JFS-A/B Audit and Conformity Assessment Program Document

Ver.1.2

Japan Food Safety Management Association

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Table of Contents

1. PROGRAM OUTLINE

1.1 Purpose

This program is established by Japan Food Safety Management Association (hereinafter referred to "JFSM") and dedicates to the assessment of food safety through second-party (purchasers) or third-party audit that verifies the food safety management system of food related organizations (hereinafter referred to "auditee") conforms to the requirements of JFS-A/B standards[1]. This program consists of requirements, procedures and other components prescribed in this document.

The purpose of this program is to improve the food safety level of organizations which utilize this Conformity Assesment[2] by standardizing practices to ensure food safety throughout the food chain. Especially small and medium sized organizations are targeted.

This program is intended to improve the food safety level throughout the chain and is expected to manage costs in the food system by eliminating redundancy and improving operational efficiency through the auditing process between the auditee and the entity which conducts audit (hereinafter referred to "assessment company" which is stipulated in 3.1.).

1.2 Features

The features of this program are as follows:

(1) This program is intended to assist primarily small and medium sized organizations to achieve the following objectives:
   a) Organizations develop and improve food safety activities through steps.
   b) Assessment companies encourage the auditees to improve the food safety management practices through auditing process.
   c) This program promotes HACCP recommended by Codex Alimentarius Commission[3].

(2) Accreditation of assessment companies which implement conformity assessment of JFS-A/B is not required whereas JFS-C standard certificate requires the accreditation of third-party audit conducted by accreditation bodies. The assessment companies are recognized by the program owner, namely JFSM, in accordance with the decision of Assessment Company Recognition Committee (refer to Assessment Company Recognition Committee stipulated in 2.2 (3), hereinafter referred to "Recognition Committee"). The recognized assessment company verifies conformity to the Standard and issues Letter of Conformance. This program is available to utilize for a third-party audit, conducted by an independent entity, and a second-party audit, conducted by a manufacturer or a distributor for its suppliers.

(3) In case the auditee does not conform to the requirements of the Standard, the assessment company is allowed not only to point out nonconformity but also to encourage the auditee to take appropriate corrective actions by giving guidance and suggestions during the auditing process.

(4) The requirements of JFS-A and B Standards respectively include[6] the requirements of Basic and Intermediate level of GFSI[4] Global Market Programme[5] which cover the scope of manufacturing.

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[1] JFS-A/B standards: JFS-A is a food safety management standard for organizations to establish basic food safety fundamentals whereas JFS-B is a food safety management standard for organizations to improve and enhance food safety level and implement HACCP.

[2] Conformity Assessment: A verification that the food safety management system of the auditee conform to JFS-A/B requirements.

[3] Codex Alimentarius Commission: An international intergovernmental body established by Food and Agriculture Organization (FAO) and World Health Organization (WHO) in 1963 to protect consumers' health and promote and ensure fair practices in food trade.

[4] GFSI: Global Food Safety Initiative. An organization launched in 2000, which consists of global retailers and food manufacturers aiming at enhancement of food safety and consumer confidence.
[5] Global Markets Programme: Program created by GFSI in order to develop food safety capability of small and medium sized organizations.
[6] The objective of Global Markets Programme is to achieve GFSI-recognized food safety certification through steps, while JFS-A/B standards are applied to achieve Conformity Assessment of each standard.

1.3 Applicable Categories

This program 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)

- 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

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

- 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.

Note: Code "E I" to "E IV" and "L" are cited from GFSI Guidance Document.
The codes will be used in this program.

2. PROGRAM OWNERSHIP REGULATIONS

2.1 Program Owner

This program is operated and managed by JFSM.

2.2 Organizational Structure

(1) JFSM establishes the Board of Directors as an executive body, Inspectors to audit the performances, the Board of Trustee, which is a governing board, is responsible for determine important matters such as the appointment of directors and inspectors, and the JFSM Secretariat to carry out the mission under the directions of the Board of Directors.

(2) To implement proper operation and management of this program, JFSM establishes the Scheme Committee as an advisory body which consists of experts, knowledgeable persons and so on to provide neutral and expert opinions to the Board of Directors. The Scheme Committee and committee members ensure no conflict of interest for securing impartiality and ethics. Under the approval of the Board of Directors, the Scheme Committee has the right to gather working groups to draft and revise documents related to this program, including the Program Document.

(3) JFSM establishes the Recognition Committee, which consists of knowledgeable individuals, in order to ensure the reliability of this program through deciding the appropriateness of the assessment company. The Recognition Committee and its member shall ensure to avoid conflict of interest for fairness and ethics.

2.3 Maintenance of Conformity Assessment Program

(1) JFSM is comprehensively responsible for establishment, operation and maintenance of this program. JFSM requests the Scheme Committee to review this program periodically. To specify needs of revision are requested to the Scheme Committee under necessity. JFSM prepares a draft and distribute it on JFSM website to call comments for a certain period. JFSM makes a revision or amendment in view of the comments and finalizes the document at the Scheme Committee. The Scheme Committee provides the proposal document to the Board of Directors. The approved document is published on JFSM website. JFSM informs details of revision to assessment companies without delay.

(2) JFSM holds a conference for the assessment companies and assessors to harmonize the level of skills and knowledge at least once a year.

(3) The Scheme Committee implements comprehensive reviews of this program at least every 4 years, as a general rule, and JFSM republishes it if necessary.

2.4 Scheme Committee Regulations

JFS-C Certification Scheme Document (the latest version) is applied to regulations concerning the Scheme Committee.

2.5 Assessment Company Recognition Committee Regulations

2.5.1 Functions and Responsibilities

The Recognition Committee makes decisions on the request from JFSM of recognition, renewal, suspension and withdrawal of the assessment companies.

2.5.2 Committee Members

(1) Recognition Committee consists of the following members:
   a) representative(s) of food manufacturing industry
   b) representative(s) of food distribution industry
   c) representative(s) of consumers
   d) representative(s) of certification bodies
   e) expert(s) in food safety

(2) Under confirmation of competency to discuss properly about the recognition of assessment companies, members are designated by the Board of Directors. Fairness and conflict of interest are to be maintained.

2.5.3 Gathering of Recognition Committee

The Recognition Committee is held by the request of JFSM on the recognition, renewal, suspension and withdrawal of assessment companies.

2.5.4 Decisions

Decisions of the Recognition Committee in principle are made based on consensus. In case of discord, simple majority vote makes the decision with attendance of at least two-thirds of the members.

2.5.5 Records of the Committee

JFSM prepares the records of the meeting of the Recognition Committee.

2.6 Response to Opinions, Queries, Complaints from Stakeholders

(1) JFSM establishes contacts and procedures to receive opinions, queries and complaints at any time from stakeholders, such as opinions on the operation and interpretation of the Program, opinions to Conformity Assessment.

(2) JFSM makes a report to the Scheme Committee at least once a year on the results of opinions, queries and complaints analysis received from the above mentioned contacts.

2.7 Registration, Announcement and Changes by Program Owner

JFSM registers the data in a) and announces the data in b) of the table below. The website of recognized assessment companies, conforming organizations and approved training organizations are linked under request with registration. In case the data a) and b) are changed, JFSM promptly updates the registration and website data on request.

