November 5, 2021

Attention: Contracted accreditation bodies
Attention: Contracted certification bodies

# (Notice) Revision of "Surveillance activity provisions for certification bodies relating to the JFS-C Certification Program"

Japan Food Safety Management Association

We would like to express our sincere gratitude for your continued support and cooperation in the activities of the Japan Food Safety Management Association (hereinafter referred to as "JFSM").

As we presented during the 4<sup>th</sup> Harmonization Meeting for the JFS-C Certification Program on September 10, 2021, we would like to inform you that we have revised and issued "Surveillance activity provisions for certification bodies relating to the JFS-C Certification Program (C01P14R04)" in accordance with the revision of the JFS-C Certification Program Document Ver. 3.1. Please refer to the following for the outline of the key changes from C01P14R03.

#### Notice

# Key Changes from C01P14R03

Item	Key changes (outline)
1. Purpose	Added the competencies required for technical reviewers and witness assessors.
	Added the reference to Annex 4 (Risk Factors of Operational Integrity)
	of the Certification Program Document for risk factors required for
	surveillance control activities.
	The annual performance analysis is referenced in Annex 4 of the
3. Activities	Certification Program Document.
5. Activities	Following additional activities are added. For the analysis of the audit
	duration, if the audit durations do not meet the requirements of the
	Certification Program Document, JFSM request the certification body
	to submit the reason in writing and JFSM confirms the validity of the
	case on the basis of the reply and the evidence and decides whether

		to approve or not.
4.	Office audit	Added the competencies required for technical reviewers and witness
	implementation	assessors.
	Procedure	
5.	Implementation	Documents to be summitted include summary of audit results,
	procedures for review	corrections, corrective actions, and certificate.
	of audit reports	

Please see the attached sheets for the revised "Surveillance activity provisions for certification bodies relating to the JFS-C Certification Program (C01P14R04)" below.

# Surveillance activity provisions for certification bodies relating to the JFS-C Certification Program<sup>1</sup>

# 1. Purpose

These provisions relate to the surveillance activities defined in 3.6.6 of the 3.6 Integrity Program section of the JFS-C Certification Program Document (hereinafter the "Program Document"), as well as the content described in 6.2.1 Auditor competence, 6.2.2 Auditor practical experience and training, 6.2.4 Audit performance, 6.3 Competence required for technical reviewers, and 6.4 Witness-assessors competence, with the purpose of enabling auditors, technical reviewers, and witness-assessors to conduct such audit activities as well as defining the details of activities for confirming audit-related information that are to be managed by the Food Safety Management Association (hereinafter "JFSM").

These provisions define the activities that JFSM, as the certification program owner (CPO), is to conduct to monitor that certification bodies are continually meeting the requirements of the Program Document.

# 2. Responsibilities

- The JFSM Secretary-General is responsible for overseeing the surveillance activities for certification bodies and dealing with any related nonconformities. The Secretariat assists the Secretary-General with these responsibilities.
- 2) The JFSM President is responsible for suspending the certification activities of certification bodies and canceling contracts between certification bodies and JFSM.

#### 3. Activities

As described in 3.6.8 of the Program Document, activities to manage various risk factors are required to enable certification bodies to continue to conduct proper certification activities. For risk factors, please refer to the Certification Program Document Annex 4 (Normative) Risk Factors of Operational Integrity in JFSM.

As the owner of the certification program, JFSM shall maintain the integrity and credibility of the Program by means of the following surveillance activities.

In addition, as described in Annex 4 of the Certification Program Document, the performance of certification bodies is monitored by means of the following surveillance activities. JFSM shall define key performance indicators (KPIs) among the activities by the certification body to maintain the integrity and credibility of the Certification Program and collaborate with the certification bodies on these KPIs as necessary.

