# JFS-A Standard [Requirements for Organizations]

Ver. 1.1

Japan Food Safety Management Association July 14, 2017

#### 1. Introduction

#### 1.1 JFS-A Standard

This JFS-A Standard (hereafter referred as "this Standard") is a food safety management standard developed by Japan Food Safety Management Association (JFSM) and is intended to assist organizations to improve their manufacturing of safe food products. In addition, this Standard can also be used for internal and external audits to verify and evaluate the safety of the food production processes of the organization\*.

\*'Organization' refers to a business entity to whom the requirements of this Standard apply. In the manufacturing sector, it refers to a business entity who manufacture food products.

#### 1.2 Scope of Application

This Standard applies to the "manufacturing sector" which consists of 4 categories, EI to EIV, which indicate businesses activities as follows:

- 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

Note: Categories EI to EIV are cited from the GFSI Guidance Document (v6.4).

#### 1.3 Structure of this Standard

This Standard consists of three layers of requirements, namely, Food Safety Management Systems (FSM), hazard control (Hazard Analysis and Critical Control Point; 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) in addition to the requirements stipulated in this Standard. Furthermore, organizations are advised to refer to JFSM guidelines.

#### 1.4 Exclusion from Application of Requirements

All the requirements in this Standard shall be applied in principle. However, if all the requirements in this Standard do not fully apply for reasons arising from the business scale, business form and so on of an organization, the organization shall provide proof of non-applicablility with explanations demonstrating their proper maintenance of food safety.

#### 1.5 Check List

At the end of this leaflet, there is a check List for organizations to complete to see if they are operating in accordance with the requirements of this Standard. Organizations are advised to complete this check list.

One of 5 boxes (conformity, minor nonconformity, major nonconformity, critical nonconformity, N/A) should be checked. There is also a space to write comments.

### 2. Requirements

## I Food Safety Management Systems(FSM)

Number	Clause name	Requirements
FSM 2	Food Safety Policy	Top management shall have a clear, concise, documented food safety policy which states how the organization ensures safety of the product.
FSM 4	Top Management Responsibility	Top management shall establish a communication structure which enables directing, reporting and consulting. Top management shall appoint person(s) responsible for food safety management.
FSM 5	Top Management Commitment	Top management shall provide job descriptions (policies of dividing duties) for workers involved with food safety and make these fully known to workers. In addition, Top management shall keep records of job description notice.
FSM 7	Resource Management	Top management shall ensure to provide resources (man power, goods and capital) necessary to implement the organization's food safety practice (Hazard Control (HACCP) and Good Manufacturing Practices (GMP)) in accordance with this Standard.
FSM 8	Record Control	Records determined necessary to demonstrate implementation of food safety management shall be kept accessible.
FSM 12	Nonconformity Control	The rules shall be established and implemented to ensure that raw materials and ingredients (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products which are potentially unsafe shall not be used or delivered.
FSM 13	Corrective Action	The procedure of corrective action (to correct nonconformity, identify the causes of nonconformity and eliminate them) shall be documented and implemented in the event that any nonconformities occur.
FSM 14	Product Release	Control (including inspection, prevention of infestation and removal of pests) of the growth in building and intrusion into building shall be implemented to minimize the food safety risks caused by insects, rodents, birds and other pests in the site or the facilities.

Number	Clause name	Requirements
FSM 20	Serious Incident Management	Effective incident response procedures shall be established and implemented in the event of an incident. A manual** detailing these procedures shall be kept up to date. Product withdrawal and product recall proedure shall be included in the manual if necessary. The effectiveness of the incident response manual shall be tested on products supplied by the organization at least once a year. ** A written list of procedures to enable proper response (response to incidents) and control (preventing incidents from getting worse) when food safety problemns occur.
FSM 21	Control of Measuring and Monitoring Devices	The measuring and monitoring equipment and devices to ensure food safety shall be calibrated with statutorily required methods or equivalent methods.
FSM 24	Traceability	<ul> <li>A traceability system shall be established which identifies: a) manufacturing lot, b) connections between raw materials and ingredients (including packaging materials) and manufacturing lot, c) information on processing and distribution. Traceability system records shall include the following:</li> <li>Identification of any outsourced raw materials and ingredients (including packaging materials), products or services.</li> <li>Identification of batches, partially processed products, work in progress, products being reprocessed, reworks, finished products, and packaging throughout the production process.</li> <li>A record of purchaser and delivery destination for all products released.</li> </ul>