	Registration Field	**a) Registration Data**	**b) Announced Data**
(1)	Recognized Assessment Company	◆ Name ◆ Address ◆ Branch Office and/or Outsourcing Company (Name and Address) ◆ Contract Date ◆ Auditable Category ◆ Contact Details ◆ Name of Assessor and Reviewer ◆ Audit and Conformity Assessment Rules (See the template in Appendix 1)	◆ Name ◆ Address ◆ Contract Date ◆ Auditable Category ◆ Contact Details

		◆ Document(s) or Manual(s) which demonstrate implementation of Audit and Conformity Assessment according to the flow and procedure described in Appendix 2 (This document may be included in the Audit and Conformity Assessment Rules.)	
(2)	Assessor and Reviewer	◆ Name ◆ Registration Date ◆ Belong (Assessment Company) ◆ Auditable or Reviewable Category ◆ Degree and Other Qualifications ◆ Training History ◆ Audit / Consultation Years of Experience ◆ Career (related to food industry)	◆ Name ◆ Registration Date ◆ Belong (Assessment Company) ◆ Auditable or Reviewable Category
(3)	Conforming organization	◆ Name ◆ Address ◆ Product (group) ◆ Category ◆ Audit Initial Date ◆ Registration Date (Reviewed Date) ◆ JFSM Registration Number ◆ Expiry Date of Conformity Assessment ◆ Assessment Company ◆ Representative Assessor ◆ Other Assessors ◆ Reviewer or Representative of Assessment Review Committee.	◆ Name ◆ Address ◆ Product (group) ◆ Category ◆ Registration Date (Reviewed Date) ◆ JFSM Registration Number ◆ Expiry Date of Conformity Assessment ◆ Assessment Company ◆ Representative Assessor ◆ Reviewer or Representative of Assessment Review Committee.
(4)	Approved Training Organization[7]	◆ Name ◆ Address ◆ Date of Approval ◆ Category ◆ Trainers ◆ Training Curriculum	◆ Name ◆ Address ◆ Date of Approval ◆ Category ◆ Trainers

2.8 Activity Report

JFSM prepares an annual report on activities related to this program and provides it to the Scheme Committee, the Recognition Committee, assessment companies and approved training organizations.

[7] Approved training organizations: Assessor training organizations which made contracts with JFSM to carry out specific training programs.

3. REQUIREMENTS FOR ASSESSMENT COMPANY

3.1 Assessment Company Criteria

The assessment companies shall be:

(1) Companies, local governments and trade associations which conduct, for instance, audits, consultations and inspections related to food safety,

Or

(2) Food-related organizations (retailers, manufacturers, distributors and so on) which conducts second party audit,

that fulfil the following requirements:

a) shall hold assessors who possess expertise of food safety (contracted assessors allowed);
b) shall hold reviewers or have Assessment Review Committee that possess ability to evaluate audit results and judge the assessment of the conformity;
c) shall have procedures to conduct Audit and Conformity Assessment. The procedures shall include internal audit, management review and processes to maintain assessor's competence;
d) shall have documented procedures necessary to implement activities, and shall retain the records which demonstrate the implementations;
e) shall provide necessary resources to implement activities such as personnel, facilities and capital.

3.2 Consultation and Audit Activities

Assessment companies are able to consult on days other than the audit period. However, persons in charge of consultation are not allowed to become an assessor nor a reviewer of the same auditee.

3.3 Application of Recognition as Assessment Company

The following documents shall be provided to JFSM on applying the assessment company recognition:

a) Application Form for Assessment Company Recognition (Form 1);
b) Document on Organization Structure (company leaflet allowed);
c) Audit and Conformity Assessment Rules (see the template in Appendix 1);
d) Document(s) or Manual(s) which demonstrate implementation of Audit and Conformity Assessment according to the flow and procedure described in Appendix 2.

Note) The above d) may be included in c).

3.4 Assessment Company Registration and Announcement

Assessment companies shall pay application fees to JFSM. Following the criteria stipulated in 3.1, audit including on-site audit is done and the results of the audit is reported to the Recognition Committee. The Recognition Committee makes decision on the recognition of the assessment company and reports the result to JFSM. The result is reported to the candidate company and contract is made between JFSM and the candidate company. Registration of the recognized assessment company is made by JFSM. Name of the assessment company, address or location, registered date, auditable category and contact details are announced on the JFSM website.

3.5 Renewal, Suspension and Withdrawal of Assessment Company Recognition

3.5.1 Renewal of Recognition

Recognized assessment companies shall submit an annual report on activities which includes results of

internal audit, management review, and processes of maintenance of assessors' competence to JFSM. Based on the report, audit of recognized assessment companies shall be done, basically, once a year.

The result of the audit is reported to the Recognition Committee, and JFSM asks the Recognition Committee for the decision whether the assessment company implements proper operations or not. The recognition is renewed by JFSM following the decision.

3.5.2 Suspension of Recognition

In case sufficient evidence of conformity to the criteria stipulated in 3.1 is not shown by the assessment company through the above mentioned audit, JFSM asks the Recognition Committee for the decision, and recognition may be suspended. The suspension is cancelled by JFSM based on the decision of the Recognition Committee with the verification of the assessment company's conformity to the criteria stipulated in 3.1.

3.5.3 Withdrawal of Recognition

In case the recognized company corresponds to any of the following cases, JFSM may ask the Recognition Committee for the decision of the withdrawal of the recognition:

a) The assessment company or its director have done any illegal act and be sentenced.
b) The assessment company is found not to conform the requirements stipulated in this program nor the criteria stipulated in 3.1.
c) The assessment company is found not to fulfil the contract with JFSM.
d) The suspension exceeds one year.

In the event of withdrawal following the decision of the Recognition Committee, JFSM notifies the assessment company in advance with reasons.

3.6 Decline of Recognition from Assessment Company

Recognition of the assessment company is removed by JFSM with a documented request of decline from the assessment company.

3.7 Retention of Documents and Security of Confidential Information

The assessment company shall retain the documents on Audit and Conformity Assessment activities (e.g. Application Form of Audit and Conformity Assessment, Conformity Assessment Audit Contract, audit report, Letter of Conformance) for five years from the expiry date of the contract. Confidential information obtained through the activities shall be securely kept from leakage.

4. AUDIT AND CONFORMITY ASSESSMENT

4.1 Validity of Audit and Conformity Assessment

Conformity Assessment of this program is valid for three years.

The assessment company conducts the initial audit, the annual surveillance audits and the renewal audit. The renewal audit shall be implemented within three years.

4.2 Application for Audit and Conformity Assessment

The organization which seeks for audit and assessment is necessary to apply one of the assessment company registered by JFSM with the Application Form on Audit and Conformity Assessment (for auditees) (Form 2).

4.3 Audit and Conformity Assessment Contract and List

In receiving the application referred in 4.2 from the organization, the assessment company shall decide the man-day for the Audit and Conformity Assessment activity, assessor(s) in charge and so on. The assessment company shall make an Audit and Conformity Assessment Agreement (Form 3) and necessary agreements for the audit with the auditee.

In addition, the assessment company shall prepare the Audit and Conformity Assessment List (Form 4) and record necessary information.

4.4 Processes of Audit

The assessment company shall audit whether the activity of the auditee conforms to the requirements of JFS-E-A/B standard and operates effectively or not. The audit may be outsourced to companies which have registered assessor(s).

Audit flow and procedure are described in Appendix 2.

4.5 Audit Report

The assessor shall make an Audit Report (Form 5) immediately after the audit of the auditee. The Audit Report shall be submitted to the reviewer or the Assessment Review Committee without delay.

4.6 Conformity Assessment Criteria

In receiving the Audit Report, the reviewer or the Assessment Review Committee shall review and verify whether the assessor's assessment is appropriate or not. Assessment criteria is described in Appendix 3. The assessment company certifies the conformity assessment of the auditee following the criteria.

Registered Reviewers may be outsourced under the condition that the assessment company owes the responsibility of the assessment.

4.7 Guidance and Suggestions during Audit

Assessment companies are recommended to provide guidance and suggestions to the auditee during the audit, with attention not to take over the autonomy of the auditee.

4.8 Audit Results Notification

The assessment company shall inform JFSM and the auditee the result determined by the reviewer or the Assessment Review Committee. In case the Letter of Conformance is not issued, the assessment company shall provide the auditee reasons with the result.

4.9 Issue of Letter of Conformance

The assessment company shall issue the Letter of Conformance (Form 6) to the conformed auditee (hereinafter referred to "conforming organization").

