle 2)  HACCP   Monitoring   Monitoring procedure shall be established for each CCP.  Step 10   Actions   Act	Step 1	Assembly	
to conduct hazard analysis. Scope of the HACCP system shall be defined per product/product group and per process line/process-location.  HACCP Intended Use Intended Use of product and target consumers shall be clearly described in written document.  HACCP Construction of Step 4 Flow Diagram  HACCP Confirmation of Flow Diagram that covers all steps in the operation shall be constructed.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be described whether it correctly reflects the existing process steps of the operation.  The flow diagram shall be established for each CCP.  Critical Control Points (CCPs) shall be established for each CCP.  Step 1 (Critical Control Points (CCPs) shall be established for each CCP.  Step 1 (Critical Limits (Principle 4) (Principle 4) (Principle 5) (Principle 5) (Principle 5) (Principle 6) (Prin	HACCP	Product	Product specifications shall be described in written document.
Scope of the HACCP system shall be defined per product/product group and per process line/process-location.  HACCP Identification of Intended Use Intended Use of product and target consumers shall be clearly described in written document.  HACCP Construction of Flow Diagram The flow diagram that covers all steps in the operation shall be constructed.  HACCP On-site The flow diagram shall be verified whether it correctly reflects to confirmation of Flow Diagram The HACCP team shall list all of the hazards that are reasonably likely to occur at each process steps, conduct an analysis, and identify any necessary measures to control them. Hazard shall include allergens where required.  HHACCP Critical Control Points (CCPs) shall be determined.  HHACCP Establishment of Critical Limits (Principle 3)  HACCP Step 8 Critical Limits (Principle 4)  HACCP Corrective Actions and removal of root cause) shall be established for deviations from critical limit.  HACCP Step 10 (Principle 5)  HACCP Verification Verification procedure shall be established to confirm (1) whether the defined instructions are working as intended.  Verification procedures shall be established to confirm (1) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  Necessary records shall be taken and retained.	Step 2	Description	The document shall describe all product information necessary
Product/product group and per process line/process-location.			to conduct hazard analysis.
HACCP Intended Use Intended use of product and target consumers shall be clearly described in written document.  HACCP Construction of Flow Diagram Flow Diagram Constructed.  HACCP On-site Confirmation of Flow Diagram Flow Dia			Scope of the HACCP system shall be defined per
Step 3			product/product group and per process line/process-location.
HACCP Step 4 Flow Diagram Flow diagram that covers all steps in the operation shall be constructed.  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  Flow Diagram  The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.  Flow Diagram  HACCP Step 5 Confirmation of Flow Diagram  HACCP Step 6 (Principle 1)  Critical Control Points  Critical Control Points  Critical Control Points (CCPs) shall be determined.  Critical Limits  Principle 3)  HACCP Step 8 Critical Limits  Principle 4)  HACCP Step 9 System  (Principle 5)  Monitoring Step 10 Actions  Critication  Verification  Verification  Verification  Verification procedure shall be established for deviations from critical limit.  Verification procedures shall be established to confirm  (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  HACCP Documents and Record  Necessary records shall be taken and retained.	HACCP	Identification of	The intended use of product and target consumers shall be
Step 4   Flow Diagram   Constructed.	Step 3	Intended Use	clearly described in written document.
HACCP Step 5 Confirmation of Flow Diagram  HACCP Step 6 (Principle 1) HACCP Step 7 (Principle 2) HACCP Step 8 (Principle 3) HACCP Step 9 (Principle 4) HACCP Step 10 (Principle 5) HACCP Step 10 (Principle 6)  HACCP Step 11 (Principle 6)  HACCP Step 12  HACCP Baccar  HA	HACCP	Construction of	The flow diagram that covers all steps in the operation shall be
Step 5	Step 4	-	
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HACCP Step 6 (Principle 1)  Hazard Analysis Step 6 (Principle 1)  HHACCP Step 7 (Principle 2)  HACCP Step 8 (Principle 3)  HACCP Step 9 (Principle 4)  HACCP Step 10 (Principle 5)  HACCP Step 10 (Principle 5)  HACCP Step 10 (Principle 6)  Werification  Verification  Ve	Step 5		the existing process steps of the operation.