### II Hazard Control (HACCP)

Number	Clause Name	Requirements		
HACCP	Assembly	A HACCP team (food safety team) shall be assembled by		
Procedure 1	HACCP Team	competent staff.		
НАССР	Product	Product specifications shall be described in writing.		
Procedure 2	Description	Product group, all raw materials and ingredients (including		
		packaging materials), and requirements for storage and		
		distribution shall be described in the product specifications.		
HACCP	Identification of	Intended use of the product and target consumers shall be		
Procedure 3	Intended Use	clearly described in written document.		
НАССР	Construction of	The flow diagram that covers all steps in the operation shall be		
Procedure 4	Flow Diagram	constructed.		
НАССР	On-site	The flow diagram shall be verified whether it correctly reflects		
Procedure 5	Confirmation of	the existing process steps of the operation.		
	Flow Diagram			

### II Good Manufacturing Practice (GMP)

Number	Clause Name	Requirements
GMP 2	Site Management	All grounds within the site shall be maintained according to appropriately established criteria.
	Facilities, Equipment	Site, building, and facility and equipment in the plant
	and Production	shall be maintained to enable controlling the risk of
GMP 3		product contamination caused by external and internal
		environment and manufacturing flow.
	Staff Facilities	Staff facilities shall be used so as to minimize food
GMP 7		safety risks.
	Identification and	All potential hazards encountered at any stage of the
	Control of	production process (from the reception of raw
	Contamination Risks	materials and ingredients to the release of products)
		including physical (e.g. metal fragments), chemical
GMP 8		(e.g. chemicals, allergens), and biological (e.g. micro-
		organisms) shall be listed.
		Based on the list, necessary control methods,
		procedures and criteria for contamination risks shall be
		established.
	Cross-contamination	Procedures to prevent contamination and cross-
		contamination shall be established for raw materials
		and ingredients (including packaging materials),
GMP 9		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.
	Stock Management	A system to use raw materials and ingredients
		(including packaging materials), partially processed
		products, work in progress, products being
GMP 10		reprocessed, reworks, and finished products in a designated order and within the defined expiry period
		shall be established and these materials shall be
		stored under the proper conditions to avoid
		contamination and deterioration.

Number	Clause Name	Requirements
GMP 11	Housekeeping, Cleaning and Hygiene	Housekeeping, cleaning and disinfecting where necessary shall be carried out throughout all the processes and stages, and an appropriate hygiene level shall be maintained at all times. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended use and stored
GMP 12	Water and Ice Management	appropriately. Quality standards classified by application shall be established for water (including steam and ice; the same applies hereafter) used in food manufacturing, and the quality of water shall be regularly monitored and recorded. Water added to food and water that potentially comes into contact with food shall be potable. Facilities, tools and procedures used for handling water shall ensure to prevent contamination.
GMP 13	Waste Management	Adequate systems for segregation, collection and disposal of waste shall be established. Locations and containers for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro-organisms. The traffic line of waste shall be established so as to prevent cross- contamination into food.
GMP 14	Pest Control	Food safety risk caused by insects, rodents and birds in the site or in the facilities shall be controlled (inspection and follow up action shall be taken if necessary). In the cases where chemicals are used, handling procedures shall be established so as not to affect food.