JFSM logo shall be attached on the Letter of Conformance with the following information:

- Name of Conforming Organization (name of the site)
- Address
- Product Name
- Category
- Registration Number
- The words “hereby certifies that the organization conforms to the Standard (e.g. JFS-A (Sector: E and/or L) Ver. 1.1, JFS-B (Sector: E and/or L) Ver. 1.1 which fully includes the Codex HACCP).”
- Registration Date (reviewed date)
- Expiry Date (three years after the registration)
- Assessment Company Name and Address (prefecture)
- Name of Representative Assessor and Other Assessors
- Name of Reviewer or the Representative of the Assessment Review Committee

The assessment company shall ensure that the requirements to the conforming organization concerning the usage of JFSM logo stipulated in Appendix 4 are kept.

4.10 Registration of Conforming Organization

The assessment company shall inform JFSM the following information of the conforming organization:

- Name
- Address
- Product (group)
- Category
- Registration Number
- Registration Date (reviewed date)
- Expiry Date (three years after registration)
- Representative Assessor
- Other Assessors
- Reviewer or Representative of the Assessment Review Committee.

Conforming organization shall make a payment of JFSM defined registration fee. The registration fee may be paid through the assessment company.

4.11 Renewal, Suspension and Withdrawal of Conformity Assessment

(1) The assessment company shall conduct audit of conforming organizations to assess conformity to the requirements of the standards, basically, once a year.

(2) The assessment company shall seize and make the conforming organization provide information at least until the initial action is done and implement extra audit under necessity in the event of prosecution or product recall concerning legal obligations or product safety.

(3) The assessment company is encouraged to give guidance and suggestions to make corrective action against nonconformity in case the conforming organization found not to conform the requirements of the standard. Suspension, withdrawal or else shall be taken in case the correction of nonconformity is beyond recovery, and shall be informed to JFSM with reasons.

4.12 Minute Changes of Registration Data on Letter of Conformance

In case minute changes of registration data occur, conforming organization shall provide information to the assessment company with a corrected copy of the Letter of Conformance and so on. The assessment company shall adjust the data if necessary and inform JFSM and conforming organization.

4.13 Announcement of Conforming organization

JFSM announces information of conforming organizations on JFSM website. Name and address of conforming organization, product (group), category, registration date, expiry date, JFSM registration number, name of assessment company, name of representative assessor, and reviewer or representative of the Assessment Review Committee are announced.

5. REQUIREMENTS FOR ASSESSOR OR REVIEWER

5.1 Competence Requirements for Assessor or Reviewer

An assessor or reviewer shall satisfy the competence requirements. The assessment company shall qualify an assessor or reviewer in accordance with b) Qualification Criteria stipulated as below:

An assessor and a reviewer may be outsourced.

	a) Competence Requirements	b) Qualification Criteria
Assessor	I. Skills and Knowledge for Audit: 1. To plan and summarize the audit effectively; 2. To conduct audit within the agreed period; 3. To communicate with people at all classes in the auditee; 4. To collect evidence by conducting interviews; 5. To collect evidence by observations and examinations; 6. To collect evidence by review of documents including records; 7. To analyze, verify and organize audit evidence and generate audit findings; 8. To prepare written audit reports. II. Technical Skills and Knowledge: 1. Knowledge of administration necessary to audit; 2. Knowledge of the management system standards; 3. Knowledge on HACCP; 4. Knowledge on Good Manufacturing Practice (GMP) ; 5. Knowledge on food safety laws and regulations. III. Behavior and System Thinking: 1. Leadership and personal behavior; 2. System thinking (ability of problem solving and root cause analysis); 3. Organizational and social moral.	◆ Competency Stipulated in I and III: Auditing and/or consulting experience related to food safety shall be required. The competency of the assessor shall be evaluated in the on-site audit. The person in charge of the assessment company shall qualify as the assessor. (Qualification records shall be retained.) ◆ Competency Stipulated in II: Training programs provided by JFSM approved training organizations or JFSM approved training programs shall be successfully completed.

Reviewer	I. Skills and Knowledge for Audit Same as the requirements mentioned above for the assessor. II Technical Skills and Knowledge Same as the requirements mentioned above for the assessor. III. Behavior and Systems Thinking Same as the requirements mentioned above for the assessor. IV. Conformity Assessment Review Skills: 1. Audit and/or consulting experience; 2. Comprehension ability of audit report; 3. Conformity assessment review (including judgement) ability.	◆ Competency Stipulated in I and III: Same as the criteria mentioned above for the assessor. ◆ Competency Stipulated in II: Same as the criteria mentioned above for the assessor. ◆ Competency Stipulated in IV: The auditing and/or consulting experience in accordance with HACCP based standards related to food safety management, such as JFS-B standard, JFS-C standard and so on shall be required. Audit and/or consulting reports shall be scrutinized by a person in charge of the assessment company to give interim approved reviewer status[8]. The reviewer shall be qualified through the review. Official registration shall be granted to the qualified reviewer. Records of qualification shall be retained.

5.2 Assessor or Reviewer Registration

Audit shall be conducted by the assessors registered by JFSM. Review of conformity assessment shall be conducted by the reviewers registered by JFSM.

An individual may possess dual qualification of assessor and reviewer. However, audit and review shall not be implemented by the same person for the same organization in spite the person has qualification as both assessor and reviewer (or a member of the Assessment Review Committee).

The assessment company shall apply for registration of the assessors or reviewers with competence evidence. The assessors or reviewers shall be registered by JFSM unless any deficiencies of documents are found.

Form 1 attachment 3 is prepared for the initial registration, and Form 7 for additional registration.

5.3 Renewal and Suspension of Assessor or Reviewer Registration

(1) Assessor or Reviewer registration stays valid under the condition of fulfilment of either of the followings:
   a) not a year has passed since the latest audit or review was done.
   b) not a year has passed since JFSM approved training program was successfully completed.

(2) In case the assessor or reviewer does not fulfil (1), qualification of assessor or reviewer shall be suspended by the assessment company. The assessment company shall notify the information to JFSM.

5.4 Withdrawal of Assessor / Reviewer Registration

(1) In case the assessor or reviewer does not conform the competence requirements stipulated in 5.1, the assessment company shall notify the information to JFSM. Registration of the assessor or reviewer may be withdrawn by JFSM based on the notification.

(2) JFSM withdraws the registration regardless of (1), with the request from the assessment company.

[8] Interim approved reviewer status: The person in charge of the assessment company is responsible to the

review during interim approval.

Appendix 1: Template of Audit and Conformity Assessment Rules

Audit and Conformity Assessment Rules Based on JFS-A/B Standards

XXXXX (Name of Assessment Company)
Effective date of this rules
Date/Month/Year
(Amendment: Date/Month/Year)

(General Provisions)

Section 1 “Audit and Conformity Assessment" activities based on JFS-A/B standards conducted by XXXXX (Name of assessment company) (hereinafter referred to “XXX”) shall be as prescribed in this rules.

(Auditable Category)

Section 2 The Auditable Category on which XXX conducts Audit and Conformity Assessment activities is/are as below:

Auditable Categories: XX, XX, XX

(Address of Office)

Section 3 The name and address of the assessment company's office is/are as below:

Name: XXXXX XXXXXXXX

Location: XXXXXXXXXXXXXXXXXXXXXXXX

(Duties and Ethics of Assessors and Reviewers)

Section 4 (a) XXX shall conduct Audit and Conformity Assessment activities following Clause 3 to 5. of JFS-A/B Audit and Conformity Assessment Program Document.

(b) Assessors, reviewers and whoever in charge of Audit and Conformity Assessment activities shall implement their duties with fairness and accuracy and shall keep any confidential information known through duties in secret.