Clause	Integrity Program and KPIs	Risk factors to be considered											
		a)	b)	c)	d)	e)	f)	g)	h)	i)	j)	k)	1)
3.6.3	Desktop review	Δ		$\triangle$	$\triangle$				$\triangle$			$\triangle$	
	(Monitoring of audit report)												
3.6.4	Office Audit	$\circ$	0	0	$\circ$		0	0	0	0	0	0	0
3.6.5	KPIs for certification body activities	0	0	0	0	0	0	0	0	0	0	0	0
3.6.6 1)	Evaluation of certification activity using the JFSM database	0		0		0	0	0	0	0	0		

<sup>\*○:</sup> Assessable risk factors

1) Checking audit information upon the entry in the JFSM database by certification body Information on certification activities for organizations (initial audit, periodic audit, recertification audit, etc.) is registered and updated by the certification body in the JFSM database, and based on this registered audit information, the JFSM Secretariat confirms whether the audit scopes registered for the auditors are consistent with the audit scopes required for the organization.

Regarding the audit duration, the built-in automatic calculation of the database disables to input audit duration that are less than the minimum man-days calculated by the number of HACCP surveys and the number of workers in the organization. Therefore, if audit duration appears on the screen of the database, it suggests that the audit duration satisfies the minimum audit duration. In case there would be deviations from the minimum audit duration, please refer to the details in 4).

## 2) Periodic office audit of certification body

As a general rule, the first periodic office audit is conducted within three months before or after reaching the third year after the contract is concluded with the certification body. Thereafter, office audits are repeated in the same cycle every three years. The method of conducting the periodic office audits and the method of dealing with any nonconformities found during periodic office audits are described in the following separate section. As a general rule, the expenses of the periodic office audits are borne by JFSM.

#### 3) Sampling review of audit report

After April every year, JFSM traces back the audit results entered in the JFSM database during the year from the beginning of April of the previous year to the end of March of the same year, and extracts the initial audits and recertification audits conducted during that year. Following the sampling rules shown in the table below, the number of audits to be sampled for each certification body is determined.

When selecting required number of audits, the audits reviewed by the desktop reviews and the office audit conducted by GFSI during the last year should be taken into consideration, since those audit instances allow to consider the review-results by GFSI on conformity with the GFSI

<sup>∆:</sup> Risk factors that may be assessable

benchmarking requirements as well

In addition, the method of conducting a review of the sampled audits is described in the following separate section.

# Audit sampling rules

Number of annual audits by certification body (initial audit, recertification audit)	Number of audits to be sampled
1 to 10	1
11 to 100	10% of the actual number (rounded down to the nearest whole number)
101 more	10

# 4) Annual performance analysis based on information input in the JFSM database.

JFSM conducts a performance analysis of the indicators listed below for each certification body based on the data registered in the JFSM database from January to December of the previous year. The indicators are set out in Annex 4 of the Certification Program document.

When there are any omissions or incorrect entries in the data, the certification body is requested to correct the data within two weeks as a general rule. This analysis is conducted for the previous year by the end of February every year, and is reported at meetings with the Board of Directors and certification bodies (such as liaison meetings and harmonization meetings).

In addition, if the analysis of the audit duration reveals that the audit duration clearly do not meet the requirements of the Certification Program Document, the certification body is requested to explain the reason in writing (including submissions by email) within two weeks, as a general rule. JFSM confirms the validity of the case on the basis of the reply and the evidence, and decides whether to approve or not.

#### 5) Audit experience by auditor in the previous year

Section 6.2.4 of the Certification Program Document sets the requirements for the audit experience of the auditors as the annual number of JFS-C audits and GFSI approved standards audits, and certification bodies are requested to report the actual number of audits for one year from January to December of the previous year during January and February of the year. Certification bodies will be notified of the reason for suspending the qualifications of auditors if any auditors do not meet the audit performance conditions described in 6.2.4 1) of the Certification Program Document.

#### 6) Auditor work experience by industrial sector

Sections 6.2.1 and 6.2.2 of the Certification Program Document state that industry-specific work experience is required as the competence of auditors. Annex 3 of the Certification Program Document defines the industrial sectors to which the work experience is applicable for each sector or sub-sector regarding an auditor's work experience before becoming an

auditor.

