

# JFS Audit and Conformity Assessment Program Document<sup>1</sup>

Ver.2.1

Japan Food Safety Management Association

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## 1. PROGRAM OUTLINE

### 1.1 Purpose

The JFS Audit and Conformity Assessment Program (hereinafter referred to as the "Program") is a program established by the Japan Food Safety Management Association (hereinafter referred to as "JFSM") which verifies that food-related business operators are implementing food safety management systems that conform to the requirements of the JFS Standards by means of third-party audits conducted by audit companies approved by JFSM.

This program aims to enable food-related business operators, particularly small and medium-sized businesses, to improve the level of their food safety by utilizing the conformity assessments of the JFS Standard (hereinafter referred to as "this Standard").

In addition, by means of program audits and assessments, the program intends to standardize food safety management systems throughout the food chain, promote the HACCP recommendations of the Codex Alimentarius Committee, further enhance food safety management levels, and contribute to cost optimization.

This program was developed by JFSM, and the copyright and other rights relating to this program are the property of JFSM.

### 1.2 Definitions

The terms used in this program are defined as follows.

- |     |                       |   |
|-----|-----------------------|---|
| (1) | Organization          | Food-related business operators that are audited under this program.  |
| (2) | Site                  | Places where food manufacturing, cooking, etc., subject to conformity assessment, is performed. Includes food manufacturing factories, their offices and their premises.  |
| (3) | Audit company         | An audit company that has been approved by the Audit Company and Training Course Recognition Committee (2.2 (2) 1) and has entered into a contract with JFSM.   |
| (4) | Training organization | An audit company that has been approved by the Training organization and Training Course Recognition Committee (2.2 (2) 1) and has entered into a contract with JFSM.   |
| (5) | Consulting            | Proposals that provide assistance in establishing, implementing, or maintaining a food safety management system of an audited organization, and provide specific suggestions, directions, or solutions, that are separate from the audit (see 3.2). |
| (6) | Guidance              | Proposals that an assessor makes to an audited organization to correct any nonconformities discovered during the audit.   |
| (7) | Suggestions           | Proposals that an assessor makes to an audited organization to ensure that the organization operates its food safety management system more effectively, although no nonconformities were found during the audit.                                   |

(8)	Conformity assessment	Assessment that the activities of the audited organization conform to the requirements of the Standard.
(9)	Stakeholders	All parties involved in food safety, such as organizations, audit companies, members, regulators, consumers, etc.
(10)	Sector	Scope of food-related operations subject to audits and certifications.
(11)	Subsector	Scope of subcategory of the sector in consideration of food safety risks.
(12)	On-site audit	An audit conducted within an audited organization's site by an assessor visiting the organization.
(13)	Walk-through audit	Audits conducted by assessors on the manufacturing lines, buildings, facilities, equipment, surroundings, storage, etc. of the audited organization.
(13)	HACCP plan	A document created by an organization in accordance with the Codex HACCP 7 Principle 12 procedures to control critical hazard factors.
(14)	JFSM-DB	A database containing information on JFS Standard audit companies, assessors, organizations that have received conformity assessments (hereinafter referred to as "certified organizations"), and approved training organizations.

### 1.3 Standard documents and applicable sectors

The following are the Standard documents used for auditing organizations in this program, including the sectors and subsectors corresponding to each Standard document.

Regarding the JFS Standard (Food Service) Sector: G (hereinafter referred to as “Food Service Standard”) and the JFS Standard for sorting and packing facilities for fruits and vegetables for Thailand (hereinafter referred to as “JFS Standard for Thailand”), in addition to this program, rules for auditing and conformity assessment shall be established separately.

Standard document	Sector symbol	Subsector symbol	Sector and subsector name
JFS-A Standard JFS-B Standard	E	EI	Processing of perishable animal products
		EII	Processing of perishable plant products
		EIII	Processing of perishable animal and plant products (mixed products)
		EIV	Processing of ambient stable products
JFS-A Standard JFS-B Standard	L	-	Manufacture of chemical products* (including biochemical products) (manufacture of additives, vitamins, minerals, cultures, fragrances, enzymes, processing aids)
JFS Standard (Catering)	G	-	Catering
JFS Standard for Thailand	DT	-	Related to sorting and packing facilities for fruits and vegetables for Thailand JFS Standard

Note: Here, chemical products refer to food-related chemical products (including biochemical products).

## 2. PROGRAM OWNERSHIP REGULATIONS

### 2.1 Program Owner

This program is operated and managed by JFSM.

### 2.2 Organizational Structure

(1) JFSM establishes a Board of Directors as an executive body, an inspector to conduct business operations audits, a Board of Trustees to decide on important matters, and a Secretariat to conduct the affairs of the association at the direction of the Board of Directors.

(2) JFSM establishes Stakeholder Committee and an Audit Company and Training Course Recognition Committee (hereinafter referred to as the “Recognition Committee”) with the approval of the Board of Directors. The duties of each committee are as follows.

- |   |  |
|---|--|
| ① Audit Company and Training Course Recognition Committee | <p>This committee reviews audit companies and training institutions, and approves, suspends, cancels, or renews their training courses.</p> <p>The establishment and operation of the Audit Company and Training Course Recognition Committee is stipulated in the “Audit Company and Training Course Recognition Committee Establishment and Operation Rules”.</p>  |
| ② Stakeholder Committee                                   | <p>This committee is an advisory body composed of stakeholders to enable this program to be operated fairly and equitably.</p> <p>This committee provides expert suggestions as consultation to the Board of Directors or the Chairman, and each member of the committee independently expresses its opinion as a stakeholder.</p> <p>The establishment and operation of the Stakeholder Committee is stipulated in the “Stakeholder Committee Establishment and Operation Rules”.</p> |

(3) With the approval of the Board of Directors, JFSM establishes working groups to develop this program document, standard documents for applicable sectors and other standard documents (hereinafter referred to as “standard documents”). The establishment and operation of the working groups is stipulated in the “Rules for Establishing and Operating Working Groups”.

### 2.3 Maintenance of Conformity Assessment Program

(1) JFSM is comprehensively responsible for establishment, operation and maintenance of this program.