(JFSM Registration Fees)

Section 5 Registration applicants of JFS-A/B Audit and Conformity Assessment shall make a payment of JFSM registration fee as prescribed below:

Each site/sector	Yen (excluding sales tax)

Appendix 2: Audit and Conformity Assessment Flow and Procedure

Audit shall be conducted following the flow and procedure below to issue Letter of Conformance:

(1) Preliminary Preparation

a) Preliminary Meeting

Preliminary meeting is to share information on the audit procedure between the assessment company and the auditee. (The meeting is recommended, not mandatory, not necessarily face-to-face.)

b) Auditee Self-check

Auditee shall verify the conformity to the requirements before the audit, using the check list attached in the Standard.

c) Document Submission

The following documents shall be submitted to the assessment company by the auditee before the on-site audit.

- Document which specifies scope of audit (name of organization, audited section, address, product (group))
- Document which specifies organization information (organizational structure chart, policies of dividing duties and so on)
- Documents describing food safety activities
- Self-check results
- HACCP related documents (e.g. Product specifications, Hazard identification list, Hazard analysis worksheets, HACCP plans) [B Standard applicant]

d) Calculating Audit Man-day (including brief guidance and suggestions)

The minimal man-day for the initial audit is as below:

Facility Scale [9]	Risk[10]	The Number of HACCP Systems[11]	Minimal man-day
Less than 50 workers	Medium	1 or less	1 man-day

Note) 1 man-day is assumed as 8 hours.

- Assessment company shall calculate the audit man-day to conduct audit based on A or B Standard sufficiently according to the table above, and the calculation rationale shall be recorded and retained.
- Hours for document review before the audit and making audit plan shall not be included in the above man-day calculation.
- Concerning the field audit (audit of processing areas, including interviews, documents and records review) significant, approximately 65 percent of audit man-day shall be field audit.
- Field audit shall include the processes significant in food safety. (Such as preparation of processing, cleaning, inspections, storage may be included in hours of field audit. Audit on CCP is mandatory for B Standard.)
- Annual surveillance audits may be implemented with approximately 65 percent of the above man-day. Field audit shall be focused in annual surveillance audit.

[9] Facility Scale: The scale of the organization to be audited.

[10] Risk (high, medium, low): Probability of occurrence of food accidents which affect human health.

[11] The number of HACCP systems: The number of systems which identify, evaluate and control significant hazards. For instance, in case that a plant manufactures both liquid food products (heat sterilization treatment and aseptic filling) and solid food products (differ from the former), the number of HACCP systems

is counted as 2.

(2) On-site Audit

a) Opening Meeting
Share how on-site audit will be conducted.

b) Field Audit
The assessor shall walk through and audit outside the buildings, inside the buildings and production lines. The assessor shall verify the actual practice of processing or handling products at the processing areas.

c) Documents and Records Review
Assessor shall perform documents and records review.

d) Action against Nonconformity
In case the auditee fail to fulfil the requirement (i.e. nonconformity), audit findings shall be filled in the “Audit Findings” column of the Check-list (Form 5), and the audit conclusion shall be made following the criteria (Appendix 3).
Active suggestions such as processes of improvement or showing clear examples, if any, are encouraged, regardless of conformity/nonconformity.

e) Closing Meeting
The assessor shall inform the auditee the findings and the audit conclusion utilizing the Check-list (Form 5). Comments from the auditee, if any, shall be recorded, and discussed, if necessary.
The assessor shall provide the audit conclusion and the nonconformity information in documents to the auditee following Appendix 3, and obtain agreement of the auditee.

(3) Actions after On-site Audit and Issue of Letter of Conformance

a) In Case of Conformity
The assessment company shall ensure that reviewer or the Assessment Review Committee reviews and approves the audit report.

b) In Case of Nonconformity
(i) The auditee shall eliminate nonconformity pointed out by the assessment company and report the actions taken to the assessment company until the specified due date.

(ii) In receiving the improvement report, the assessment company shall make the final decision of the Letter of Conformance. The decision shall be made by the reviewer or the Assessment Review Committee, different from the person in charge of the audit. Following the criteria (Appendix 3), the audit report and the improvement report shall be approved.

(iii) In case the criteria (Appendix 3) is not fulfilled, the assessment company shall again request the auditee to take proper actions.

c) Audit Result Notification to Auditee and JFSM
After the approval of the audit report, the assessment company shall inform the audit result to the auditee and JFSM. JFSM notifies the assessment company of JFSM registration number.

d) Issue of Letter of Conformance
The assessment company issues Letter of Conformance (Form 6) with description of JFSM registration number and send to the auditee. JFSM registration number shall be printed under the JFSM logo. The assessment company’s original registration number may be printed together in a

certain place prescribed by the assessment company.

Detailed audit procedures in ISO 19011 may be helpful.

Appendix 3: Conformity Assessment Procedure and Criteria

(1) Assessment of Each Requirement

a) Using the Check-list (Form 5), the assessor shall describe observations in column (a) for each requirement.

(Unnecessary to describe in details, however, remarkable elements shall be described.)

b) One of 4 boxes (conformity, minor nonconformity, major nonconformity, critical nonconformity) shall be checked, following the described audit findings in the “observations” column.

(a) Critical Nonconformity: Cause a direct impact on food safety, or legality being at stake.

Note) Conformity to the requirements is not fulfilled, and the product consequently become unsafe and/or illegal.

(b) Major Nonconformity: Likely to cause risk on food safety.

Note) Conformity to the requirements is not fulfilled, and the product consequently may be unsafe and/or the food safety risk may increase.

(c) Minor Nonconformity: Less likely to cause risk on food safety.

Notes) Conformity to the requirements is not fulfilled, however, the product consequently is considered to be virtually safe and/or the food safety risk does not increase.

(d) Conformity: Requirements fully satisfied.

c) After informing the auditee the result of the above b) and encouraging proper actions in case the result being (a) to (c) mentioned above, final decision shall be made and one of the followings shall be selected:

(i) Nonconformity is not corrected.
(ii) Nonconformity is corrected, however, the cause of nonconformity is not eliminated.
(iii) Corrective actions are taken and the cause of nonconformity is eliminated.

Comments or notices shall be made and described in b) Remarks Column of the Check-list (Form 5).

(2) Final Decision of Conformity Assessment

In case the below (a) being pointed out, corrective actions shall be requested to the auditee, and guidance and suggestions shall be provided, if necessary. After the designated period, on-site audit shall be implemented again, and if the completion of corrective actions is confirmed through the on-site audit, the result shall be taken as a pass.

Including the above, pass/fail of each case will be assessed following the table below:

[Table: Nonconformity Response Criteria]

	(i) Nonconformity not corrected	(ii) Nonconformity eliminated	(iii) Corrective action completed
(a) Critical Nonconformity	Implement the second on-site audit and assess from (i) to (iii)		
	Fail	Fail	Pass
(b) Major nonconformity	Fail	Pass (corrective action plan is required and the plan is adequate)	Pass
(c) Minor nonconformity	Fail	Pass (elimination of the nonconformity can be verified in the next annual audit depending on the improvement processes)	Pass

Appendix 4: Rule for JFSM Logo Use (Requirements for Conforming organizations)

1. Terms and Conditions for Usage of JFSM Logo

JFS-A/B Standard conforming organizations may use the JFSM Logo of the certified standard (hereinafter referred to “Logo”). JFSM Registration number shall be printed under the Logo. In using the Logo, with the approval of the assessment company, the Logo may be printed with the assessment company’s logo.

2. Logo Use

Following the “Logo Design Manual[12]”, stipulated separately, Logo may be used on leaflets regarding the standard to which the Letter of Conformance being issued, advertising materials, envelope, printing materials such as business cards, and on website. However, Logo shall not to be used on products.

3. Duration of Use

Logo may be used from the date the Letter of Conformance being issued, to the date of withdrawal.

4. Obligations for users

(1) Logo users shall conform to related law, regulations, this rule, “Logo Design Manual”, and are required to pay close attention to ensure that the Logo is not used against the aim of the Letter of Conformance. In addition, users are obliged not to harm the image nor lose credit of the Logo.

(2) In case the fact that a third party infringes copyright of the Logo or other rights being found, users are obliged to notify JFSM immediately.