The industrial sectors for an auditor's work experience can be extended even after the person starts working as an auditor. When the number of certification audits of the relevant organization is three or more for each industrial sector, the scope can be expanded equivalent to the work experience in that industrial sector. It is necessary to manage information on industrial sectors that have been audited not only by this Certification Program but also by GFSI approved standards. Regarding the auditing experience for the one year from January to December of the previous year collected in 5) above, information on the industrial sectors of each audited organization is obtained, and the scope of the industrial sectors for each auditor is managed.

- 7) Interim office visit to certification bodies as required
  - JFSM may conduct an on-site investigation of a certification body's offices to collect information required for determining conformity in any of the following cases:
  - a) When the activities in accordance with the Provision for Handling of Appeals Concerning the JFS-C Cert. Program (C01P08) and the provision for the handling of complaints (M01P05) received by JFSM raise doubts about the integrity related to the above-mentioned risk factors in the activities of the certification body and an office visit is deemed necessary
  - b) When there is a significant change in the structure or personnel of the certification body,
  - c) When, as a result of database analysis and audit report monitoring by JFSM, there is a possibility that the certification activities of the certification body do not meet the requirements, or
  - d) When, for other reasons, it is determined that it is necessary to visit the office of the certification body directly and conduct an investigation.

As a general rule, the certification body is notified of the office visit in advance and in writing regarding the date and time of the investigation, the location of the investigation, the matters to be investigated, etc. However, if there is a risk that the proper execution of the investigation may be hindered by such advance details, the on-site investigation may be conducted by only giving an advance notice without setting a specific schedule.

#### 4. Office audit implementation procedures

1) Appointment of auditors

JFSM shall appoint the leader and members of the audit team that will perform the office audit. The leader and members must satisfy either of the following and have no vested interests in the certification body to be audited:

- a) Person who understands the JFS-C Certification Program Document and has experience in internal audits, second-party audits or third-party audits.
- b) Person whose competency is acknowledged as an auditor who performs the office audit by the Secretary-general according to a) above.
- 2) Audit planning and preparation

The audit team leader shall prepare an audit plan and an audit checklist according to the instructions from JFSM. The audit team leader shall send the audit checklist to the certification body no later than three months before the implementation date of the office audit, in principle. The certification body must identify the probative documents and records, complete the audit checklist and submit the list to JFSM no later than four weeks before the office audit date, in principle. JFSM shall check the list and may ask the certification body to submit the documents, and other necessary materials that it decides to check in advance.

JFSM shall submit the audit plan to the certification body no later than three weeks before the office audit date, in principle. The form of the audit plan is shown in Form 1.

The audit shall be performed in one day, in principle.

### 3) Audit perspectives

Audit shall be conducted based on the following points and perspectives:

- a) if the certification body implements the certification process in accordance with the requirements of the Certification Program Document;
- b) if the certification body evaluates competence of auditors, technical reviewers, and witness-assessors in accordance with the requirements of the Certification Program Document (in particular, whether the certification body properly evaluates new auditors and continuously evaluates existing auditors);
- c) if the personnel involved in certification activities are provided with regular training;
- d) if the certification system periodically has been reviewed and improved; and
- e) if the JFSM logo used in accordance with the provisions of JFSM.

# 4) Implementation of the audit

The audit team leader shall check the participants and explain the details of the audit and the required items to the certification body according to the audit plan before starting the audit. The certification body must secure the attendance of the respective managers (or persons in charge if absolutely necessary) of the JFS-C Certification Program, certification activities, JFSM database, and other related works during the office audit and be able to explain the certification activities, related management system, and work processes to the audit team. The audit team shall ask questions to the relevant certification body by using the audit checklist to collect objective evidence. If required, the team shall communicate with the certification body about the observed items (including nonconformity items) aiming for mutual understanding. The audit team shall judge the conformity status of the performance of the certification body for each item on the audit checklist based on the collected objective evidence. The conformity status shall be one of the following two categories:

- a) Nonconformity (not satisfying the requirements of the Certification Program Document)
- b) Conformity (satisfying the requirements of the Certification Program Document)

Based on the discussions with the audit team members, the audit team leader shall judge the audit result and prepare an audit report. Upon the review of the audit report by the person who has competency regarding the review of the audit reports, JFSM shall confirm the audit report

and submit it to the relevant certification body within two weeks after the office audit date, in principle.