- (2) 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.
- (3) JFSM meets at least once a year to adjust levels with the participation of audit companies for the purpose of accepting and discussing proposals for the operation of this program and exchanging opinions on improving the competence of assessors and reviewers (hereinafter referred to as “Harmonization Meeting”).
- (4) JFSM reviews this program at least once a year through management reviews and internal audits, and revises it as necessary. When reviewing, JFSM confirms that the standard documents of the program are up-to-date and that opinions, questions and complaints from stakeholders are taken into account.

## 2.4 Communication with stakeholders

JFSM establishes a contact point for opinions, inquiries and complaints from stakeholders regarding the Program. JFSM establishes and discloses rules regarding the handling of objections and complaints relating to the Program.

## 2.5 Registration, publication and changes of information by the program owner

JFSM registers information on the audit companies, assessors, reviewers, certified organizations, and approved training organizations in the JFSM-DB and publishes the following items.

	Registration Field	Announced Data
①	Recognized Audit Company	Name of audit company and its location (prefecture) Date of contract with JFSM Registered sector (subsector in the case of sector E) Contact information (URL, etc.)
②	Auditor and Reviewer	Name Registration date Affiliated audit company Qualification (assessor/reviewer) Registered sector (subsector in the case of sector E)
③	Certified Organization	Name of certified organization and its location (prefecture) Product (group) Sector (subsector in the case of sector E) Applicable standard version Conformity assessment date (initial registration date shall be taken as the conformity assessment date) JFSM registration number Expiration date of conformity assessment



		Audit company name Name of representative assessor, name of reviewer or name of representative of Assessment Review Committee
④	Approved Training Organization	Date of contract with JFSM Institution name and location (prefecture) Contact information (URL, etc.) Category of training course Lecturer name

## 2.6 Activity Report

Once a year, JFSM prepares a report of its annual activities, including the results of analyzing the opinions, inquiries and complaints received by JFSM regarding this program, and submits the report to the Recognition Committee. In addition, the annual activity report is submitted to the Stakeholder Committee, audit companies, approved training organizations and other stakeholders.

### **3. REQUIREMENTS FOR AUDIT COMPANY**

#### **3.1 Audit Company Criteria**

The audit 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:

- ① shall have assessors with the competence specified in 5.1 (including assessors under outsourcing contracts).
- ② shall have reviewers or a Assessment Review Committee capable of evaluating the audit results of the assessors and determining the assessment of the conformity.
- ③ shall have procedures for conducting Audit and Conformity Assessment activities. The procedures shall include internal audits, management reviews, and procedures for maintaining the competence of assessors and reviewers.
- ④ shall document and maintain records of the procedures deemed necessary for executing their activities.
- ⑤ shall have the resources (personnel, equipment, and funds) necessary to continually conduct Audit and Conformity Assessment activities.
- ⑥ shall have a system in place based on ISO19011:2018, Paragraph 4 (Audit Principles) for assessors, reviewers, and other personnel involved in auditing activities to conduct independent and fair audits.

#### **3.2 Consultation and Audit Activities**

Audit companies may provide consulting to an audited organization at a different date and time than the audit. However, a person who has provided consulting to an organization shall not, as an assessor or reviewer, conduct an audit of the same organization or review the audit until two years have passed since the consulting ended.

#### **3.3 Application of Recognition as Audit Company**

- (1) A company that intends to receive recognition as an audit company (hereinafter referred to as “applicant company”) shall apply to JFSM for recognition of its audit and conformity assessment business using the prescribed application form.
- (2) JFSM receives from the applicant company the submitted application for the audit and conformity assessment business related to this program, confirms the content, and if there are no irregularities, concludes a contract for a recognition audit with the applicant company.

- (3) The applicant company submits all documents related to the audit business as specified by JFSM. After all documents related to the audit business have been submitted, JFSM will begin a document audit. If a nonconformity is detected as a result of the document audit, JFSM will request the applicant to correct the nonconformity within a certain time limit. If the applicant does not correct the nonconformity within the time limit, JFSM may reject the application.
- (4) After the document audit, JFSM will conduct an on-site audit at the offices of the applicant company.
- (5) JFSM reports the results of the document audit and on-site audit to the Recognition Committee. JFSM approves the application if the Recognition Committee determines that the applicant company meets the requirements of 3.1. If the application is rejected, JFSM shall notify the applicant company of the reason.
- (6) JFSM enters into a contract with the recognized applicant company for audit business. JFSM will register the recognized applicant company as an audit company and announce the 2.5 ① and ② information on its website.

### 3.4 Audit Company Registration and Announcement

The audit company shall submit or report information on the audit company, including assessors and reviewers, certified organizations, and audits by submitting them to JFSM or entering them in the JFSM-DB based on the following table.

Event	Notification and reporting items	Notification and reporting method	Notification and reporting deadline
Signing of contract related to audit business	Information on audit company structure	Notify JFSM in the prescribed format. After confirmation by JFSM, enter in the JFSM-DB.	Immediately after contract
	Information on competence of assessors and reviewers		
Change to audit company system information	Information on changed audit company structure		Promptly if there is a change
Annual activity report	Annual activity report (including information on the status of internal audits, management reviews, and maintenance of competence of assessors and reviewers)	Submit to JFSM in writing.	Once a year starting from the contract date with JFSM

Additional registration of assessors and reviewers	Information on competence of assessors and reviewers	Notify JFSM in the prescribed format. After confirmation by JFSM, enter in the JFSM-DB.	Immediately when registering additional assessors and reviewers
Change of registered information on assessors and reviewers	Information on competence of changed assessors and reviewers		Immediately if there is a registration change
Initial or renewal audit	Information on first or renewed audit of organization, and the conformity, and the audit information	Enter in the JFSM-DB.	By the 15th of the month following the month of conformity assessment
Periodic audit	Periodic audit information		By the 15th of the month following the month of the periodic audit
Change of registered information on certified organization	Registered information on changed certified organization	Report to JFSM by email and enter in the JFSM-DB.	Promptly if there is a change

### 3.5 Renewal, Suspension and Withdrawal of Audit Company Recognition

#### 3.5.1 Renewal of Recognition

JFSM conducts periodic audits of the audit company once a year, in principle, based on the content of 3.4, to confirm the conformity and effectiveness of the requirements of the audit company as specified in this program. JFSM may also conduct extraordinary audits if there is a risk that the audit company may not meet the requirements of 3.1. The audits performed by JFSM are separately stipulated in the “Business Office Audit Rules”.

JFSM reports the results of the audit of the audit company to the Recognition Committee and, decides on maintaining the recognition of the audit company based on the decision of the committee.

