

**JFS-B Standard
(Sectors: E/L)
<Food Manufacturing>**

[Requirements for Organizations]

Ver.2.0

Japan Food Safety Management Association

October 21, 2019

1. Introduction

1.1 JFS-B Standard Ver.2.0

This JFS-B 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*. It can also be used by internal auditors and external assessors to verify and assess the organization's efforts. Notably, the B standard includes the HACCP7 principle 12 procedures. In accordance with the GFSI Benchmark Requirements Ver. 7.2, in April 2019 the JFS-C Standard (sector: E) was released to ver. 2.3 and released. Following this revision, the JFS-B Standard Ver. 1.1 requirements were added and revised as Ver. 2.0.

*‘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 “Food manufacturing sector (E)” and to the “Chemical Products (including biochemical products) manufacturing sector (L)”, which consist of the following sub-sectors from E I to E IV. Here, the chemical products refer to chemical products (including biochemical products) related to foods, and include the production of additives, vitamins, minerals, cultures, flavors, enzymes, processing aids, etc. (See to JFS Standard sector list on page 2.)

Food manufacturing sector (E)

E I : Processing of perishable animal products

E II : Processing of perishable plant products

E III : Processing of perishable animal and plant products (mixed products)

E IV : Processing of ambient stable products

Chemical product manufacturing (including biochemical products) (L)

L : Production of (Bio) Chemical (Additives, Vitamins, Minerals, Bio-cultures, Flavourings, Enzymes and Processing aids)

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), and the Codex Alimentarius Annex to the General Principles of Food Hygiene (* 2) or the specific code of practice), in addition to the requirements stipulated in this Standard. Furthermore, organizations are advised to refer to JFSM guidelines.

(* 2) Codex Committee “RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE” CAC / RCP 1-1969, Rev.4 (2003)

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-applicability with explanations demonstrating their rationale for proper maintenance of food safety without application.

1.5 Check List

A separate checklist has been prepared for organizations to audit and document the organization's performance in light of the requirements of this Standard (describing any nonconformities, inadequacies, accomplishments, etc.). (Reference) Sector categories are as follows:

1.6 Sector categories (reference)

This JFS Food Safety Management Standard utilizes the following sector categories.

SECTOR	Sub-sector	CATEGORY
A	AI	Farming of Animals for Meat/ Milk / Eggs / Honey
	AII	Farming of Fish and Seafood
B	BI	Farming of Plants (Other than grain and pulses)
	BII	Farming of Grain and Pulses
C	-	Animal Conversion
D	-	Pre-process handling of plant products, nuts and grain
E	EI	Processing of perishable animal products
	EII	Processing of perishable plant products
	EIII	Processing of perishable animal and plant products (mixed products)
	EIV	Processing of ambient stable products
F	-	Production of feed
G	-	Catering
H	-	Retail / Wholesale
I	-	Provision of Food Safety Services
J	-	Provision of Storage and Distribution Services
K	-	Manufacture of Food Processing Equipment
L	-	Production of (Bio) Chemical (Additives, Vitamins, Minerals, Bio-cultures, Flavourings, Enzymes and Processing aids)
M	-	Production of Food Packing
N	-	Food Broker / Agent

*: indicates the target sectors of this Standard

Requirements

I Food Safety Management Systems(FSM)

Number	Clause name	Requirements
FSM 2	Food Safety Policy	The 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	The top management shall establish a communication structure which enables directing, reporting and consulting. The top management shall appoint person(s) responsible for food safety management.
FSM 5	Top Management Commitment	The 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, the top management shall keep records of job description notice.
FSM 7	Resource Management	The 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 10	Procedure	The relevant safety requirements shall be taken into consideration when designing products and manufacturing processes. For all processes and operations that affect food safety, good manufacturing practice (GMP) shall be developed, and the work procedures and directions for implementing GMP and HACCP shall be made visible to workers.
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	Product specifications which conform to food safety requirements, statutory and regulatory requirements and customer requirements shall be prepared and proper procedures for product release (shipping) shall be made and implemented.