Number	Clause Name	Requirements
GMP 15	Transport	Containers and vehicles, including contracted out vehicles, used for the transportation of raw materials and ingredients including packaging materials, partially processed products, work in progress, products being reprocessed, reworks and finished products including packed fresh produce in final packaging, shall be suitable for the intended use, maintained and kept clean.
GMP 16	Personal Hygiene and Health Management	Documented appropriate personal hygiene criteria for workers shall be established and implemented. The requirements shall include hand washing methods and frequency, health status confirmation methods, rules on workwear and shoes, methods of entry to and exit from the production area, food handling methods and prevention of foreign material contamination. These requirements shall be made known to workers, and shall also apply to contractors and visitors without exception.
GMP 17	Training	A system shall be established to ensure all workers are adequately educated and trained on food safety principles and practices commensurate with their activities. A system shall be established to ensure all workers are adequately instructed and supervised. This education and training shall ensure all workers are aware of their own roles in food safety and the significance of their activities.

# JFS-A Standard (Ver. 1.1) Self-check List

Select one of 5 boxes in the "Observations" column.

□Conformity: Requirement fully satisfied.

 $\Box$  Minor Nonconformity: Less likely to cause risk on food safety.

 $\Box {\sf M}{\sf ajor}$  Nonconformity: Likely to cause risk on food safety.

 $\Box$ Critical Nonconformity: Cause a direct impact on food safety, or legality being at stake.

 $\Box$ N/A: Requirement not applied.

Number / Clause Name / Requirements	Observations	Remarks
FSM 2 Food Safety Policy Top management shall have a clear, concise, documented food safety policy which states how the organization ensures safety of the product.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
FSM 4 Top Management Responsibility Top management shall establish a communication structure which enables directing, reporting and consulting. Top management shall appoint person(s) responsible for the food safety management.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
Guideline FSM 4-1 Does the organization have an up-to-date chart which describes organizational structure?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
FSM 5 Top Management Commitment Top management shall provide job descriptions (policies of dividing duties) for workers involved with food safety and make these fully known to workers. In addition, top management shall keep records of job description notice.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
FSM 5-1 Guideline Are the responsibilities for product safety and compliance clearly defined, documented, and communicated to the workers?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
FSM 7 Resource Management Top management shall ensure to provide resources (man power, goods and capital) necessary to implement the organization's food safety practice (Hazard Control (HACCP) and Good Manufacturing Practices (GMP)) in accordance with this Standard.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
FSM 7-1           Guideline         Is there evidence that top management is committed to provide the resources necessary to implement and comply with the food safety program?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

FSM 8 Reco	rd Control	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
Records detern accessible.	nined necessary to demonstrate implementation of food safety management shall be kept	
Guideline	FSM 8-1 Does the organization have records to support the compliance with the food safety management system which covers the regulatory and customer requirements applied?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
	FSM 8-2 Does the organization have record retention period that complies with regulatory and customer requirements?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
FSM 12 Nor	nconformity Control	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
packaging mat	be established and implemented to ensure that raw materials and ingredients (including erials), partially processed products, work in progress, products being reprocessed, nished products which are potentially unsafe shall not be used or delivered.	
Guideline	FSM 12-1 Does the organization have documented procedure in place to identify and manage all nonconformity of raw materials (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
	FSM 12-2 Is the control of nonconforming materials carried out by competent personnel?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
FSM 13 Cor	rective Action	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
	of corrective action (to correct nonconformity, identify the causes of nonconformity and ) shall be documented and implemented in the event that any nonconformities occur.	
Guideline	FSM 13-1 Does the organization have documented procedure in place to investigate nonconformities and prevent recurrence?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A
	FSM 13-2 Does the organization specify root cause and take corrective action to prevent recurrence, on the incident related to raw materials and ingredients, finished product or procedure of manufacturing process.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A