#### 3.5.2 Suspension of Recognition

In the event that the audit company falls under any of the following cases, JFSM may seek a decision by the Recognition Committee and suspend the recognition of the audit company based on the committee's decision.

- ① The audit company has neglected to notify or report to JFSM or has given a false notification or report.
- ② The audit company has intentionally misused the logo provided by JFSM.
- ③ The audit company cannot provide sufficient evidence to confirm that the requirements of 3.1 are satisfied.

If the recognition is suspended, the audit company shall be notified of the reason for suspension.

If JFSM receives a notification from the suspended audit company offering to take corrective action for the reason for the suspension, JFSM audits the conformity and effectiveness of the audit company with the requirements of 3.1 and cancels the suspension of recognition based on the decision of the Recognition Committee.

### 3.5.3 Withdrawal of Recognition

In the event that the audit company falls under any of the following cases, JFSM may seek a decision by the Recognition Committee and withdraw the recognition of the audit company based on the committee's decision.

- ① The contract between JFSM and the audit company has terminated.
- ② No effective corrective action has been taken by the audit company within a considerable period of time after the suspension.
- ③ The audit company has refused, hindered, or evaded a business office audit by JFSM, rejected questions from JFSM without justifiable cause, or provided false answers.
- ④ JFSM has determined that it will damage the reputation of the JFS Standard or cause undue disadvantage to the organization.

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

### 3.5.4 Succession of certified organization

If there is a compelling reason for the audit company to be unable to continue its audit business, a certified organization may change to another audit company while maintaining its conformity. The audit company that has assessed the conformity of the certified organization shall ensure that there is no disadvantage to the certified organization when the certified organization is succeeded by another audit company. If a certified organization is succeeded by another audit company, the former audit company shall agree to submit information on the certified organization (including an audit report and other audit documents) to JFSM.

### 3.6 Decline of Recognition from Audit Company

If an audit company seeks to decline its recognition, it shall consult with JFSM prior to declining its recognition. If there are any certified organizations that have had their conformity assessed by the audit company, the audit company shall take care to ensure that there is no disadvantage to those certified organizations.

An audit company may decline recognition only with the agreement of JFSM upon the recommendation of the Recognition Committee.

### 3.7 Retention of Documents and Security of Confidential Information

The audit company shall retain documents (hereinafter referred to as “audit reports and documents”) on its Audit and Conformity Assessment activities (e.g. Application Forms for Audit and Conformity Assessment, Conformity Assessment Audit Contracts, audit reports, Certificate of Conformity) for five years after the contract for audit activities with an organization that has received a conformity assessment (hereinafter referred to as a “certified organization”) has been completed.

The audit company shall retain documents (hereinafter referred to as “audit reports and documents”) on its Audit and Conformity Assessment activities (e.g. Application Forms for Audit and Conformity Assessment, Conformity Assessment Audit Contracts, audit reports, Certificate of Conformity) for five years after the contract for audit activities with an organization that has received a conformity assessment (hereinafter referred to as a “certified organization”) has been completed.

Even after the contract with a certified organization has been terminated, the audit company shall not disclose the business secrets of the certified organization obtained during the audit and conformity assessment to a third party without the consent of the organization.

The audit company shall handle audit reports and documents as confidential information. In principle, the audit company shall obtain written consent from a certified organization when providing or disclosing audit reports and documents to a third party. However, audit reports and documents may be provided to JFSM to confirm that the assessor has properly performed the audit in accordance with the requirements. The audit company shall obtain the prior written consent of the certified organization that the audit reports and documents will be provided to JFSM for the purpose of a review of the audit company by JFSM.

### 3.8 Objections from audit companies

An audit company or applicant company (see 3.3 (1)) shall be able to respond with an objection to any unfavorable decision made by JFSM only within 30 days from the day following the date that the decision is received. JFSM shall respond to the objection based on the “Rules for Treatment of Objections”.

### 3.9 Participation in Harmonization Meetings

The audit company shall participate in the Harmonization Meeting specified in 2.3.

If requested by JFSM, the audit company shall participate in meetings and training designated by JFSM.

## 4. AUDIT AND CONFORMITY ASSESSMENT

### 4.1 Validity of Audit and Conformity Assessment

Conformity Assessment of this program is valid for three years.

The valid period of the conformity assessment shall be from the date of the conformity assessment.

In this program, one conformity assessment shall be issued for one sector. For Sector E, one conformity assessment can be issued for a plurality of subsectors.

Also, as a general rule, one conformity assessment shall be issued for one site.

The audit company audits, in principle, once a year to confirm whether the certified organizations are conforming to the requirements of the Standard. Audits include the following:

Audit type	Content	Implementation period
Initial audit	Confirm that the organization that seeks to receive the conformity assessment has established and effectively operates a system that conforms to the requirements of the JFS Standard.	When the application (4.2) is received from the organization
Renewal audit	Confirm and evaluate that the certified organization has continually conformed to the requirements of the JFS Standard and has been operating effectively throughout the valid period (3 years) of the conformity assessment.	In principle, before the expiration date of the conformity assessment
Periodic audit	Verify that certified organizations continue to meet and maintain the JFS Standard requirements.	Once a year, in principle, within the valid period of the conformity assessment, based on the date of the conformity assessment
Extraordinary audit	If an event as specified in 4.11 occurs, the audit is conducted on a temporary basis to confirm the conformity and effectiveness of the certified organization.	When necessary

### 4.2 Application for Audit and Conformity Assessment

The audit company accepts applications for an audit and conformity assessment from organizations seeking to receive an audit and conformity assessment that are submitted using an Application Form on Audit and Conformity Assessment (for the organization to be audited).

#### 4.3 Audit and Conformity Assessment Contract and List

If an audit company receives an Application Form on Audit and Conformity Assessment as stipulated in 4.2 from an organization seeking to receive a conformity assessment, the audit company shall specify the labor-hours for performing the audit and conformity assessment, the assessor in charge, and other necessary items related to the audit, and upon the agreement of the organization to be audited with such terms, a contract for the audit and conformity assessment shall be concluded.

The audit company shall maintain the conformity assessment list, and record the labor-hours, the assessor in charge of the audit and conformity assessment, and other necessary items related to the audit.