Number	Clause name	Requirements
FSM 15	Purchasing	<p>Purchasing procedures shall be developed and implemented to ensure that all outsourced raw materials, materials and services that may affect food safety meet the requirements of the organization.</p> <p>When outsourcing a process that may affect food safety, the process shall be controlled properly, such as by providing specifications or contracts that specify the control method to the subcontractors.</p> <p>When purchasing or outsourcing from a previously unused supplier in an emergency (such as a natural disaster), the supplier's facility shall be assessed to confirm that it meets the specifications required for the product and that there are no problems with food safety.</p>
FSM 16	Supplier Performance	<p>The organization shall establish, implement and maintain procedures for continuing to assess, approve and monitor suppliers for effects on food safety. The results of the assessments, surveys and follow-ups on suppliers shall be recorded.</p>
FSM 18	Complaint Handling	<p>A management system that utilizes complaints from business partners and consumers shall be established and implemented, and its data shall be maintained to detect, correct, and manage omissions and oversights from food safety initiatives.</p>
FSM 20	Serious Incident Management	<p>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.</p> <p>Product withdrawal and product recall procedure shall be included in the manual if necessary.</p> <p>The effectiveness of the incident response manual shall be tested on products supplied by the organization at least once a year.</p> <p>** A written list of procedures to enable proper response (response to incidents) and control (preventing incidents from getting worse) when food safety problems occur.</p>
FSM 21	Control of Measuring and Monitoring Devices	<p>The measuring and monitoring equipment and devices to ensure food safety shall be calibrated with statutorily required methods or equivalent methods.</p>
FSM 22	Food Defense	<p>The risk of intentional food contamination by people inside or outside the organization shall be identified, the magnitude of that risk assessed and prioritized, and measures implemented to reduce or eliminate the risk.</p>

Number	Clause name	Requirements
FSM 23	Product Labeling	<p>Information shall be displayed or attached to products so that they can be safely handled, displayed, stored, prepared, and used by business partners or consumers.</p> <p>Procedures for displaying or attaching correct information shall be established and implemented.</p>
FSM 24	Traceability	<p>A traceability system shall be established to enable a) identification of production lots, b) identification of relationships between raw materials, product packaging materials and production lots, and c) identification of processing and distribution, and the system shall be verified at least once a year.</p> <p>The records that comprise the traceability system shall include:</p> <ul style="list-style-type: none"> • Identification of all raw materials (including containers and packaging materials), products, and services • Identification of batches, semi-finished products, work in process, remanufactured products, reworked products, finished products and packaging throughout the entire manufacturing process • Records of buyers and destinations for all products supplied
FSM 25	Analysis of Environments, Inputs and Products	<p>Appropriate inspections shall be conducted for items that affect food safety. Inspections shall also be performed by a competent testing department or laboratory.</p>
FSM 29	Allergen Management	<p>All manufacturing facilities shall develop and implement an allergen management plan. This plan shall include a risk assessment for allergen cross-contamination and control procedures to reduce or eliminate the risk of cross-contamination.</p> <p>All final products containing or potentially containing allergens shall be identified in accordance with the legislation of the intended destination country.</p>

II Hazard Control (HACCP)

Number	Clause Name	Requirements
HACCP Procedure 1	Assembly HACCP Team	A HACCP team (food safety team) shall be assembled by competent staff.
HACCP Procedure 2	Product Description	Product specifications shall be described in writing. Product category, all raw materials and ingredients (including packaging materials), and requirements for storage and distribution shall be described in the product specifications.
HACCP Procedure 3	Identification of Intended Use	The intended use of product and target consumers shall be clearly described in written document.
HACCP Procedure 4	Construction of Flow Diagram	The flow diagram that covers all steps in the operation shall be constructed.
HACCP Procedure 5	On-site Confirmation of Flow Diagram	The flow diagram shall be reviewed to ensure it correctly reflects the existing process steps of the operation.
HACCP Procedure 6 (Principle 1)	Hazard factor analysis	All available means of identifying, analyzing, and managing potential hazards in each process shall be considered. Hazard factors shall include allergens, as necessary.
HACCP Procedure 7 (Principle 2)	Establishment of Critical Control Points (CCP)	Critical control points (CCP) shall be determined.
HACCP Procedure 8 (Principle 3)	Establishment of Critical Limits	Limits shall be established for critical control points.
HACCP Procedure 9 (Principle 4)	Monitoring System	A monitoring method shall be established for each critical control point.
HACCP Procedure 10 (Principle 5)	Corrective Actions	Methods for corrective action (correction, investigation of the cause of occurrence, and elimination of the cause) must be established for deviations from the allowable CL range.
HACCP Procedure 11 (Principle 6)	Establishment of verification procedures	Verification procedures shall be established to confirm whether the established handling (HACCP plan) is being performed as planned and whether it needs to be modified. Verification shall be performed to adapt to changes in equipment design and processing methods as well as technological development in the manufacturing process.
HACCP Procedure 12 (Principle 7)	Documentation and Recordkeeping	The necessary documents shall be created, recorded and maintained.