FSM 14 Pro	duct Release	□ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A	
intrusion into b	ng inspection, prevention of infestation and removal of pests) of the growth in building and uilding shall be implemented to minimize the food safety risks caused by insects, rodents, pests in the site or the facilities.		
Guideline	FSM 14-1 Are the specifications defined for all raw materials and ingredients, additives, packaging materials, products being reprocessed, reworks and finished products?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	FSM 14-2 Does the organization have written specifications which complies with relevant food safety, regulatory and customer requirements?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	FSM 14-3 Does the organization have a system in place to communicate changes of written specifications of products to personnel in and out of the organization on update?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	FSM 14-4 Is there a designated person responsible for controlling specifications?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	FSM 14-5 Does the organization have a procedure in place to confirm if the releasing products conform the written specification?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	FSM 14-6 Does the organization have a written procedure in place for releasing products?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
FSM 20 Ser	ious Incident Management	□ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A	
A manual detai Product withdra The effectivene	Int response procedures shall be established and implemented in the event of an incident. Ing these procedures shall be kept up to date. awal and product recall procedure shall be included in the manual if necessary. iss of the incident response manual shall be tested on products supplied by the least once a year.		
Guideline	FSM 20-1 Does the organization have a written incident response manual to report incidents, withdraw products and recall products? Is a test or practice based on the manual done and the manual reviewed more than once a year?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	FSM 20-2 Are incident records kept and assessed to establish severity and consumer risks?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

The	measuring a	trol of Measuring and Monitoring Devices and monitoring equipment and devices to ensure food safety shall be calibrated with red methods or equivalent methods.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		FSM 21-1 Are measuring and monitoring devices critical to food safety and regulatory requirements reliable?	□ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A	
A tra raw proce · Id prod · Id rewo	materials a essing and o lentification ucts or serv lentification orks, finishe	stem shall be established which identifies: a) manufacturing lot, b) connections between nd ingredients (including packaging materials) and manufacturing lot, c) information on distribution. Traceability system records shall include the following: of any outsourced raw materials and ingredients (including packaging materials),	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	Guideline	FSM 24-1 Does the organization have a written procedure for traceability in place for each product including identification of product, raw materials and ingredients, and outsourced materials and services?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		FSM 24-2 Is the traceability system effective including partially processed products, work in progress, products being reprocessed and reworks?	□ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A	
		FSM 24-3 Are products traceable (i.e. all the materials are identified and records are kept) through all processes from purchasing raw materials and ingredients to storage and release.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

HACCP Step	1 HACCP Team Assembly	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
A HACCP team	(food safety team) shall be assembled by competent staff.		
Guideline	HACCP 1-1 Does a multi-disciplinary team with different responsibilities carry out the tasks described in HACCP Steps 2 to 12 in this check list?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
-	2 Product Description	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
Product group,	cations shall be described in writing. all raw materials and ingredients (including packaging materials), and requirements for stribution shall be described in the product specifications.		
Guideline	HACCP 2-1 Does the organization identify all the regulatory and customer requirements relevant to the product or the product group? Does the product or the product group conform the requirements?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	HACCP 2-2 Does the organization have complete product specifications for all the products and product groups covering raw materials and ingredients, packaging materials, finished products and storage and distribution conditions?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
HACCP Step	3 Identification of Intended Use	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
The intended u	se of product and target consumers shall be clearly described in written document.		
Guideline	HACCP 3-1 Is the intended use of the product described, and are the target consumers identified?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
HACCP Step	4 Construction of Flow Diagram	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
The flow diagra	am that covers all steps in the operation shall be constructed.		
Guideline	HACCP 4-1 Does the organization have a flow diagram describing all the process steps of product manufacturing and processing?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
HACCP Step	5 On-site Confirmation of Flow Diagram	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
The flow diagra	am shall be reviewed whether it correctly reflects the existing process steps of the		
Guideline	HACCP 5-1 Is an on-site verification carried out to make the flow diagram accurately reflect the existing process?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