#### 4.4 Appointment of assessors and reviewers, and determination of audit labor-hours

- (1) The assessors audit the activities of the organization seeking to be audited to confirm that it conforms to the JFS Standard requirements relevant to the organization, and that the organization's systems are functioning effectively.

The audit company may outsource the audit work to assessors who do not have a direct employment relationship with the audit company and meet the requirements set forth in this program (called "outside assessors").

- (2) After confirming the following matters, the audit company shall appoint an assessor and a reviewer who are registered at JFSM, and notify the organization to be audited of the name of the assessor in advance.
- ① The assessor shall be an assessor registered for the sector (for the subsector in the case of sector E) to be audited.
  - ② The reviewer (at least one reviewer in the case of the Review Committee) shall be a reviewer registered for the sector to be reviewed. However, a reviewer registered for sector E can also review sector L.
  - ③ Assessors and reviewers shall have no interest in the audited organization including consulting.
- (3) The audit company shall determine the labor-hours to be audited based on Annex 1 and keep a record as a basis for the calculation.

#### 4.5 Implementation of audit

Assessors shall conduct audits in accordance with the audit procedures in the Annex. Assessors shall prepare an audit report immediately after the audit of the organization to be audited, and submit requests for correction requests and reports to the organization as necessary. Assessors shall confirm the completion of the correction based on the correction request and report submitted by the organization, and promptly submit the necessary documents for review, including the audit reports, checklists, and correction requests and reports to the reviewer or Review Committee.

#### 4.6 Conformity Assessment Criteria

After receiving the documents submitted by the assessor, the reviewer or the Assessment Review Committee confirms the content and determines whether the content of the audit is appropriate.

The reviewer or the Assessment Review Committee shall confirm the following items in the review.



a) Is the content of the audit report adequate in light of the requirements of the JFS Standard and the scope of the audit?

b) Have corrections and corrective actions for all nonconformities been reviewed and confirmed?

Details on the method and criteria for determining conformity shall be as specified in Annex 2.

If the audit company determines that the organization conforms to the standard, the audit company shall certify the organization. The audit company shall record the basis for its decision. Anyone consulting with the organization to be reviewed shall not be involved in the review.

The audit company may outsource the review to a reviewer who has no direct employment relationship with the audit company and meets the requirements defined in this program (called an “outside reviewer”). However, the audit company shall clearly assume responsibility for the review.

#### 4.7 Guidance and Suggestions during Audit

Assessors are encouraged to provide guidance and suggestions during the audit, keeping in mind that the organization shall remain autonomous. If any guidance or suggestions have been given, the assessor shall record this fact.

#### 4.8 Audit Results Notification

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

#### 4.9 Issue of Certificate of Conformity

(1) If the audit company determines that an organization is in conformity in the initial audit and the renewal audit, the audit company registers the organization in the JFSM-DB after confirmation by JFSM, and issues a certificate of conformity to the organization. The valid period of the certificate of conformity shall be three years.

(2) The certificate of conformity shall have the registration number assigned by JFSM (hereinafter referred to as the “JFSM registration number”) written below the JFS Standard logo, and shall include the following items. The audit company may separately write a uniquely determined registration number at a position decided by the audit company.

- Certified organization name (site name)
- Location
- Product group
- Sector (subsector in the case of sector E)
- JFSM registration number
- Conformity to applicable standards
- Evidence of conformity in writing
- Applicable standards and their version numbers
- Certificate of conformity

- Expiration date of certificate of conformity (Three years after the review)
- Name and location of the audit company (prefecture)
- Audit company representative name and seal
- Name of representative assessor
- Name of the reviewer or representative of Assessment Review Committee

- (3) The audit company shall ensure that, when a certified organization uses the JFS standard logo, the certified organization complies with Annex 3 “Rule for JFSM Logo Use”.

#### 4.10 Registration of Certified Organization

- (1) The audit company shall report to JFSM the following items by entering the information into the JFSM-DB, register the information of the certified organization, and submit audit reports to JFSM (see 3.4).

- Name of certified organization and its location
- Product group, sector (Subsector for sector E)
- Certificate of conformity
- Expiration date of certificate of conformity (Three years after the date of conformity assessment)
- Name of representative assessor and assessors
- Name of the reviewer or representative of Assessment Review Committee

- (2) Certified organizations shall pay registration fees to JFSM through an audit company. The registration fee is determined separately by JFSM.

- (3) If requested by JFSM, the audit company shall submit documents related to the audit to JFSM. Handling of confidential information is specified in 3.7.

#### 4.11 Renewal, Suspension and Withdrawal of Conformity Assessment

- (1) In the event that any of the following applies and after the certified organization has completed its initial response, the audit company shall receive a report from the certified organization and conduct an extraordinary audit when it is determined that conformity needs to be confirmed. If the audit company conducts an extraordinary audit, the audit company shall report the results to JFSM in writing.

- ① If products manufactured on lines subject to conformity assessment are seized (recalled) or voluntarily collected for food safety reasons
- ② If the certified organization receives an administrative action, such as administrative guidance or a business suspension order, due to a food safety problem.
- ③ If there is a possibility that product may not conform to the requirements of the standard due to a natural disaster, fire, etc.

- (2) The audit company shall suspend the conformity assessment of the certified organization in the event that any of the following applies.

- ① If the certified organization does not conform to the requirements of the standard and there is no prospect of correction (including cases in which the organization's operations are continually stopped due to a natural disaster, fire, etc.)
  - ② If there is a major nonconformity with the requirements of the standard at the certified organization
  - ③ If the certified organization has not taken corrective action within a considerable period of time (in principle, within three months) after the certified organization was found to have a major nonconformity with the requirements of the standard and the audit company requested a correction
  - ④ If the certified organization does not allow a periodic or renewal audit to be conducted
- (3) The audit company shall notify the certified organization and JFSM of the suspension of the conformity assessment in writing with the reason for the suspension.
  - (4) The period of the suspension of the conformity assessment shall, in principle, be six months from the date of notification to the certified organization. The audit company shall cancel the suspension after confirming that the nonconformity that caused the suspension has been corrected. The audit company is encouraged to provide appropriate guidance and suggestions for correcting the nonconformity to the relevant organization.
  - (5) The audit company shall withdraw the conformity assessment of the certified organization in the event that any of the following applies.
    - ① If no corrective action has been taken by the certified organization within six months, in principle, after the suspension of the conformity assessment and the conformity and effectiveness of the identified nonconformity cannot be confirmed.
    - ② If the contract between the audit company and the certified organization has been canceled.
  - (6) The audit company shall notify the relevant certified organization and JFSM of the withdrawal of the conformity assessment in writing with the reason for the withdrawal.