# 5. Implementation procedures for review of audit reports

- 1) Each certification body is requested to submit the following documents for conducting the sampling review of the audit report determined as described in 3. 3) above.
  - a) A set of audit report, checklist, summary, summary of audit results, and documents related to corrections and corrective actions, etc.
  - b) Documents explaining the audit plan (if not included in the audit report)
  - c) Certificate
  - d) Documents explaining the rationale for calculating the audit durations
  - e) Documents explaining the competence of the auditors and reviewers (technical reviewers) who have conducted the audit
- 2) As a general rule, the certification body shall submit the above documents in 1) within two weeks after receiving a request from JFSM.
  - JFSM conducts monitoring based on the following items. When additional information is needed for monitoring, JFSM requests the certification body to identify the required information and provide additional information (including documentation). As a general rule, the certification body shall submit this information within two weeks after receiving a request from JFSM.
  - a) Check sheet and summary confirming that all requirements of this Certification Program have been reviewed
  - b) Has the conformity of each site been determined properly based on adequate evidence?
  - c) When nonconformities have been identified at each site, have the determinations been made based on adequate evidence?
  - d) Have the auditors properly verified the nonconformity corrections or corrective actions undertaken by the sites?
  - e) Is the basis for calculating the audit durations appropriate?
  - f) Other confirmation items related to the appropriateness of the certification audit
- 3) When, as a result of the monitoring, JFSM determines that the audit report, including related documents, does not meet the requirements of this Certification Program Document, JFSM requests an explanation for the reason to the audited certification body and request improvements as required. The audited certification body shall respond promptly and report the results of its response to JFSM.

# 6. Handling of nonconformities

- 1) Correction and corrective action
  - a) If any nonconformities are found as a result of each surveillance activity in three items (Section 5), JFSM shall agree the content of nonconformities with the certification body and ask the certification body to perform corrections and/or corrective actions. The certification body shall submit a corrective action plan to JFSM within 30 days, in principle, from the date of fore mentioned agreement.

- b) JFSM shall validate the above-mentioned corrective action plan
- c) The certification body must complete the corrective actions within 90 days, in principle, from the date of agreement mentioned in 1) above. However, if JFSM judges that it is difficult to complete the corrective actions within that period given the details of the nonconformities, JFSM may extend the period based on discussions with the certification body.
- d) JFSM shall, if required, perform the re-audit to confirm the completion of the corrective actions and their conformity and effectiveness.
- e) If it is found as a result of d) above that the certification body failed to correct or perform corrective actions against the relevant nonconformities, JFSM shall grant the certification body a postponement of another 30 days. After that, JFSM shall perform the re-re-audit if required to confirm the completion of the corrections and corrective actions and their conformity and effectiveness. However, this does not apply in the case where the certification body neglects the implementation of the corrections or corrective actions without reasonable grounds, and such neglect leads to the process in 2) Suspension of the certification activities mentioned below.
- f) When this re-re-audit is performed, the costs required for it (including traffic expenses and expenses equivalent to labor costs) shall be paid by the certification body.
- 2) Suspension of the certification activities
  - a) If one of the following applies, JFSM shall suspend the certification activities of the relevant certification body.
    - Despite the request for corrective actions described in 1) a) above, the relevant certification body neglected to perform corrections or corrective actions without reasonable grounds.
    - Even with the results of 1) e) above (including the re-re-audit), JFSM failed to confirm the completion of the corrective actions against the relevant nonconformities and their conformity or effectiveness.
  - b) JFSM shall announce the suspension of the certification activities of the certification body on JFSM's website, report it to the Board of directors, and notify certification body's accreditation body and GFSI of it.
  - c) The certification body must not perform the initial audit based on the JFS-C Certification Program Document during the suspension period of the certification activities. With regard to the work required to maintain or recertify valid certifications that have already become effective (including the surveillance audit and recertification audit), it might be suspended taking into consideration the significance of the relevant nonconformities.
  - d) JFSM shall perform the audit again to confirm that corrective actions were taken against the relevant nonconformities within 90 days after the suspension, in principle. When it is confirmed as a result of the audit that corrective actions were taken against the relevant nonconformities, JFSM may lift the suspension of the certification activities.
    - When it is required to visit the office of the certification body to perform this audit, the costs (including traffic expenses and expenses equivalent to labor costs) shall be paid by the

