

JFS-A/B/C Standards <Manufacturing> [Interpretations]

JFS-A Standard Ver. 1.1

JFS-B Standard Ver. 1.1

JFS-C Standard Ver. 2.2

Japan Food Safety Management Association

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Characters in brackets indicate the standard.

Introduction

This document is prepared by Japan Food Safety Association (JFSM) to support JFS series standard users, together with another supportive document, the "Guidelines", to get better understanding of the standards, through providing the explanation of words and clarifying the range of the requirements. This document is intended to be referred when users, or organizations introducing or operating systems based on JFS Standards, have any questions or feel unsure of the meaning or interpretation of the requirements of the standards.

The Guidelines give examples of activities and measures in order to comply with the requirements of the standards, which would be useful for the users.

JFS-A Standard (hereinafter referred to as "A Standard") and JFS-B Standard ("B Standard") put an importance on the easiness of understanding, especially for newly introducing organizations, by using simple words. A Standard covers all the requirements of GFSI Global Markets Programme (manufacturing) 2nd Edition Basic Level whereas B Standard covers those of Intermediate Level.

JFS-C Standard (hereinafter referred to as "C Standard") covers all the requirements of GFSI Benchmarking Requirements and the intention of each requirement corresponds the GFSI Benchmarking Requirements in spite of the expression is more natural in Japanese.

Words and explanations may differ between A/B Standard and C Standard, to be suitable for the intended organization, even in a case that the meaning of the requirements are identical.

Requirements for these standards are described concisely in order for the organization to grasp the whole relational structure of requirements more easily. In order to allow the organization to develop a system best for the organization by making every part of the system suitable to the organization, and the system not to become too complicated or excessive burden. The organization decides the details complying the requirements of each standard and build up into a system. To do so, the organization is to introduce management and control that comply with the requirements under consideration of the type and size of the organization and its processes, or organizational culture.

In order to develop a management system which works effectively, it is useful to consider the requirements not separately but to take correlations and interactions of all the requirements into account.

Interpretation

I Food Safety Management System (FSM)

FSM 1 Food Safety Management System General Requirements

[C standard]

The organization shall document, implement and maintain the elements of the organization's Food Safety Management Systems. Additionally, the organization shall continuously improve the organization's Food Safety Management Systems properly adapting to changes in the surrounding social environment.

The food safety management systems shall:

- a) clarify the scope of application of the food safety management systems,
- b) comply with laws and regulations related to food safety in the country of manufacture and the country of destination.
- c) identify the processes needed for the food safety management systems,
- d) determine the sequence and interaction of these processes,
- e) determine the criteria and methods required to ensure the effective operation and control of these processes,
- f) continue and maintain the operation and monitoring of these processes, ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- g) measure, monitor and analyze these processes and implement actions necessary to achieve planned results and continuous improvement.
- h) include a procedure for verification of the food safety management system to confirm that the system continues to be effective.

Updating of a food safety management system shall be planned and conducted. On updating, considerations shall be given to maintain the integrity of the food safety management system.

FSM 1 requires the organization to apply the requirements to the activities and operations, make up into a management system, follow the system, improve the system and enhance as the consequence the organization's food safety. FSM 1 appears only in C Standard. As A/B Standard focus on activities based on individual requirement, FSM 1 is not required.

In developing a management system, to clarify the scope of application is critical. The scope of application may be a part or all of organization that handle food, however, in principle, a series of activities like designing and development (of product), material procurement, processing, packaging, storage, release and transport needs to be fully included. For instance, it is possible to develop a management system for one out of two food production lines, if all the activities from designing and development through transport are included. It is not possible, however, to develop a system that covers only the processes of production and packaging, and exclude the rest of the processes from the scope of application. In case part of the activities are out of the organization's control, for instance, producing food designed and developed by a third party or product delivery arranged by customer, such activities are able to be excluded from the scope

of application, although the food safety in the excluded processes is necessary to be ensured.

"Processes" in the requirements mean parts of activities conducted by the organization with some function, such as manufacturing, maintenance and internal audit. FSM 1 requires that the way of process control is planned with reasonable basis and implemented. "Sequence and interaction of these processes" mean not only the flow of food and/or information but also relationship between processes such as management, control, monitoring, and support. Clarifying the interaction between processes helps to make food safety activities more effective.

"Updating of a food safety management system shall be planned and conducted" means that modification of the management system which is invoked based on the result of management review, internal audit or response to non-conformity or complaints, or following the change in the activities of the organizational or social changes is to follow the predetermined procedure.

FSM 2 Food Safety Policy

[A/B standards]

Top management shall have a clear, concise, documented food safety policy which states how the organization ensures safety of the product.

[C standard]

Top management shall have a clear, concise and documented food safety policy statement and objectives specifying the extent of the organization's commitment to meet the safety needs of its products.

Top management shall ensure the organization to establish measurable objectives consistent with the organization's food safety policy, formulate plans to achieve the objectives, monitor the progresses against the objectives, and to update the objectives as necessary.