#### 4.12 Minute Changes of Registration Data on Certificate of Conformity

If any part of the information described in the certificate of conformity needs to be changed, the certified organization shall submit a copy of the certificate of conformity that describes the changes to the audit company that issued the certificate of conformity.

If it is deemed necessary to change the registered items of the certificate of conformity, the audit company shall promptly notify JFSM of the change, and after confirmation by JFSM, make changes to the JFSM-DB and the certificate of conformity (See 3.4).

#### 4.13 Announcement of Certified Organization

JFSM announces the information specified in 2.5 ③ about certified organizations on the JFSM website.

## 5. REQUIREMENTS FOR ASSESSOR OR REVIEWER

### 5.1 Competence Requirements for Auditor or Reviewer

Regardless of whether or not personnel are outsourced, the audit company shall ensure that the assessor possesses the competence stipulated in (1) to (3) below and that the reviewer possesses the competence stipulated in (1) to (4) below.

#### (1) Audit skills and knowledge to

- ① Effectively plan and organize the audit
- ② Conduct audits within the agreed period
- ③ Communicate with people at all levels of the audited organization
- ④ Conduct interviews and gather evidence
- ⑤ Gather evidence by observation and investigation
- ⑥ Review materials and records and gather evidence
- ⑦ Analyze, verify, and organize audit evidence and summarize audit findings
- ⑧ Prepare audit reports

#### (2) Technical skills and knowledge related to

- ① Management system standards
- ② Codex HACCP
- ③ Good Manufacturing Practices (GMP)
- ④ Food safety laws and regulations

#### (3) Behavior and systematic thinking

- ① Leadership and behavior
- ② Systematic thinking (problem solving, root cause analysis)
- ③ Organization and social code of conduct

#### (4) Skills to review conformity

- ① Auditing or consulting experience
- ② Ability to understand and confirm the content of the audit report
- ③ Ability to review conformity

### 5.2 Assessor or Reviewer Registration

#### (1) Initial registration

The audit company evaluates whether the person has the competence stipulated in 5.1 by the following method, and submits an application for registration of the assessor to JFSM along with documents supporting the evaluation.

- ① Confirm that the candidate for assessor has completed training conducted by a training organization approved by JFSM or the designated training by JFSM.
- ② A manager at the audit company shall witness an audit conducted by the candidate for assessor and evaluate the competence of the audit. The audits to be witnessed include two-party audits on food safety, including HACCP, and two-party audits and third-party audits conducted as a substitute. In addition, a manager at the audit company may appoint a competent representative who is capable of evaluating the competence at the audit site.

- ③ A manager at the audit company shall confirm that the assessor has food safety work experience for each sector (subsector in the case of sector E, and the same applies hereafter), or experience in auditing or consulting on food safety by sector, or the ability to audit by sector. Work experience in food safety by sector is stipulated in Annex 4.

One person may be registered as an assessor and a reviewer at the same time. However, an assessor who has conducted an audit of an organization cannot concurrently conduct a review of the same organization. The audit company shall maintain a record of these evaluations and, if requested by JFSM, submit this record to JFSM.

## (2) Maintaining registration

In order to maintain auditing competence, an assessor shall conduct at least one audit of sector E or sector L according to the JFS standard each year. Assessors who do not conduct at least one audit each year shall complete the maintenance training provided by JFSM.

Assessors shall complete examinations or training designated by JFSM if requested by JFSM.

## (3) Expansion of sector or subsector

When seeking to expand the registration of assessors in sectors E, L, or subsectors, a manager at the audit company shall evaluate whether the audit company has adequate auditing competence for each sector or subsector as specified in 5.2 (1) ③ and shall provide the evaluation results when applying to JFSM for an expansion of the sector or subsectors.

# 5.3 Renewal and Suspension of Reviewer Registration

## (1) Initial registration

The audit company evaluates whether the person has the competence stipulated in 5.1 by the following method, submits an application for registration of the reviewer to JFSM along with documents supporting the evaluation, and JFSM examines the audit competence of the reviewer.

- ① Confirm that the candidate for reviewer has audit experience according to JFS standards or other food safety management standards including HACCP.
- ② The candidate for the reviewer conducts one or more simulated reviews on audit reports by JFS standards or other food safety management including HACCP, and prepares reports. A manager at the audit company examines the content of the reports and evaluates the person's review skills.
- ③ A manager at the audit company shall confirm that the reviewer has food safety work experience for each sector (subsector in the case of sector E, and the same applies hereafter), or experience in auditing or consulting on food safety by sector, or the ability to review by sector. Work experience in food safety by sector is stipulated in Annex 4.

One person may be registered as an assessor and a reviewer at the same time.

However, an assessor who has conducted an audit of an organization cannot concurrently conduct a review of the same organization.

The audit company shall maintain a record of these evaluations and, if requested by JFSM, submit this record to JFSM.

(2) Maintaining registration

In order to maintain review competence, a reviewer shall conduct at least one review of sector E or sector L according to the JFS standard each year. Reviewers who do not conduct at least one review each year shall complete the maintenance training provided by JFSM.

Reviewers shall complete examinations or training designated by JFSM if requested by JFSM.

(3) Expansion of sector or subsector

When seeking to expand the registration of reviewers in sectors E, L, or subsectors, a manager at the audit company shall evaluate whether the audit company has adequate auditing competence for each sector or subsector as specified in 5.2 (1) ③ and shall provide the evaluation results when applying to JFSM for an expansion of the sector or subsectors.

#### 5.4 Withdrawal of Assessor / Reviewer Registration

(1) JFSM suspends the registration of assessors or reviewers who fall under any of the following cases.

① Persons who have not conducted at least one JFS standard audit or review per year and have not completed the maintenance training prescribed in 5.2 (2) and 5.3 (2)

② Persons who have not, as a result of examination by JFSM, conducted appropriate audits or reviews and who have not had their audit or review competence confirmed

JFSM notifies assessors and reviewers when their registration has been suspended.

Assessors or reviewers whose registration has been suspended shall not conduct audits or reviews.

Assessors or reviewers who have been suspended due to ① can have the suspension canceled after completing the maintenance training. Assessors or reviewers who have been suspended due to ② can the suspension canceled after JFSM confirms that they completed correction of the nonconformity.