GMP 2 Site	Management	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
An appropriate	e standard for all grounds within the site shall be established and maintained.		
Guideline	GMP 2-1 Are the surrounding areas of the facilities always controlled and kept free of hygienic problems? For instance, is vegetation periodically trimmed or mowed?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
GMP 3 Des	ign, Construction and Layout of Facilities, Equipment and Production	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	ing, and facilities and equipment in the plant shall be maintained to enable the control of duct contamination caused by the external and internal environment, and by the process flow.		
Guideline	GMP 3-1 Are the facilities designed, constructed, layouted suitable to maintain and clean?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 3-2 Is the lighting adequate in brightness and color to prevent mistake?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 3-3 Is the drainage system designed and controlled to minimize potential risks of product contamination? Are the floor and catch basin sloped to facilitate water flow and cleaning?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
GMP 7 Staf	ff Facilities shall be used so as to minimize food safety risks.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
Guideline	GMP 7-1 Does the organization have changing room located to enable personnel handling food to move to the production areas in such a way that cleanliness of their workwear is kept?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 7-2 Does the organization have hygienically designed toilets that are sufficiently isolated from food handling areas?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 7-3 Does the organization provide adequate numbers, locations and means of hygienic hand washing facilities?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 7-4 Are canteens and designated areas for food and drink storage and consumption apart from manufacturing, packaging and storage areas?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

GMP 8	8 Ident	ification and Control of Contamination Risks	□ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A	
All potential hazards encountered at any stage of the production process (from the reception of raw materials and ingredients to the release of products) including physical (e.g. metal fragments), chemical (e.g. chemicals, allergens), and biological (e.g. micro-organisms) shall be listed. Based on the list, necessary control methods, procedures and criteria for contamination risks shall be established.		gredients to the release of products) including physical (e.g. metal fragments), chemical allergens), and biological (e.g. micro-organisms) shall be listed.		
G	Guideline	GMP 8-1 Does the organization have physical barriers or effective procedures in place to eliminate potential hazard of physical, chemical or biological contamination or minimize the hazard to acceptable level?	Conformity I Minor Nonconformity Major Nonconformity I Critical Nonconformity N/A	
Proced ingredi being r	GMP 9 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.		Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
G	Guideline	GMP 9-1 Does the organization have a procedure of cross-contamination prevention which includes identification of the potentially hazardous areas due to flows of workers and materials in food manufacturing, and preparation of prevention plan?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 9-2 Does the organization identify all the allergens that need to be controlled in products or processes through risk assessment?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 9-3 On specifying allergens to be controlled, are specifications, including regulatory and customer requirements, taken into consideration?	Conformity I Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 9-4 Does the organization have a procedure to prevent cross-contamination in handling raw materials and ingredients including packaging materials, and products including partially processed products, work in progress, products being reprocessed, reworks, and finished products?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 9-5 Does the organization have a written procedure of allergen control which includes method of cleaning to remove undeclared allergens and to prevent cross-contamination, and method of verification?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 9-6 Is the product labeling of allergens that are based on risk assessment appropriate?		

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 in a designated order and within the defined expiry period shall be established and these materials shall be stored under the proper conditions to avoid contamination and deterioration.		Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
Guideline	GMP 10-1 Does the organization have facilities to store raw materials and ingredients, partially processed products, work in progress, products being reprocessed, reworks and finished products without contamination and deterioration due to in appropriate temperature, relative humidity or other factors?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
Housekeeping a process steps a disinfecting whe	usekeeping, Cleaning and Hygiene and cleaning shall be carried out following the documented criteria throughout all the nd stages, and an appropriate hygiene level shall be maintained at all times by ere necessary. Cleaning tools, cleaning agents and disinfectants shall be suitable for their id stored appropriately.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
Guideline	GMP 11-1 Does the organization have a procedure in place for housekeeping, cleaning and hygiene?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 11-2 Are the devices, equipment and tools used for cleaning and sanitizing kept clean and stored in designated areas?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 11-3 Are chemicals for cleaning and sanitizing identified and stored in the designated areas?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 11-4 Are cleaning and sanitizing carried out by trained or competent workers?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