(3) In case of disputes, trials, lawsuits and so on concerning the use of Logo with a third party, users shall confer with JFSM and decide what actions to take. Users shall bear the cost for such as disputes, trials and lawsuits (including reasonable attorneys’ fees, court costs and so on).

(4) In case users cause damage to a third party concerning the use of Logo, the concerned users take full responsibility for the damage, and JFSM and the third party do not owe any loss, damage nor responsibility.

(5) Under the request of JFSM, users shall report actual status of the use of Logo, submit the sample of the use of Logo and so on.

5. Prohibition

The following uses of Logo are prohibited:

(1) Single use of Logo, use of Logo on the products.

(2) Use of Logo contrary to this rule or “Logo Design Manual”.

(3) Use of Logo contrary to law, regulations, public order or morality.

---

[12] Logo Design Manual: A manual which stipulates colors, aspect ratio, fonts, size of letters and else of the JFSM Logo.

6. Measures against improper use of Logo

In case of improper use of Logo as mentioned in the above 5, the following measures shall be taken in sequence as necessary:

(1) Improvement request for correction;

(2) Warning;

(3) Withdrawal of Logo use permission;

(4) Disclosure of organization name;

(5) Legal actions.

Form 1　Template of Application Form for Assessment Company Recognition

Attention: Japan Food Safety Management Association

Date/Month/Year

Application on Audit and Conformity Assessment based on JFS-A/B Program

Applicant (Juristic Person)

Name: _____

Address: _____

_____

Title of Representative: _____

Name of Representative (Print): _____

Name of Representative (Signature): _____

We hereby apply for Audit and Conformity Assessment based on JFS-A/B program.

1. Information on auditing organization (Juristic person name, or part of the organization.　Trade name not permitted.)

Name: _____

Abbreviated name: _____

Representative: _____

1) Name and title of top management
(Management executor who holds the accountability of the Audit and Conformity Assessment confidentiality.)

_____

2) Headquarters or main office location

_____

TEL: (　　) 　　- _____　　FAX: (　　) 　　- _____

URL: _____

3) Contact details on this application

_____

a) Main　: Dpt. or Div./Title _____ Name _____

TEL: (　　) 　　- _____　　FAX: (　　) 　　- _____

E-mail: _____

b) Sub　: Dpt. or Div./Title _____ Name _____

TEL: (　　) 　　- _____　　FAX: (　　) 　　- _____

E-mail: _____

4) Accountant (Billing address)

_____

Dpt. or Div./Title _____ Name _____

TEL: (　　) 　　- _____　　FAX: (　　) 　　- _____

E-mail: _____

2. Information on application for Audit and Conformity Assessment based on JFS-A/B program

1) Application category

---

3. Information on the office(s) which conducts Audit and Conformity Assessment

1) Office(s) which conducts Audit and Conformity Assessment

Whether the auditing organization possesses any branch office which conducts Audit and Conformity Assessment of the applying categories beside the headquarters/main business office or not. If the auditing organization has such branch office, select 'Yes' below, fill out name and address of the branch office in the Attachment 1 of this application form, and attach.

☐Yes ☐No

2) Office and branch office(s) of the consignee or the outsourced auditing organization which conducts Audit and Conformity Assessment

Whether the consignee or the outsourced auditing organization possesses any office or branch office or not. If the consignee or the outsourced auditing organization has such office, select 'Yes' below, fill out name and address of the office and branch office in Attachment 2 of this application form, and attach.

☐Yes ☐No

4. Information on assessors and reviewers

Auditable categories, qualifications, training history, audit/consulting years of experience, and career (years of experience related to the food industry) of assessors and reviewers who engage in Audit and Conformity Assessment shall be filled out in Form 3 of this application and attach.

Attachment 1

Information on Branch Office(s) Conducting Audit and Conformity Assessment

Add lines if necessary.

	Branch Office(s) Information
1	**Name**
	Address
	Business Activities
2	**Name**
	Address
	Business Activities

Attachment 2

Information on Consignee or Outsourced Auditing Organization Office and Branch Office Conducting Audit and Conformity Assessment

Add lines if necessary.

	Consignee or Outsourced Auditing Organization Office Information
1	**Name**
	Address
	Business Activities

	Consignee or Outsourced Auditing Organization Branch Office Information
2	**Name**
	Address
	Business Activities

Attachment 3

Assessor and/or Reviewer Information

Name of Applicant (Name of office): (　　)

Please copy this page for each office and fill out this form.

[Assessor and/or Reviewer who conduct Audit and Conformity Assessment]

	Name	Assessor	Reviewer	Auditable or Reviewable category	Degree and other Qualifications	Training-history	Audit/ Consulting Years of experience	Career (years of experience related to food industry)
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								

Note) Check the assessor/reviewer column, if qualified.

Form 2　Template of Application Form on Audit and Conformity Assessment (for Auditees)

Application on JFS-XX (e.g. JFS-A, JFS-B) Audit and Conformity Assessment

Date/Month/Year

Attention: Name of Assessment Company

Address of the Auditee
Name of Juristic Person
Name of Representative (Printed)
Name of Representative (Signature)

We hereby apply for the Audit and Conformity Assessment as is stipulated in 4.1 of “JFS-A/B Audit and Conformity Assessment Program Document” of Japan Food Safety Management Association.

1. Name of the Auditee (Name of the site)
2. Address
3. Product (group)
4. Category
5. Operation hours (with/without shift working)
6. The number of HACCP systems [B Standard applicant]
7. Information on recall, regulatory order, deviation of laws within 3 years.

Note 1) Auditee seal can be substitute for signature of the representative.
Note 2) Please attach the outline of the Auditee, products (including specifications), document on organization structure, and the facility drawing.
Note 3) Please attach other useful documents for the audit.

Form 3　Template of Audit and Conformity Assessment Agreement

AGREEMENT CONCERNING JFS-A/B AUDIT AND CONFORMITY ASSESSMENT

(Name of juristic person) (hereinafter referred to "Auditee") and XXXX Assessment Company (hereinafter referred to "Assessor") make agreement (hereinafter referred to “This Agreement”) that Assessor conducts Audit and Conformity Assessment according to JFS-A/B standard for the food safety management system of Auditee as mentioned below:

(Audit Requirements)

Section 1

Assessor establishes the procedures and rules for implementation of Audit and Conformity Assessment in accordance with the latest JFS-A/B standard (issued on date/month/2016) issued by Japan Food Safety Management Association (hereinafter referred to "JFSM") and Auditee accepts such procedures and rules and make application on Letter of Conformance to Assessor.

(Implementation of Audit and Conformity Certificate Practices)

Section 2

Assessor issues Letter of Conformance on the condition that Auditee conforms the audit requirements on the food safety management system through the audit carried out by Assessor.

(Fees)

Section 3

(a) Auditee makes payment of designated amount of audit fee within the period specified by Assessor for receiving Audit and Conformity Assessment conducted by Assessor.
(b) Auditee makes payment to JFSM of the initial registration fee stipulated by JFSM through Assessor in receiving the Letter of Conformance and makes payment to JFSM of the annual maintenance fee through Assessor for each year within the effective period of the Certificate.

(Sharing Information)

Section 4

When the procedures/rules stipulated by Assessor have been revised, Assessor informs Auditee in document (including digital document, hereafter the same).

Furthermore, the procedures/rules of Assessor mentioned in Section 1 of This Agreement includes the latest versions of procedures/rules issued or revised after This Agreement made.

(Confidentiality)

Section 5

Auditee and Assessor are obliged to keep confidential information properly, for instance, to prevent the information from leakage, disclosing to any third party and improper use (including use out of purpose), in receiving confidential information from the other.

In case incidents of leakage or unintended disclosure of confidential information being recognized, either

Auditee or Assessor retains mutually the right to claim the damages. The obligations of confidentiality continues for ten (10) years after the expiry of This Agreement.

(Incidents, Claims and Complaints)

Section 6

(a) Auditee shall record all incidents, claims and complaints by stakeholders concerning food safety management of Auditee and corrective actions taken, and inform Assessor upon request of Assessor. In significant case, inform Assessor without request immediately.