reasonably likely to occur at each process steps, conduct an analysis, and identify any necessary measures to control them. Hazard shall include allergens where required.  Critical Control Points (CCPs) shall be determined.  Points  Critical Limits  Critical limit(s) shall be specified for each CCP.  Critical Limits  Critical limit(s) shall be established for each CCP.  Step 8  (Principle 3)  Critical limit(s) shall be established for each CCP.  Corrective  Monitoring  System  Monitoring procedure shall be established for each CCP.  Corrective  Actions  Actions  Actions  Procedure of corrective action (correction, and investigation and removal of root cause) shall be established for deviations from critical limit.  Verification procedures shall be established to confirm  (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  HACCP  Documents and Record  Necessary records shall be taken and retained.			
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HHACCP Step 7 (Principle 2)  HACCP Establishment of Step 8 (Principle 3)  HACCP System Monitoring System  HACCP Corrective Actions (Principle 5)  HACCP Step 10 (Principle 5)  HACCP Step 11 (Principle 6)  HACCP Step 12 (	(Principle 1)		
Step 7 (Principle 2)  HACCP Step 8 (Principle 3)  HACCP Step 9 (Principle 4)  HACCP Step 10 (Principle 5)  HACCP Step 11 (Principle 6)  HACCP Step 12  Record  HACCP Step 12  Critical limit(s) shall be specified for each CCP.  Critical limit(s) shall be established for each CCP.  Monitoring procedure shall be established for each CCP.  Procedure of corrective action (correction, and investigation and investigation and removal of root cause) shall be established for deviations (Principle 6)  HACCP Step 12  Record  HACCP Step 1			
Critical limit(s) shall be specified for each CCP.			Critical Control Points (CCPs) shall be determined.
HACCP Step 8 (Principle 3)  HACCP Step 9 (Principle 4)  HACCP Step 10 (Principle 5)  HACCP Step 10 (Principle 5)  HACCP Step 11 (Principle 6)  HACCP Step 12 (Pri	•	Points	
Step 8 (Principle 3)  HACCP Step 9 (Principle 4)  HACCP Step 10 (Principle 5)  HACCP Step 11 (Principle 6)  Werification Step 11 (Principle 6)  HACCP Step 11 (Principle 6)  HACCP Step 11 (Principle 6)  Werification Step 11 (Principle 6)  Werification Step 11 (Principle 6)  Necessary records shall be established for deviations are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  Necessary documents shall be taken and retained.			
Company of the procedure of the procedure shall be established for each CCP.			Critical limit(s) shall be specified for each CCP.
HACCP System  System  Corrective Actions  HACCP Step 10  (Principle 5)  HACCP Verification  Step 11  (Principle 6)  Werification procedures shall be established for deviations from critical limit.  Werification procedures shall be established to confirm  (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  HACCP Documents and Record  Necessary documents shall be taken and retained.	•	Critical Limits	
Step 9 (Principle 4)  HACCP Step 10 (Principle 5)  HACCP Step 11 (Principle 6)  Step 11 (Principle 6)  Step 12  System  Procedure of corrective action (correction, and investigation and removal of root cause) shall be established for deviations from critical limit.  Verification  Verification  Verification procedures shall be established to confirm (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  HACCP Documents and Record  Necessary documents shall be prepared and maintained.  Necessary records shall be taken and retained.		NA iti	Manifesia na cara de manada II bana a Cabillaba di Cara a de COD
(Principle 4)  HACCP Step 10 (Principle 5)  HACCP Step 11 (Principle 6)  Verification  (Principle 6)  Corrective Actions  From critical limit.  Verification procedures shall be established to confirm (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  HACCP Documents and Record  Necessary documents shall be taken and retained.		_	Monitoring procedure shall be established for each CCP.