(2) If the audit company suspends the registration of an assessor or reviewer on its own judgment, the company shall notify JFSM that they have taken such action.

#### 5.5 Cancellation of assessor/reviewer registration

(1) If the audit company determines that an assessor or reviewer does not meet the competence requirements stipulated in 5.1, the company notifies JFSM to that effect. JFSM may cancel the registration of the assessor or reviewer based on the notification.

(2) If the audit company cancels the registration of an assessor or reviewer on its own judgment, the company notifies JFSM of that fact, and JFSM cancels the registration.

## **Annex1: Template of Audit and Conformity Assessment Rules**

The audit company or assessor shall conduct audits and conformity assessments based on JFS standards as follows. Detailed audit procedures may also be based on ISO19011.

### **(1) Prerequisites for a fair audit**

#### **① Investigation of audit threats**

In order to conduct an impartial audit, the audit company shall investigate in advance whether there are any potential threats to impartiality when accepting an application from an organization that seeks to receive an audit and conformity assessment. An audit company shall not conduct audits of organizations for which threats that cannot be removed remain or concerns about fairness are raised from a third-party perspective.

Investigations on threats are conducted by a manager at the audit company, regarding items that are determined to pose a threat to the implementation of fair audits. It is recommended that the investigations include the relationship with the person who received the order, the relationship with the organization, the relationship with the consultant, and the public and private relationships of the assessor and reviewer with the organization.

The results of the threat investigation shall be recorded.

#### **② Determination of assessors and reviewers**

The audit company determines assessors and reviewers based on the investigation conducted in ① together with the application it received from an organization that seeks to receive an audit and conformity assessment. The audit company shall give due consideration to the assessors and reviewers it determines so that fairness is not impaired through the audit and review.

The result of the determination shall be recorded.

### **(2) Preliminary Preparation**

In the preliminary preparation, the audit team shall check the HACCP-related documents and the results of self-check, etc., and audit in advance whether HACCP has been properly established based on the standard requirements. The number of audit duration for preparation of audit plan and checking documents shall be 0.5 man-days.

#### **① Preliminary Meeting**

It is recommended that the audit company consult with the organization to be audited in advance on how to proceed with the audit. Note that a preliminary meeting is not essential. Also, the meeting format is not limited to a face-to-face direct meeting.

#### **② Submission of audit plan**

The audit company sends an audit plan in advance to the organization to be audited, and informs the organization about the composition of the assessors and the schedule of the on-site audit (department to be audited and timetable).

#### **③ Self-check by organization to be audited**

The audit company requests the organization to be audited to conduct a self-check of its

conformity against the requirements of the JFS standard prior to the audit. The self-check sheet will be published on the JFSM website.



#### ④ Advance document confirmation

The audit company requests the organization to be audited to submit the following documents prior to the on-site audit. Assessors shall confirm the documents in advance.

- Scope of audit (organization name, organization (application) scope, location, product (group))
- Organization information (organization chart, roles and responsibilities, etc.)
- Documents that explain initiatives related to food safety
- Records of the results of self-checks conducted by the organization based on ③
- HACCP-related documents (product specifications, flow diagrams, hazard factor analysis tables, HACCP plans, etc.)

#### (3) Calculation of audit duration

The audit company shall calculate audit duration for the organization being audited to, which the audit can be properly performed in accordance with the formula and criteria for calculating on-site audit duration set out in this paragraph, and shall maintain records of the basis for the calculation. The audit company may increase or decrease the number of man-days from the number of man-days calculated in accordance with the formula and the calculation criteria, taking into account other factors such as the HACCP plan, the size of the facility, and whether the audit is a JFS-A/B audit, if the audit company considers it necessary to do so in order to conduct an appropriate audit. However, the auditor shall document the rationale for any increase or decrease in the number of audit hours calculated in accordance with the calculation criteria.

The minimum number of audit duration for initial and renewal audits shall be one man-day, which in principle shall be eight hours (excluding travel time and including lunch breaks).

The audit duration for periodic audit) may be 65% of the initial audit. In this case, however, the on-site audit shall be the main focus of audit.

#### ① Calculation formula for the on-site audit durations

Calculation formula for the on-site audit durations for initial and periodic audits(surveillance audit) is as follows

man-daysman-days

$$T_s = T_D + T_H + T_{FTW} + T_{GMP}$$

$T_D$  Basic audit labor-hours for conducting on-site audits (0.5 man-days in principle)

$T_H$  Additional audit man-hours when the number of HACCP plans exceeds 2 (as shown in Table 1)  
Even if there are multiple products to be audited, the number of HACCP plans can be set to 1 if the plan to control the hazards related to the target products (groups) based on the 7

principles of HACCP 12 procedures can be said to be the same.

(as shown in Table 1)

$T_{FTW}$

Audit duration according to the number of workers (as shown in Table 1)

The number of employees shall be taken as the number of full-time equivalent employees (full-time workers), calculated on the basis of an eight-hour working day, five days a week.

Where shifts are worked (including seasonal workers) and the products and/or processes are similar, the number of full-time equivalents shall be the number of employees involved in the main shift plus administrative staff.

$T_{GMP}$

Audit labor-hours for GMP (in principle, 0.5 man-days)

② Calculation formula for the on-site audit durations

The criteria for calculating the audit duration required for the on-site audit are set out in Table 1.

Table 1 Criteria for calculating durations of on-site audit

Sector	T <sub>D</sub>	T <sub>H</sub>	T <sub>FTW</sub>	T <sub>GMP</sub>	T <sub>S</sub>
E/L	0.5	Number of HACCP plans 1~2=0 3~4=0.25 5~6=0.5 7~8=0.75 >9=1.0	1~50=0 51~100=0.25 101~500=0.5 501~1000=1.0 1001~5000=1.5 >5000=2.0	0.5	≥1.0

### ③ Periodic Audit

The number of on-site duration for a

surveillance audit may be 65% of the initial on-site audit. However, in such cases, the on-site audit shall be the main focus of audit.

### (3) On-site audit

#### ① Preliminary meeting

The audit team shares how the on-site audit will be conducted with the organization to be audited.

#### ② On-site audit

The audit team visits the manufacturing site and audits the surroundings, buildings, production lines, etc. At this time, the audit team shall confirm that the product in question is manufactured or handled on the site based on the information obtained from the document confirmation in advance.