III Good Manufacturing Practice (GMP)

Number	Clause Name	Requirements
GMP 2	Site Management	An appropriate standard for all grounds within the site shall be established and maintained.
GMP 3	Facilities, Equipment and Production	The site, buildings, facilities and equipment shall be maintained in order to minimize the risk of product contamination caused by the external and internal environment.
GMP 4	Specifications of Manufacturing and Storage Area, and Utility Management	Factory buildings and facilities (receiving areas, raw material and product handling areas, preparation areas, packaging and storage areas) shall have specifications suitable for their intended use. Controls shall be established and implemented, as necessary, for utilities such as air, high-pressure air and other gases that may come into contact with food to prevent contamination and condensation.
GMP 5	Equipment	Equipment shall be designed and selected for its intended use, and used, maintained and stored to minimize food safety risks.
GMP 6	Maintenance	A system shall be established to systematically maintain all equipment that is critical to product safety.
GMP 7	Staff Facilities	Staff facilities shall be used so as to minimize food safety risks.
GMP 8	Identification and Control of Contamination Risks	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.
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.
GMP 10	Stock Management	A system shall be established to ensure use of 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 period.
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 appropriately.

Number	Clause Name	Requirements
GMP 12	Water and Ice Management	<p>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.</p> <p>Water added to food and water that potentially comes into contact with food shall be potable.</p> <p>Facilities, tools and procedures used for handling water shall ensure to prevent contamination.</p>
GMP 13	Waste Management	<p>Adequate systems shall be established for the segregation, collection and disposal of waste material.</p> <p>Locations and containers for placing waste material shall be managed in order to prevent attraction of pests or generation of harmful organisms/micro-organisms.</p> <p>A path for disposal of waste material shall be established so as to prevent cross-contamination for food.</p>
GMP 14	Pest Control	<p>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).</p> <p>In the cases where chemicals are used, handling procedures shall be established so as not to affect food.</p>
GMP 15	Transport	<p>Containers and vehicles, including contracted out vehicles, used for the transportation of materials and ingredients (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks and finished products (including packed, fresh product in final packaging) shall be suitable for the intended use, maintained and kept clean.</p>
GMP 16	Personnel Hygiene and Health Management	<p>Documented appropriate personnel 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.</p>
GMP 17	Education and Training	<p>A system shall be established to ensure all workers are adequately educated and trained on food safety principles and practices commensurate with their activities.</p> <p>A system shall be established to ensure all workers are adequately instructed and supervised.</p> <p>This education and training shall ensure all workers are aware of their own roles in food safety and the significance of their activities.</p>