HACCP Corrective Actions Procedure of corrective action (correction, and investigation and removal of root cause) shall be established for deviations from critical limit.  HACCP Verification Verification procedures shall be established to confirm (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  HACCP Documents and Record Necessary documents shall be prepared and maintained.  Necessary records shall be taken and retained.	•	System	
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(Principle 5)  HACCP Step 11 (Principle 6)  Verification  Verification procedures shall be established to confirm (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended.  Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.  HACCP Documents and Record  Necessary documents shall be prepared and maintained. Necessary records shall be taken and retained.			, ,
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# 2.3 Good Manufacturing Practice (GMP)

Number	Clause Name	Requirements
GMP 1	Facility Environment	The site shall be located and maintained so as to prevent contamination and enable the production of safe products.
GMP 2	Site Management	An appropriate standard for all grounds in the site shall be established and kept.
GMP 3	Design, Construction and Layout of Facilities, Equipment and Production	Site, building, and facility and equipment in plant shall be laid out, designed, constructed and maintained, to enable controlling the risk of product contamination caused by external and internal environment.
GMP 4	Manufacturing and Storage Area Specifications, and Utility Management	Specifications of manufacturing and storage areas shall meet the intended purpose.  Procedures to control contamination and condensation shall be established and implemented, as necessary, for utilities such as air, compressed air and other gases which may come into contact with food.
GMP 5	Devices and Tools	Devices and tools shall be suitably designed for the intended uses and shall be used, maintained and stored so as to minimize food safety risks.
GMP 6	Maintenance	A system of planned maintenance covering all items of equipment which are critical to product safety shall be established.
GMP 7	Staff Facilities	Staff facilities shall be designed and used so as to minimize food safety risks including allergen.
GMP 8	Physical, Chemical and Biological Product Contamination Risks	Appropriate facilities and procedures to control the risks of physical, chemical (including allergen) and biological contamination of product shall be established.
GMP 9	Segregation and Cross-contamination	Procedures to prevent contamination and cross- contamination shall be established for raw materials and ingredients (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products, covering all aspects of food safety including micro organisms, chemicals and allergens.
GMP 10	Stock Management	A system to use raw materials and ingredients (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products by a designated order and within the defined expiry period shall be established and stored under the proper conditions to avoid contamination and deterioration.
GMP 11	Housekeeping, Cleaning and Hygiene	Housekeeping and cleaning shall be carried out following the documented standard throughout all the process steps and stages, and an appropriate hygiene level shall be maintained at all times by disinfecting where necessary. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended use and stored appropriately.

Number	Clause Name	Requirements
GMP 12	Water and Ice Management	Application-dependent quality standards shall be established for waters (including steam and ice; the same applies hereinafter) used in food manufacturing, and the quality of water shall be regularly monitored and recorded.  Facilities, tools and procedures used for handling water shall
GMP 13	Waste Management	be checked to prevent contamination.  Adequate systems for segregation, collection and disposal of waste material shall be established.  Locations and containers for placing waste material shall be controlled to prevent attraction of pests or growth of harmful organisms/micro organisms. The traffic line of waste material shall be established so as to prevent crosscontamination into food.
GMP 14	Pest Control	A system shall be established to control or eliminate the food safety risks caused by pests in the site or in the facilities. In case where chemicals are used, handling procedure shall be established not to affect food.
GMP 15	Transport	A documented system shall be established to ensure that containers and vehicles, including contracted vehicles, used for the transportation of raw materials and ingredients (including packaging materials), partially processed products, works in progress, products being reprocessed, reworks, and finished products (including packed fresh products in final packaging) are suitable for the intended use, maintained in good repair and clean.
GMP 16	Personnel Hygiene and Health Management	Documented personal hygiene criteria based on contamination risks due to product characteristics shall be established and implemented.  The criteria shall include provision of hand washing and toilet facilities, ways and frequency of hand washing, medical screening procedure to identify conditions impacting food safety, proper protective clothing, rules on the clothing and shoes, rules on accessing production area, ways of food handling, and control measures for foreign materials.  The criteria shall be made fully known, trained and applied to workers, contractors and visitors without exception.