(b) Assessor informs JFSM of significant information mentioned in Section 6 (a) of This Agreement without delay.
Auditee may not deny Assessor from disclosing such information to JFSM.

(c) Auditee may appeal or make complaints against Assessor under the procedure/rules of Assessor.

(Liability for Damages)

Section 7

Auditee and Assessor are accountable against any of the counterparty organization or individuals for loss, damages or incurred expenses arising from the infringement of This Agreement by the counterparty. However, this does not apply in the event of the infringement by force majeure.

(Effective Period)

Section 8

This Agreement is effective for three (3) years from the day of agreement.
This Agreement is renewed for another three (3) years under the same terms and conditions unless Auditee or Assessor send notification of the intent of expiration of This Agreement in document to the other in ninety (90) days advance.
The same applies in successive terms forward.

(Termination of Agreement)

Section 9

(a) In case of the counterparty's infringement or non-fulfilment of This Agreement, Auditee or Assessor notifies the request against the other party in document to correct the situation within ninety (90) days. In case correction not being done, Auditee or Assessor may terminate This Agreement.
In the event that serious damages caused by infringement or non-fulfillment of This Agreement incurred or likely to incur, Auditee or Assessor may shorten the designated period.

(b) In case Auditee is found impossible to continue activities as an organization due to allegations of bankruptcy, civil rehabilitation proceedings, corporate arrangement, and corporate reorganization, special liquidation, or of commencement of other similar proceedings, Assessor may terminate This Agreement immediately.

(c) Auditee may file an objection against Assessor within thirty (30) days after the termination of This Agreement by Assessor. The effectiveness of This Agreement continues until the conclusion.

(Obligations after Termination of Agreement)

Section 10

(a) Obligation mentioned in Section 5 continues for ten (10) years after the termination of This Agreement.
(b) At the time of termination, in case the debts/credits and liability occurred by non-fulfilment in duration, sections of This Agreement related to such debts/credits and liability stay valid.

(Court of Jurisdiction and Governing Law)

Section 11

This Agreement shall be interpreted in accordance with the laws of XXXXX (Country).
In case judicial action concerning This Agreement is necessary, XXX District Court or XXX Summary Court shall have the exclusive agreement jurisdictional court.

(Consultation)

Section 12

In case any ambiguous interpretation concerning This Agreement arises, Auditee and Assessor shall reach solution by mutual consultation.

In witness, whereof, the parties hereto have caused This Agreement to be executed by their representatives in duplicate with signatures on This Agreement and, each party retaining one (1) copy thereof respectively.

Date/Month/Year

Auditee: (Address of organization to be audited)
(Name of company)
(Title of representative) Name (Printed)
Name (Signature)

Assessor: (Address)
XXXX Assessment Company

(Title of person responsible) Name (Printed)
Name (Signature)

Form 4 Template with filled examples of Audit and Conformity Assessment List

JFS-A/B Standard - Audit and Conformity Assessment List

No.	Application Date	Accepted Date	Standard and Category	Name and Representative of Juristic Person	Name of Plant	Address	Name and Belong in Charge	Assessor (or Representative Assessor)	Reviewer (or representative of Assessment Review Committee)	Document Audit Date	On-site Audit Date	Conformity/ Nonconformity	Registration Date (Reviewed Date)	Date of Certificate issued	Remarks
1	22/ 10/ 2016	25/ 10/ 2016	A EI	XXX food Co., Ltd.	XXX plant	123-45, XXX town, XXXX city, XXX prefecture,	QC dev. Mr. Food Maker	XXX Co., Ltd. XXXXX	-	27/ 10/ 2016 ~ 28/ 10/ 2016	29/ 10/ 2016 ~ 30/ 10/ 2016	-			guidance and suggestions
								XXX Co., Ltd. XXXXX	-		10/11/ 2016 ~ 12/ 11/ 2016	-			
									XX Co., Ltd. XXXX			Confo rmity	12/ 11/ 2016	15/ 11/ 2016	

Form 5 Templates of Audit Report (JFS-A Standard and JFS-B Standard)

JFS-A Audit Report

<table>
<tr><td>Name of Organization</td><td colspan="2"></td><td>Audit Date</td><td></td></tr>
<tr><td>Number of workers</td><td colspan="2"></td><td>Man-days</td><td></td></tr>
<tr><td rowspan="2">Address</td><td colspan="2" rowspan="2"></td><td>Representative of auditee</td><td></td></tr>
<tr><td>Person responsible for Food safety management</td><td></td></tr>
<tr><td rowspan="2">Scope of Registration</td><td colspan="2">Plant/Line</td><td>Representative Assessor</td><td></td></tr>
<tr><td colspan="2">Registration category</td><td>Other Assessors</td><td></td></tr>
<tr><td colspan="3">Basic Information</td><td colspan="2">Document Review</td></tr>
<tr><td>Product (group)

Type of Product

With/without Outsourcing

Products Out of Scope (if any)

Operation License

Organization Structure
(within scope of audit)

HACCP Team
(if not, record “None”)

Past Critical Accident

Capacity of Plant</td><td></td><td>☐Product Specifications

☐Flow Diagram (process chart)

☐Documents on Raw Material/ Ingredient Safety

☐Chemical Control (Procedure and List)

☐Product Test Records

☐Accuracy of Sterilization & Foreign Material Control

☐Verification Records

☐Complaints Records

☐List of Customers

☐Inventory

☐Procedures and Instructions on GMP

☐List of Documents and Records</td><td></td></tr>
</table>

JFS-A Check list

For “Audit Findings” column, select one from the 4 boxes.

☐Conformity: Requirements fully satisfied.

☐Minor Nonconformity: Less likely to cause risk on food safety.

☐Major Nonconformity: Likely to cause risk on food safety.

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

Number / Clause Name / Requirements		Audit Findings	Remarks
FSM 2 Food Safety Policy		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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 Responsibilty		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.			
Guideline	FSM 4-1 Does the organization have an up-to-date chart which describes organizational structure?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 5 Top Management Commitment		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.			
Guideline	FSM 5-1 Are the responsibilities for product safety and compliance clearly defined, documented, and communicated to the workers?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 7 Resource Management		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.			
Guideline	FSM 7-1 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	

FSM 8 Record Control Records determined necessary to demonstrate implementation of food safety management shall be kept accessible.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	FSM 8-2 Does the organization have record retention period that complies with regulatory and customer requirements?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	FSM 12-2 Is the control of nonconforming materials carried out by competent personnel?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	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	

FSM 14 Product Release		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.			
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	
	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	
	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	
	FSM 14-4 Is there a designated person responsible for controlling specifications?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
	FSM 14-6 Does the organization have a written procedure in place for releasing products?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 20 Serious Incident Management		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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 procedure 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.			
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	
	FSM 20-2 Are incident records kept and assessed to establish severity and consumer risks?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	FSM 21-1 Are measuring and monitoring devices critical to food safety and regulatory requirements reliable?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 24 Traceability 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: ・ Identification of any outsourced raw materials and ingredients (including packaging materials), products or services. ・ Identification of batches, partially processed products, work inprogress, products being reprocessed, reworks, finished products, and packaging throughout the production process. ・ A record of purchaser and delivery destination for all products released.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	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	
	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	

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

GMP 2　Site Management An appropriate standard for all grounds within the site shall be established and maintained.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
GMP 3　Design, Construction and Layout of Facilities, Equipment and Production The site, building, and facilities and equipment in the plant shall be maintained to enable the control of the risk of product contamination caused by the external and internal environment, and by the manufacturing process flow.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	GMP 3-1 Are the facilities designed, constructed, layouted suitable to maintain and clean?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 3-2 Is the lighting adequate in brightness and color to prevent mistake?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
GMP 7　Staff Facilities Staff facilities shall be used so as to minimize food safety risks.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	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	
	GMP 7-3 Does the organization provide adequate numbers, locations and means of hygienic hand washing facilities?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	