Annex

• Definition of terms

	Clause Name	Related item number	Requirements
1.	Intended use	HACCP Procedure 3	Methods of use and consumption methods established at the time of planning and design for products, buildings and equipment.
2.	Sector, sub-sector		Scope of conformity certification
3.	Recall	FSM20	Suspend supply and recall all products, including consumer goods, stores and distribution inventory.
4.	Withdrawal	FSM20	Action to withdraw from sales (Withdrawal from the market, removal from stores, and withdrawal at the distribution stage)
5.	Hazard	HACCP Procedure 6	Biological, chemical and physical substances in food, or the condition of food, that can have adverse effects on health. (Source: General Principles of Food Hygiene, Codex Alimentarius Committee)
6.	Critical limit	HACCP Procedure 8	Note: Established to determine if a CCP is being controlled. If an acceptable limit is exceeded or deviated, the affected product is considered to be potentially unsafe. (Source: definition in ISO 22000: 2018 {3.12})
7.	Record	FSM8 HACCP Procedure 12	Note 1: Records may be used, for example, to: — Formalize traceability. — Provide evidence of verification, preventive or corrective actions. Note 2: Normally, it is not necessary to control the revision of records.
8.	Verification	HACCP Procedure 11	To confirm that the prescribed requirements have been met by presenting objective evidence. Note 1: The objective evidence required for verification may be the results of an inspection or other form of confirmation, such as performing an alternative calculation or the review of a document. Note 2: Activities performed for verification are sometimes referred to as "eligibility processes." Note 3: The term "verified" is used to indicate a state that verification has been completed. (Source: definition in ISO 22000: 2018 3.45)
9.	Raw materials and ingredients	FSM12,15 GMP8,9,15	Raw materials refer to those materials usually used for a part of the product. Note that the raw materials also include the container packaging materials and water.

	Clause Name	Related item number	Requirements
10.	CCP (critical control point)	HACCP Procedure 8	A step that is controllable and essential to prevent or eliminate food safety hazard factors or reduce them to acceptable levels.
11.	Correction	HACCP Procedure 11	A step that is controllable and essential to prevent or eliminate food safety hazard factors or reduce them to acceptable levels.
12.	Employee, personnel	GMP16	All personnel involved in food safety-related duties, including part-time staff, contractors, and temporary employees working in the organization.
13.	Serious incident	FSM20	Food accidents that can potentially affect food safety. These do not include accidents that do not affect food safety but may affect quality.
14.	Food		All substances that have been processed, semi-processed or remain intact for human consumption. Note: Includes all substances used in the manufacture, preparation and processing of beverages, gums and foods. However, this does not include substances used only in cosmetics, tobacco, and medicine. (Source: definition in ISO 22000: 2018 3.18)
15.	Food safety management system		A system for establishing policies and targets and achieving the targets so as not to cause harm to consumers when foods are cooked and/or eaten according to their intended use.
16.	Corrective action	FSM13 HACCP Procedure 10	Action to eliminate the cause of a nonconformity and prevent its recurrence. Note: A nonconformity can have multiple causes. (Source: definition in ISO 22000: 2018 3.10)
17.	Top management	FSM4,5	An individual or group that directs and manages an organization at the highest level. Note 1: Top management has the power to delegate authority and provide resources within the organization. Note 2: If the scope of the management system is only part of the organization, top management is the person who directs and manages that part of the organization. (Source: definition in ISO 22000: 2018 3.41)
18.	Flow diagram	HACCP Procedure 4,5	A drawing that includes the sequence and interrelationships of all the steps involved in the work of the specified product. (Source: definition in ISO 22000: 2018 {3.17})

	Clause Name	Related item number	Requirements
19.	Document	FSM8 HACCP Procedure 12	Information and the medium on which it is contained. Examples: records, specifications, procedural documents, drawings, reports, standards Note: The medium can be paper, magnetic, electronic or optical computer disk, photograph or master sample, or a combination thereof. (Source: definition in ISO 22000: 2018 3.13)
20.	Nonconformities	FSM12	Not meeting requirements. (Source: definition in ISO 22000: 3.28 2018)
21.	Management		Coordinated activities to direct and manage an organization. Note: Management may include establishing policies and objectives and the processes to achieve those objectives.
22.	Management system		A set of interrelated or interacting elements of an organization that establishes policies, goals, and processes for achieving those goals. (Source: definition in ISO 22000: 2018 {3.25})
23.	Monitoring	FSM21 HACCP Procedure 9	To perform a planned series of observations or measurements to determine whether measures to control food safety are performing as intended. (Refer to: ISO 22000: 2018 3.27)
24.	Packaging materials	GMP10,15	Materials for packaging food, such as paper, plastic, wooden boxes, cardboard boxes, PET bottles, and cans.