GMP 17	Education and Training	A system shall be in place to ensure all workers are adequately educated and trained on food safety principles (including HACCP) and practices, commensurate with the worker's activity.  A system to ensure all workers are adequately instructed and supervised shall be established.  Education and training shall ensure all workers to be aware of the roles in food safety and the significance of the activities.

Number	Clause Name	Requirements
GMP 18	Packing and Storage	Packaging materials shall be obtained with information of
	of Product	origin, be appropriate for use and be used and stored so as
		not to be a source of contamination to the product.
		Products shall be handled, sorted, graded and packaged in a
		way to minimize biological, chemical and physical
		contamination.
		Products shall be stored in designated areas and handled
		under proper condition to minimize contamination.

### Annex

### • Definitions

	Term	Definition
1.	categories	Range of application of certification.
2.	CCP (critical control point)	Step at which control can be applied and is essential or eliminate a food safety hazard
		or reduce it to an acceptable level.
		(Cited from the definition in ISO 22000:2005)
3.	competence	Ability to apply knowledge and skills to achieve intended results.
		Note to entry: Demonstrated competence is sometimes referred to as qualification.
		(Cited from the definition in ISO 9000:2015. Note 2 to entry is not included in the
		definition of "competence" in this document.)
4.	control	The state wherein correct procedures are being followed and criteria are being met.
		(Cited from the definition in CAC/RCP 1-1969, Rev. 4-2003 - Annex)
5.	correction	Action to eliminate a detected nonconformity.
		Note 1 to entry: A correction can be made in advance of, in conjunction with or after
		a corrective action.
		Note 2 to entry: A correction can be, for example, rework or regrade.
		(Cited from the definition in ISO 9000:2015)
6.	corrective action	Action to eliminate the cause of a nonconformity and to prevent recurrence.
		Note to entry: There can be more than one cause for a nonconformity.
		(Cited from the definition in ISO 9000:2015)
7.	critical limit	Criterion which separates acceptability from unacceptability.
		Note to entry: Critical limits are established to determine whether a CCP remains in
		control. If a critical limit is exceeded or violated, the products affected are deemed to
		be potentially unsafe.
		(Cited from the definition in ISO 22000:2005)
8.	document	Information and the medium on which it is contained.
		Example: Record, specification, procedure document, drawing, report, standard
		Note to entry: The medium can be paper, magnetic, electronic or optical computer
		disc, photographic or master sample, or combination thereof.
		(Cited from the definition in ISO 9000:2015. Notes 2 and 3 to entry are not included
		in the definition of "document" in this document.)
9.	employee, personnel	All personnel in an organization who are involved in work related to food safety,
		including part-timers, contractors, and dispatched workers.
10.	flow diagram	Diagrams constructed to show all the process steps for specified product.
11.	food	All substances that are processed, semi-processed or unprocessed with the intention
		of human consumption.
		Note to entry: Food includes all substances used for manufacturing, preparation and
		processing of beverages, chewing gums and foods. However, it does not include
		substances used solely for cosmetics, cigarettes and drugs.
12.	food supply chain	Sequence of the stages and operations involved in the production, processing,
		distribution, storage and handling of a food and its ingredients, from primary
		production to consumption.
L		(Cited from the definition in ISO 22000:2005)
13.	food safety management	A system to specify policies and objectives and to achieve these objectives so that
	system	food does not harm the consumer for when the food is cooked and/or consumed in
		accordance with the intended use.
L		(Referenced to ISO 9000:2015 and ISO 22000:2005)

	Term	Definition
14.	food safety policy	Overall intentions and direction of an organization related to food safety as formally
		expressed by top management.
		(Cited from the definition in ISO 22000:2005)
15.	hazard	A biological, chemical or physical agent in, or condition of, food with the potential to
		cause an adverse health effect.
		(Cited from the definition in the Codex General Principles of food hygiene, Codex
		Alimentarius Commission (CAC/RCP 1-1969, Rev. 4-2003))
16.	intended use	Way of use or consumption of product or building/equipment designated at the time
10.		of planning and designing.