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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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 ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
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	
	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	
	GMP 9-3 On specifying allergens to be controlled, are specifications, including regulatory and customer requirements, taken into consideration?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
	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	
	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	
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	
GMP 11 Housekeeping, Cleaning and Hygiene Housekeeping and cleaning shall be carried out following the documented criteria 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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	GMP 11-1 Does the organization have a procedure in place for housekeeping, cleaning and hygiene?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
	GMP 11-3 Are chemicals for cleaning and sanitizing identified and stored in the designated areas?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 11-4 Are cleaning and sanitizing carried out by trained or competent workers?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

GMP 12 Water and Ice Management 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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	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	
	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	
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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	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	
	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	
	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	

GMP 14 Pest Control			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
		GMP 14-2 Does the organization monitor periodically if pests are controlled effectively?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		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	
		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	
GMP 15 Transport			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.				
	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	
		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	

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.			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
		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	
		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	
		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	
		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	
		GMP 16-6 Does the organization have a rule of laundering and/or switching workwear?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

GMP 17　Training			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.				
	Guideline	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	
		GMP 17-2 Does the organization implement a refresher training (including personal hygiene) to all relevant workers?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

JFS-B Audit report

Name of Organization		Audit Date	
Number of workers		Man-days	
Address		Representative of auditee	
		Person responsible for Food safety management	
Scope of Registration	Plant/Line	Representative Assessor	
	Registration category	Other Assessors	

Basic Information		Document Review	
Product (group) The Number of HACCP Systems Type of Product With/without Outsourcing Products Out of Scope (if any) Operation License Organization Structure (within scope of audit) HACCP Team Past Critical Accident Capacity of Plant		☐Product Specifications ☐Flow Diagram (process chart) ☐Hazards Analysis Worksheet ☐HACCP Plan ☐Documents on Raw Material/ Ingredient Safety ☐Chemical Control (Procedure and List) ☐Product Test Records ☐Accuracy of Sterilization & Foreign Material Control ☐Verification Records ☐Complaints Records ☐List of Customers ☐Inventory ☐Procedures and Instructions on GMP ☐List of Documents and Records	

JFS-B Check list

For “Audit Findings” column, select one from the 4 boxes.

☐Conformity: Requirements fully satisfied.
☐Minor Nonconformity: Less likely to cause risk on food safety.
☐Major Nonconformity: Likely to cause risk on food safety.
☐Critical Nonconformity: Cause a direct impact on food safety, or legality being at stake.

Number / Clause Name / Requirements			Audit Findings	Remarks
FSM 2 Food Safety Policy			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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 Responsibilty			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.				
	Guideline	FSM 4-1 Does the organization have an up-to-date chart which describes organizational structure?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		FSM 4-2 Does the organization have a communication system in place for directing, reporting and consulting?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 5 Top Management Commitment			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.				
	Guideline	FSM 5-1 Are the responsibilities for product safety and compliance clearly defined, documented, and communicated to the workers?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		FSM 5-2 Is there record or displayed information which demonstrates communication with the workers?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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	
Guideline	FSM 7-1 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	
FSM 8 Document and Record Control The organization shall have documented procedure to control documents, which enables effective operation, and records, which demonstrates conformity and effectiveness of the organization's activity. The procedure shall include ways to prepare and maintain documents, and ways to keep and retain records. Records determined necessary to demonstrate implementation of food safety management shall be retained properly.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	FSM 8-2 Does the organization have record retention period that complies with regulatory and customer requirements?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 8-3 Does the organization have written document control procedures in place, and implement the procedure effectively?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 10 Procedures and Instrucructions The organization shall design its products taking into account all relevant safety requirements. The organization shall establish appropriate GMP for all processes and operations which has an effect on food safety. Work procedures and instructions shall be shown to workers in a visible way for implementing GMP and HACCP.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	FSM 10-1 Does the organization have detailed procedures in place and implement the procedures effectively for all processes and operations that affect food safety?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 10-2 Are the procedures clearly communicated to relevant workers?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	FSM 12-2 Is the control of nonconforming materials carried out by competent personnel?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	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	

FSM 14 Product Release			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.				
	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	
		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	
		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	
		FSM 14-4 Is there a designated person responsible for controlling specifications?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		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	
		FSM 14-6 Does the organization have a written procedure in place for releasing products?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 15 Purchasing			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
The procedure for purchasing shall be established and implemented. Externally sourced raw materials and ingredients, supplies and services which have potential effect on food safety shall conform to all the purchasing requirements of the organization. In case the processes which have potential effect on food safety are outsourced, the control of the processes shall be properly implemented with specifications or contracts providing the requirements for control to the supplier, or by other ways. In case of emergency, such as a 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.				
	Guideline	FSM 15-1 Do purchased material and services conform current written specifications and contracts?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

FSM 16 Supplier Performance The organization shall establish, implement and maintain procedures for the evaluation, approval and continual monitoring of suppliers, which have an effect on food safety. The results of evaluations, inspections and follow-up actions shall be recorded.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	FSM 16-1 Does the organization have a written procedure in place to evaluate and approve suppliers and implement the procedure?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 16-2 Does the organization have a written procedure in place to monitor suppliers and effectively implement?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 18 Complaint Handling A control system shall be established, implemented and maintained for managing complaints and complaint data from customers and consumers in order to be aware of, correct and control defects in food safety activities.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	FSM 18-1 Does the organization have a manual to handle complaints, and effectively implement?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 18-2 Are records of all customer and consumer complaints, result of investigations and corrective actions kept and retained?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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 procedure 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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	FSM 20-2 Are incident records kept and assessed to establish severity and consumer risks?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 20-3 Does the organization have capability of withdrawal and recall of products affected by an incident?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 20-4 Does the organization have a plan to enhance effective communication to customers, consumers and regulatory authorities by designating a person responsible to provide information?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 21 Control of Measuring and Monitoring Devices The organization shall identify the methods for measurement of parameters critical to ensure food safety, identify the measuring and monitoring devices required, and carry out calibration of these measuring and monitoring devices by a method traceable to a national, international or equivalent standard.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	FSM 21-1 Are measuring and monitoring devices critical to food safety and regulatory requirements reliable?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 21-2 Are measuring and monitoring devices critical to food safety identified, calibrated and traceable to national, international or other recognized standards?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 21-3 Are appropriate actions taken and recorded in case the measuring and monitoring devices are found to be out of specified limits?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

FSM 22 Food Defense Risks of intentional food contamination caused by workers or persons outside the organization shall be identified, evaluated and prioritized. The organization shall determine and implement measures to mitigate or eliminate the risks.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	FSM 22-1 Does the organization identify potential risks of intentional food contamination and analyze the risks?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 22-2 Does the organization identify vulnerable points in intentional product tampering or contamination in the process, and take measures to mitigate the vulnerability?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 22-3 Does the organization have a procedure in place to deal with products which is suspected to be intentionally contaminated?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 23 Product Labeling All products shall have information that allow customers and consumers to handle, display, store, prepare and use the product in safe ways. In addition, procedures to ensure the product to provide correct information shall be established and implemented.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

FSM 24 Traceability 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. The system shall be verified at least once a year. Records of the system shall include the following: ・ Identification of any outsourced raw materials and ingredients (including packaging materials), products or services. ・ Identification of batches, partially processed products, work in progress, products being reprocessed, reworks, finished products, and packaging throughout the production process. ・ A record of purchaser and delivery destination for all products released.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	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	
	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	
	FSM 24-4 Does the organization verify the effectiveness of traceability system more than once a year, review the system as necessary, and retain the records?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
FSM 25 Analysis of Input Materials The process environments and foods (e.g. raw materials and ingredients, and finished products) which potentially have effects on food safety shall be appropriately tested. It is recommended that tests are conducted in compliance with ISO 17025.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	FSM 25-1 Does the organization have a procedure for analysis to ensure that products conforms all the specified requirements including food safety, regulatory and customer requirements for a determined period?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	FSM 25-2 Does the organization use appropriate methods for analysis which provide valid results for food safety? (e.g. procedure conforming ISO 17025 and/or methods recognized by the industry)	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