GMI	P12 Wat	er and Ice Management	□ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A	
sam and Wate	Quality standards classified by applications shall be established for water (including steam and ice; the same applies hereafter) used in food manufacturing, and the quality of water shall be regularly monitored and recorded. Water added to food and water that potentially comes into contact with food shall be potable. Facilities, tools and procedures used for handling water shall ensure to prevent contamination.			
		GMP 12-1 Does the organization periodically test water for food manufacturing to verify the quality conforms to the regulation?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 12-2 Does the organization have a written procedure to control waters for each purpose such as water added into food or water not come into contact with food such as cooling water?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
Adeo Loca harn	GMP 13         Waste Management           Adequate systems for segregation, collection and disposal of waste shall be established.         Include the systems for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro-organisms. The traffic line of waste shall be established so as to prevent cross-contamination into food.		🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🗍 Critical Nonconformity 🗌 N/A	
		GMP 13-1 Does the organization have a suitable procedure in place for the storage and removal of waste (including inedible by-products)?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 13-2 Does the organization periodically verify the result of waste control including the implementation of the procedure?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 13-3 To prevent cross-contamination between waste and food, is waste stored not to affect food safety?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

GM	P 14 Pes	t Control	🗌 Conformity 📋 Minor Nonconformity 🗌 Major Nonconformity 📋 Critical Nonconformity 🗌 N/A	
(ins	Food safety risk caused by insects, rodents and birds in the site or in the facilities shall be controlled (inspection and follow up action shall be taken if necessary). In the cases where chemicals are used, handling procedures shall be established so as not to affect food.			
	Guideline	GMP 14-1 Does the organization identify pests targeted through experience, scientific data and information of product characteristics, and establish an effective pest control plan?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 14-2 Does the organization monitor periodically if pests are controlled effectively?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 14-3 In case monitoring indicates infestation of pests and suggest control, does the organization prepare a plan to remove pests which does not have impact on food safety and facility operation? Does a competent or qualified personnel implement the plan?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 14-4 Does the organization have a procedure to treat pests with chemical and to restart production following the treatment?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
GM	P 15 Tra	nsport	🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🗌 Critical Nonconformity 🗌 N/A	
ingr beir	Containers and vehicles, including contracted out vehicles, used for the transportation of materials and ngredients (including packaging materials), partially processed products, work in progress, products weing reprocessed, reworks and finished products (including packed, fresh product in final packaging) shall we suitable for the intended use, maintained and kept clean.			
	Guideline	GMP 15-1 Does the organization have a procedure to make containers and vehicles, which are used for transportation of raw materials and ingredient (including packaging material), and products (partially processed products, work in progress, products being reprocessed, reworks and finished products) suitable to the purpose, well maintained, and kept clean and hygienic? Is the procedure implemented effectively?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 15-2 Are the containers or vehicles equipped with temperature or relative humidity control if the products require? Are the measuring instruments in transport vehicles verified periodically, and the records kept?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

GMP 16 Per	sonal Hygiene and Health Management	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
The requirement methods, rules handling metho	ppropriate personal hygiene criteria for workers shall be established and implemented. Ints shall include hand washing methods and frequency, health status confirmation on workwear and shoes, methods of entry to and exit from the production area, food ods and prevention of foreign material contamination. Inents shall be made known to workers, and shall also apply to contractors and visitors ion.		
Guideline	GMP 16-1 Do the organization's criteria for personal hygiene comply with legal and regulatory requirements?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 16-2 Are the personal hygiene criteria applied and communicated to all the workers including contractors and visitors?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 16-3 Does the organization have a procedure to announce to workers including contractors and visitors to take an action to prevent spread of infectious diseases and pathogen contamination into food.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 16-4 Does the organization have a procedure to report to the top management and/or persons in charge of food safety/production, as necessary, about a suspected worker of infection, and to keep the worker away from food handling areas?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 16-5 Do workers including contractors and visitors change, as necessary, workwear and footwear which is clean, intact and suitable to the purpose?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
	GMP 16-6 Does the organization have a rule of laundering and/or switching workwear?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	

A sy prin A sy This	ciples and portion of the second s	ning be established to ensure all workers are adequately educated and trained on food safety ractices commensurate with their activities. be established to ensure all workers are adequately instructed and supervised. and training shall ensure all workers are aware of their own roles in food safety and the heir activities.	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 17-1 Does the organization provide training to all workers, including new members, to obtain necessary competence and knowledge for each specific role in food handing, and is it recorded?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	
		GMP 17-2 Does the organization implement a refresher training (including personal hygiene) to all relevant workers?	Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A	