relevant certification body.

## 3) Termination of the contract

If one of the following applies to the certification body, JFSM may terminate the contract with the relevant certification body. JFSM shall announce the termination of the contract with the certification body on JFSM's website, report it to the Board of directors, and notify the certification body's accreditation body and GFSI.

- a) The certification body does not perform appropriate corrections and/or take corrective actions without reasonable grounds even when 90 days have passed after the suspension of the certification activities and it is not expected that the nonconformities will be corrected or their corrective actions will be taken.
- b) The accreditation body has canceled the accreditation of the certification body.
- c) A petition for bankruptcy, civil rehabilitation proceedings, corporate arrangement, corporate reorganization, special liquidation or other similar procedures was filed against the certification body, and it was revealed that the certification body cannot perform its activities.

Form: Audit plan	
Attn:	

# Periodic office audit plan for certification body (example)

[Month] [Day], [Year]

Food Safety Management Association						
Certification body						
Certification b	ody name					
Address						
Certification s	cope					
JFSM audit t	eam					
Audit team lea	ader					
Audit team m	ember					
Audit team m	ember					
Contact email	address	(Name of person in charge:				
Overview of office audit						
Audit date (planned) [Month] [Day], [Year]						
Audit criteria	Audit criteria JFS-C Certification Program Document Ver. XX					
Audit perspec	udit perspective • Management system of the certification body					
· Audit and certification performance						
Auditor competence, other items						
(Refer to the audit checklist for specific audit items.)			it items.)			
Audit time schedule						
Estimated	Audit details		Persons in charge			

Audit time Schedule					
Estimated time	Audit details	Persons in charge			
09:30-10:00	Opening meeting	CB management department  JFS-C staff in charge			
10:00-12:00	Use of quality management system (QMS), CB business staff accreditation/license, logo				
	Contractual relationship between certification body and organization				
	Audit process, certification process				
12:00-13:00	Lunch break				
13:00-16:30	Communication with the organization and JFSM Training of auditors and other personnel Auditor competence and registration	CB business staff			
16:30-17:00	JFSM audit team meeting	JFSM audit team only			
17:00-17:30	Closing meeting	CB management department			

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#### Note:

- We request that the responsible person of the JFS-C Certification Program, certification work, JFSM database, and other related work (or an administrator if unavailable) participates in the office audit. In addition, we request that the responsible parson of the overall JFS-C business also participates in the opening and closing meetings.
- Together with the review of documents and records during the office audit, interviews on business processes will also be conducted with the staff in charge of each related aspect of the business.
- · Use the email address for the JFSM audit team to contact us for inquiries regarding office audits.
- <sup>1</sup> Disclaimer: This translated document is provided for information purposes only. In the event of a difference of interpretation or a dispute, the original Japanese version of this document is binding.

Version	Issue Date	Revision History
R00	July 5, 2018	First edition
R01	April 23, 2019	Revised version conforms to JFS-C Ver2.3
R02	October 28, 2019	Corrective Action to GFSI NC
R03	November 11, 2020	Revised version conforms to BR2020.1
R04	August 23, 2021	Revised version conforms to Program Document ver.3.1