On-site audits (including interviews and confirmation of documents and records) must be emphasized in initial and renewal audits.

#### ③ Audit of documents and records

The audit team audits the documents and records.

#### ④ Determination of conformity / nonconformity

The audit team determines conformity with each requirement of the JFS standard. The assessor uses the audit checklist to record the audit findings for each requirement. At that time, it is not necessary to describe all the findings in detail, but it is important to describe the points.

If conformity to the requirements cannot be confirmed or a nonconformity is detected, the nonconformity category is determined based on Annex 2 and the status of the nonconformity is recorded in the audit checklist. In the event of a nonconformity, audit evidence shall be included in the audit checklist.

#### ⑤ Final meeting

The audit team uses the audit checklist to indicate the audit findings and the results of the conformity determination to the audited organization. If there are any opinions from the audited organization, they are recorded in the audit checklist and reviewed as necessary.

If a nonconformity is detected, the audit team shall explain the nonconformity to the audited organization by means of a request for correction and a report, obtain the agreement of the audited organization, set a time limit for the correction, and request the organization to make the correction.

(4) Determination of audit result and issuance of certificate of conformity

① If conformity is confirmed

The audit company confirms the audit results in the audit report, and if conformity is confirmed with regard to all the requirements, the determination is made by a reviewer or the Assessment Review Committee and the audit report is recognized.

② If a nonconformity is detected

The audit team shall review the identified nonconformities of the audited organization in accordance with the procedures for each nonconformity category in Annex 2, and confirm that corrective actions have been completed or that a correction plan is valid by the deadline set by the audit team. At this time, the completion of the corrective action shall be confirmed by documents or photographs.

③ Implementation of reviews or Assessment Review Committee

The reviewer or the Assessment Review Committee makes a determination based on the audit report, the correction report, the evaluation result of the correction report by the assessor, etc. The review method is stipulated in 4.6.

The result of the determination shall be recorded.

④ Notification of audit result to audited organization and entry into the JFSM-DB

The audit company notifies the audited organization of the result of the determination together with the audit report. Additionally, the audit company shall notify JFSM by entering the information of the certified organization into the JFSM-DB based on the JFSM-DB system operation manual and receive confirmation from JFSM.

JFSM notifies the audit company of the JFSM registration number of the certified organization.

⑤ Issuance of certificate of conformity

The audit company issues a certificate of conformity based on 4.9 and delivers it to the certified organization.

## Annex 2: Audit and Conformity Assessment Flow and Procedure

### (1) Conformity assessment criteria and handling method

Table 2 shows the assessment criteria and handling methods for each conformity or nonconformity category.

Table 2-Conformity assessment criteria and handling methods for each conformity or nonconformity category

Symbol	Status of conformity	Definition	Assessment criteria	Handling method
a	Fatal nonconformity	Has a direct impact on food safety or has failed to comply with food safety regulations.	If the requirements are not met and the safety of the product has not been ensured, or the laws relating to food safety have not been complied with	In the case of an initial audit, the audit shall be stopped, and after the fatal nonconformity is eliminated, the audit shall be conducted again.  In the case of a periodic or renewal audit, suspend the audit and conformity assessment (4.11 (2) ②), request that corrective actions be completed within six months, and conduct the audit again after the corrections are completed
b	Major nonconformity	Likely to impact food safety.	If the requirements are not met and the product may no longer be safe, or the risk to food safety may increase	In principle, the completion of corrective actions shall be confirmed within 30 days.

c	Minor nonconformity	Less likely to impact food safety.	If the requirements are not met, but the resulting product is safe, or the risk to food safety is unlikely to increase	Request and confirm that corrective action is taken within 30 days and that a corrective action plan be developed. Completion of the correction shall be confirmed by an audit one year later.
d	Conformity	The requirements are being met.		
	Observations	Same as above	If the determination is "conformity" but there are suggestions to be given, or if there is a possibility that nonconformity may occur if operation is continued in that state	Record the observations to be pointed out in the observation column of the audit checklist.

If the status of the audited organization with regard to the requirements is deemed to be excellent, that fact can be noted in the remarks column using an expression such as "good point".

## (2) Procedures for nonconformities

If the audit company and the assessor determine that the audited organization is nonconforming and request the organization to correct the nonconformity or take corrective action, after confirming that the nonconformity has been corrected, a determination of conformity shall be made and a review shall be conducted.