17.	management	Coordinated activities to direct and control an organization.
		Note to entry: Management can include establishing policies and objectives, and
		processes to achieve these objectives.
		(Cited from the definition in ISO 9000:2015. Note 2 to entry is not included in the
		definition of "management" in this document.)
18.	management system	Set of interrelated or interacting elements of an organization to establish policies and
		objectives, and processes to achieve these objectives.
		(Cited from the definition in ISO 9000:2015)
19.	monitoring	Conducting a planned sequence of observations or measurements to assess whether
		action taken to control the food safety is operating as intended.
		(Referenced to ISO 22000:2005)
20.	nonconformities	Non-fulfilment of a requirement.
		(Cited from the definition in ISO 9000:2015)
21.	packaging materials	Materials used for packaging food products, such as papers, plastics, wooden boxes,
		cardboards, PET bottles, and tin cans.
22.	product	Output of an organization that can be produced without any transaction taking place
		between the organization and the customer.
		Note 1 to entry: Production of a product is achieved without any transaction
		necessarily taking place between provider and customer, but can often involve this
		service element upon its delivery to the customer.
		Note 2 to entry: The dominant element of product is that it is generally tangible.
		Note 3 to entry: Hardware is tangible and its amount is a countable characteristic (e.g.
		tyres). Processed materials are tangible and their amount is a continuous characteristic
		(e.g. fuel and soft drinks). Hardware and processed materials are often referred to as
		goods. Software consists of information regardless of delivery medium (e.g. computer
		programme, mobile phone app, instruction manual dictionary content, musical
		composition copyright, driver's license).
		(Cited from the definition in ISO 9000:2015)
23.	raw materials and	Ingredients refer to those used as part of product and do not retain the original form
	ingredients	when the product is finished. Examples are sugar, powdered milk, additives, and
		spices. Materials is a general term referring to packaging materials, processing aids,
		cleaning/cleansing agents, lubricants, etc.
24.	recall	Cessation of supply of product and recovering of all the products including those kept
		by consumers, retail stores, and stocks under distribution.
25.	record	Document stating results achieved or providing evidence of activities performed.
		Note 1 to entry: Records can be used, for example, to formalize traceability and to
		provide evidence of verification, preventive action and corrective action.
		Note 2 to entry: Generally records need not be under revision control.
		(Cited from the definition in ISO 9000:2015)

	Term	Definition
26.	review	Determination of the suitability, adequacy or effectiveness of an object to achieve
		established objectives
		EXAMPLE: Management review, design and development review, review of
		customer requirements, review of corrective action and peer review.
		Note to entry: Review can also include the determination of efficiency.
		(Cited from the definition in ISO 9000:2015)
27.	serious incident	Food incident that may have an effect on food safety. Does not include incidents that
		do not have an effect on food safety but may have an effect on the quality.
28.	supplier, customer	Business operators from whom materials and ingredients, utilities, services, etc., are
		provided, and business operators to whom manufactured food is sold.
29.	top management	Person or group of people who directs and controls an organization at the highest level
		Note 1 to entry: Top management has the power to delegate authority and provide
		resources within the organization.
		Note 2 to entry: If the scope of the management system covers only part of an
		organization, then top management refers to those who direct and control that part of
		the organization.
		(Cited from the definition in ISO 9000:2015. Note 3 to entry is not included in the
		definition of "top management" in this document.)
30.	updating	Immediate and/or planned activity to ensure application of the most recent
		information.
		(Cited from the definition in ISO 22000:2005)
31.	verification	Confirmation, through the provision of objective evidence, that specified
		requirements have been fulfilled.
		Note 1 to entry: The objective evidence needed for a verification can be the result of
		an inspection or of other forms of determination such as performing alternative
		calculations or reviewing documents.
		Note 2 to entry: The activities carried out for verification are sometimes called a
		qualification process.
		Note 3 to entry: The word "verified" is used to designate the corresponding status.
		(Cited from the definition in ISO 9000:2015)
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