HACCP Step 1 HACCP Team Assembly A HACCP team shall be assembled with competent staff.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
HACCP Step 2 Product Description Product specifications shall be described documented. The document shall describe all product information necessary to conduct hazard analysis. Scope of the HACCP system shall be defined per product or product group and per process line or process location.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	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	
HACCP Step 3 Identification of Intended Use The intended use of product and target consumers shall be clearly described in written document.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
HACCP Step 4 Construction of Flow Diagram The flow diagram that covers all steps in the operation shall be constructed.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
HACCP Step 5 On-site Confirmation of Flow Diagram The flow diagram shall be reviewed whether it correctly reflects the existing process steps of the operation.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	

HACCP Step 6（Principle 1） Hazard Analysis The HACCP team shall list all hazards that are reasonably likely to occur at each process steps, conduct an analysis, and identify any necessary means to control them. Hazard shall include allergens where required.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	HACCP 6-1 Is a hazard analysis implemented for each process step in food manufacturing?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	HACCP 6-2 Is the hazard analysis performed by competent HACCP team members?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
HACCP Step 7（Principle 2） Critical Control Points Critical Control Points (CCPs) shall be determined.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	HACCP 7-1 In case hazard analysis identifies significant hazards which are not eliminated nor minimized to acceptable level through controls in Good Manufacturing Practice (GMP), are the hazards specified as Critical Control Points (CCPs)?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
HACCP Step 8（Principle 3） Establishment of Critical Limits Critical limit(s) shall be specified for each CCP.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	HACCP 8-1 Are Critical Limits established for each CCP?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
HACCP Step 9（Principle 4） Monitoring System Monitoring procedure shall be established for each CCP.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	HACCP 9-1 Are monitoring procedures established for each CCP?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	HACCP 9-2 Are the CCPs monitored effectively?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
HACCP Step 10（Principle 5） Corrective Actions Procedure of corrective action (correction, investigation and removal of root cause) shall be established for deviations from critical limit.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	HACCP 10-1 Are corrective actions in deviation of critical limits established for each CCP?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	HACCP 11-1 Are verification procedures established?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	HACCP 11-2 Are the verification procedures implemented effectively?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
HACCP Step 12（Principle 7） Documents and Records Necessary documents shall be prepared and maintained. Necessary records shall be taken and retained.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	HACCP12-1 Are records and documents controlled to implement HACCP plan?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	HACCP12-2 Are all the procedures for HACCP-related record and document control implemented effectively?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
GMP 2 Site Management An appropriate standard for all grounds within the site shall be established and maintained.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	

GMP 3 Design, Construction and Layout of Facilities, Equipment and Producti		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
The site, building, and facilities and equipment in the plant shall be maintained to enable the control of the risk of product contamination caused by the external and internal environment, and by the manufacturing process flow.			
Guideline	GMP 3-1 Are the facilities designed, constructed, layouted suitable to maintain and clean?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 3-2 Is the lighting adequate in brightness and color to prevent mistake?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
GMP 4 Manufacturing and Storage Areas Specifications, and Utility Managem		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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.			
Guideline	GMP 4-1 Is the boiler compound, a chemical agent for steam boiler, approved for food manufacturing use? Is the boiler designed to prevent contamination of the compound?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 4-2 Are air conditioning and/or ventilation systems designed and constructed, if necessary, to prevent air contamination?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	GMP 5-1 Are the devices and tools designed to facilitate cleaning, sanitizing, maintenance and drainage?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	GMP 5-2 Are the food contact surfaces durable, easy to maintain, clean, sanitize and monitor, and made of materials that withstand cleaning materials and methods?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
GMP 6 Maintenance A system of planned maintenance covering all items of equipment which are critical to product safety shall be established.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	GMP 6-1 Does the organization have written procedure for maintenance of all equipment which have impact on food safety?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 6-2 Is the maintenance procedure effectively implemented?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 6-3 Does the maintenance procedure requires hygienic and clearance criteria for all maintenance activities?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 6-4 Are all the materials used in maintenance appropriate for intended use?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

GMP 7 Staff Facilities Staff facilities shall be designed and used so as to minimize food safety risks.			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
		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	
		GMP 7-3 Does the organization provide adequate numbers, locations and means of hygienic hand washing facilities?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		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	
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.			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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 ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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	
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	
	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	
	GMP 9-3 On specifying allergens to be controlled, are specifications, including regulatory and customer requirements, taken into consideration?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
	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	
	GMP 9-6 Is the product labeling of allergens that are based on risk assessment appropriate?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

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	
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	
GMP 11 Housekeeping, Cleaning and Hygiene Housekeeping and cleaning shall be carried out following the documented criteria 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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	GMP 11-1 Does the organization have a procedure in place for housekeeping, cleaning and hygiene?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
	GMP 11-3 Are chemicals for cleaning and sanitizing identified and stored in the designated areas?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	GMP 11-4 Are cleaning and sanitizing carried out by trained or competent workers?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

GMP 12 Water and Ice Management 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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	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	
	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	
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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
Guideline	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	
	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	
	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	

GMP 14 Pest Control			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
		GMP 14-2 Does the organization monitor periodically if pests are controlled effectively?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		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	
		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	
GMP 15 Transport			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
A documented system shall be established to ensure that 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 product in final packaging) are suitable for the intended use, maintained in good repair and 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	
		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	

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.		☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
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	
	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	
	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	
	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	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	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	
	GMP 16-6 Does the organization have a rule of laundering and/or switching workwear?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

GMP 17 Training A system shall be in place to ensure all workers are adequately trained on food safety principles (including HACCP) and practices, commensurate with the worker's activity. A system shall be established to ensure all workers are adequately instructed and supervised. Training shall ensure all workers to be aware of the roles in food safety and the significance of the activities.			☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
	Guideline	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	
		GMP 17-2 Does the organization have a plan for taininig in place and the plan is implemented effectively?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		GMP 17-3 Is the HACCP training plan implemented?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		GMP 17-4 Is training record kept properly and available?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	
		GMP 17-5 Is a refresher training plan documented and implemented?	☐Conformity ☐Minor Nonconformity ☐Major Nonconformity ☐Critical Nonconformity	

Form 6　Template of Letter of Conformance

JFSM logo

JFSM registration number

JFS-XX (e.g. JFS-A, JFS-B) Letter of Conformance

Date/Month/Year

Conforming organization name

Attention: Name of Representative

Address
Assessment company name and
Representative name (Printed)
Representative name (Signature)

This is to confirm that below mentioned conformance to JFS-XX (e.g. JFS-A, JFS-B) in accordance with 4.4 of "JFS-A/B Audit and Conformity Assessment Program Document" of Japan Food Safety Management Association.

JFSM Registration Number	
Conforming Organization Name (Name of Site)	
Address	
Product (Group)	
Category	
Registration Date (Reviewed Date)	
Expiry Date	

Names of representative assessor and other assessors

Name of reviewer or representative of Assessment Review Committee

Note 1)　Company seal can be substituted for signature of the representative.

Form 7　Template of Application Form for Assessor and Reviewer Registration

Application for Assessor & Reviewer Registration

Date/Month/Year

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Attention: Japan Food Safety Management Association

Address
Assessment company name and
Representative name (Printed)
Representative name (Signature)

We hereby apply for Registration of Assessor/Reviewer in accordance with 5.2 of “JFS-A/B Audit and Conformity Assessment Program Document” of Japan Food Safety Management Association.

1. Name
2. Assessor/Reviewer
3. Auditable or Reviewable Category
4. Degree or Other Qualifications
5. Training History
6. Audit/Consulting Years of Experience
7. Career (years of experience related to food)

Note 1)　Seal can be substituted for own handwriting signature of the representative.
Note 2)　Please attach other useful documents for the application.