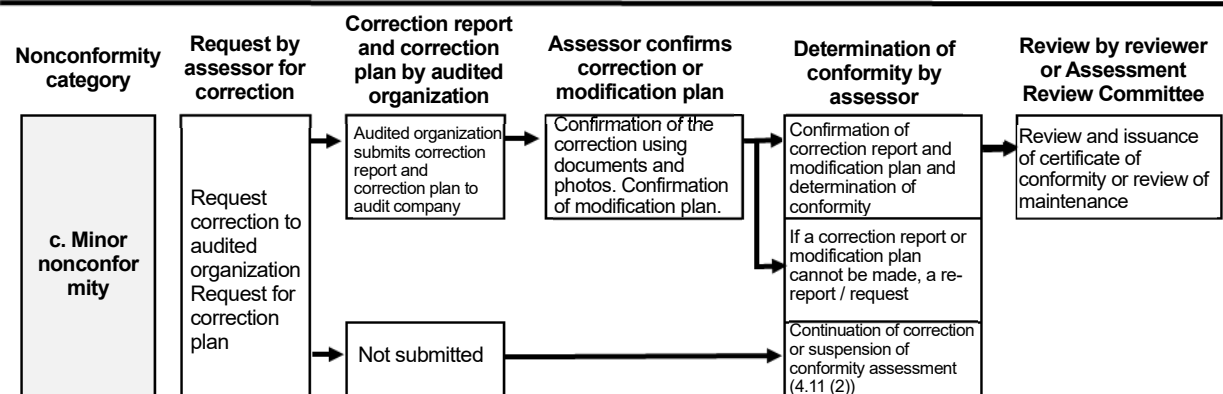
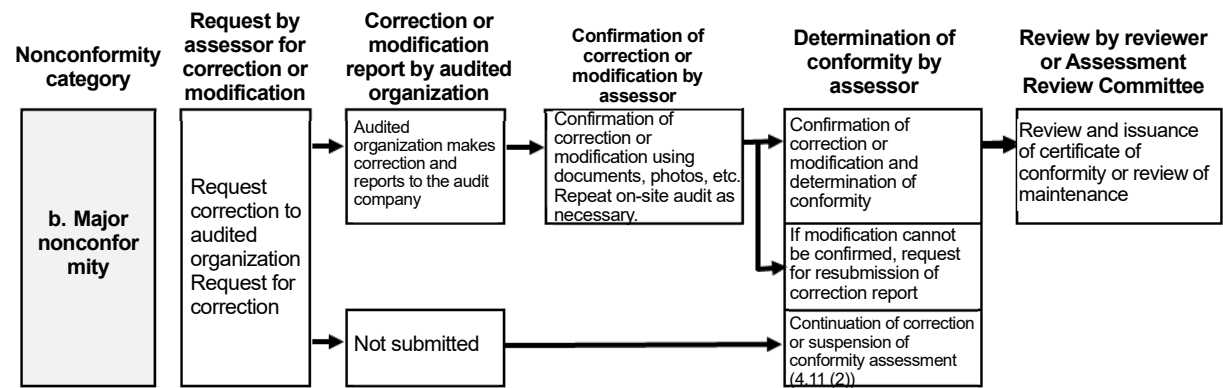
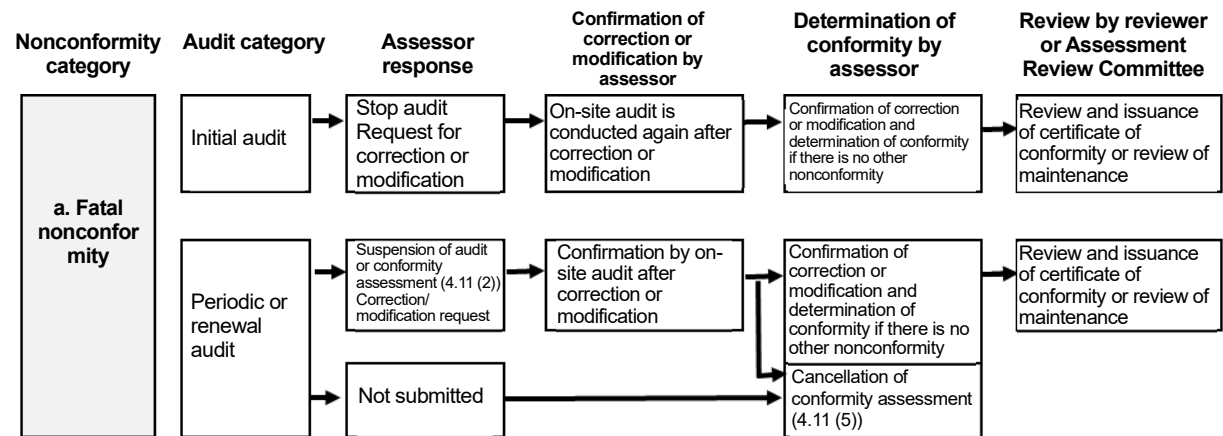
"Corrective action" is a measure taken to eliminate the cause of the nonconformity in order to prevent the nonconformity identified in the audit from recurring. The audited organization implements the action laterally to other lines and other departments and reviews the risks as necessary to prevent recurrence of the nonconformity.

The audit company shall confirm whether the corrective action is appropriate for preventing a recurrence and whether the nonconformity has recurred.

"Correction" is a measure to eliminate the nonconformity identified in the audit.

The audited organization shall take action to eliminate nonconformities that directly or potentially affect food safety as identified in the audit and to prevent the manufacture and shipment of nonconforming products.

The following figure shows the flow of the response procedure for each nonconformity category.



## **Annex 3: Rule for JFSM Logo Use (Requirements for Certified Organizations)**

### **1. Terms and Conditions for Usage of JFSM Logo**

JFS-A/B Standard certified 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 audit company, the Logo may be printed with the audit company’s logo.

### **2. Logo Use**

Following the “Logo Design Manual<sup>1</sup>”, stipulated separately, Logo may be used on leaflets regarding the standard to which the Certificate of Conformity 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 Certificate of Conformity 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 Certificate of Conformity. 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.

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<sup>1</sup> Logo Mark Design Manual: Defines the logo color, aspect ratio, font, character size, etc.



## **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.

## **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.

## Annex 4: Food safety work experience (requirements for assessors and reviewers)

Table 3 shows the required food safety work experience for each sector or subsector required for assessors and reviewers (subsectors for assessors in the case of sector E).

Table 3 Food safety work experience by sector and subsector

Sector or subsector	Work experience by sector or subsector (examples)
EI Processing of perishable animal products	<ul style="list-style-type: none"> <li>▶ Meat processing</li> <li>▶ Poultry processing</li> <li>▶ Fish processing</li> <li>▶ Seafood processing</li> <li>▶ Manufacture of meat products</li> <li>▶ Manufacture of fish meat products</li> <li>▶ Manufacture of dairy products</li> <li>▶ Egg processing</li> </ul>
EII Processing of perishable plant products	<ul style="list-style-type: none"> <li>▶ Processing of fruits and vegetables</li> </ul>
EIII Processing of perishable animal and plant products (mixed products)	<ul style="list-style-type: none"> <li>▶ Manufacture of meat products</li> <li>▶ Manufacture of fish meat products</li> <li>▶ Manufacture of dairy products</li> <li>▶ Manufacture of non-heated eating and cooking products</li> </ul>
EIV Processing of ambient stable products	<ul style="list-style-type: none"> <li>▶ Heat treatment</li> <li>▶ Baking processing</li> <li>▶ Manufacture of dairy products</li> <li>▶ Brewing</li> <li>▶ Extruded products</li> <li>▶ Vegetable and animal fats</li> <li>▶ Sugar refining</li> <li>▶ Manufacture of beverages</li> <li>▶ Manufacture of alcoholic beverages</li> </ul>
L Manufacture of chemical products (including biochemical products) (manufacture of additives, vitamins, minerals, cultures, fragrances, enzymes, processing aids)	<ul style="list-style-type: none"> <li>▶ Fermentation technology</li> <li>▶ Chemical engineering</li> <li>▶ Biochemical engineering</li> </ul>

<sup>1</sup> Disclaimer: This translation is provided for information purposes only. In the event of a difference of interpretation or a dispute, the original Dutch version of this document is binding.