A/B Standard require that the top management has clearly stated food safety policy.

"Top management" means a highest executive of an organization, and usually a president or a plant manager comes under this title. If the person is responsible for and has authority over comprehensive food safety management, top management does not necessarily have to be in a highest position of the organization. Top management can be a group of persons.

"Food safety policy", which states "to what extent the organization engages in product safety", means a policy that clarifies the range of safety management activities. "Policy" includes organization's attitude, philosophy, and/or management policy which promote food safety or provision of safe food. This food safety policy needs to be not only clearly stated, but also understood by all workers. For instance, to teach the policy on every workers' training, to notice on places where workers often see, or to recite at morning gathering are such examples.

C Standard requires "objectives" in the first sentence adding to the requirement of A/B Standard.

C Standard requires the top management to set "measurable objectives" that are consistent with food safety policy and formulate plans to achieve the objectives, monitor the progress against the objectives and update objectives as necessary in the second sentence. The top management is required to develop a system that enables PDCA cycle to implement to achieve the objectives. Preferably, "measurable objectives" are objectives with specific numerical target like the number of non-conformities. In case the objectives are difficult to quantify, to evaluate whether or to what extent the objectives are achieved is necessary.

"Update" of the objectives includes the modification of the objectives in case the original objectives become improper due to the change in causes out of the organization like changes in business environment.

FSM 3 Food Safety Manual

[C standard]

The organization shall have a documented Food Safety Manual having a scope appropriate for the range of business activities to be covered, including documented procedures or specific references to them and describing the interaction of the related process steps.

FSM 3 requires the organization to prepare a food safety manual that can be referred when necessary by workers relevant to food safety. "Documented procedures or specific reference to them" mean either necessary information contained in the manual or described in other way to access to the document, need to be specified in the manual. Regardless of the order of clauses in the Standard, manual and other documents need to cover all the requirements. "Interaction of the related process steps" mean the way processes relate and/or affect each other through the function like management, control, monitor or support. Processes may not be effective under operation if the relations to other processes are not considered, and the order of processes and flow of food and information are to be taken into account.

FSM 4 Top Management Responsibility

[A/B standards]

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.

[C standard]

Top management shall establish a clear organizational structure which unambiguously defines and documents the job functions, responsibilities, directing and reporting structure and information sharing of at least the workers whose activities affect food safety.

Top management shall appoint personnel responsible for the operation of the organization's food safety management system.

Organization using A/B Standard preferably has a chart of organizational structure, however, in small

sized organization, communication network for direction, report and having conversations may be considered to comply the requirement of FSM 4 if the network is recognized by all workers.

"Information sharing" in C Standard includes the provision of the information which may affect food safety to persons or department that needs such information. Changes that may cause modification to HACCP plan such as introduction of new products or changes in manufacturing line, in particular, are to be surely reported to HACCP team.

Person(s) with responsibility and authority on the operation of organization's food safety management system is to be appointed. The responsible person(s) may be a leader of HACCP team, or other person may be in charge. (For HACCP team, see HACCP Step 1.) In case HACCP team leader differs from the responsible person(s), HACCP team leader comes under the control of the responsible person(s). The responsible person(s) can be a group of persons.

FSM 5 Top Management Commitment

[A/B standards]

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.

[C standard]

Top management shall provide evidence of the commitment to establish, implement, maintain and improve the food safety management system.

A/B Standard requires the top management to prepare the document that describes assignment and responsibility of workers relevant to food safety, and make all workers fully known. The top management is required to demonstrate that all workers are informed about the assignment and responsibility with evidence such as documents or images. "Evidence" is retained for audits.

C Standard requires the top management to involve in wider range of activities than B Standard.

"Commitment" is an engagement with responsibility, and to "provide evidence of commitment" is to adopt proper policy, implement management review in FSM 6, provide resources in a timely manner in FSM 7, involve in other activities when necessary to give positive effect on the organization, as a result, promote organization's food safety effectively, and to achieve the objectives.

FSM 6 Management Review

[C standard]

Top management shall review the verification of the food safety management system and HACCP Plan, at planned intervals, to ensure the continuing conformity, suitability and effectiveness.

The HACCP Plan shall also be reviewed in the event of any change that impacts food safety. Such a review shall evaluate the need for changes to the entire food safety management system, including the

food safety policy and food safety objectives.

"Management Review" means an act that top management monitors and evaluates the appropriateness, validity and effectiveness of the activities that are planned to achieve the objectives, and points out the direction of improvement. The review is carried out comprehensively considering information and including the information on non-conformity and corrective action, results of process monitor measurement, audit and supplier management, the organization's surrounding environment, result of analysis in FSM 27, and improvement or update in FSM 28. The top management is required to show management policy including necessity of resources and changes in the system.

Review of HACCP Plan, may be done by HACCP team. However, the result of the review is to be reported to the top management. Review of HACCP plan means to check and update the HACCP plan based on introduction of new product, change in manufacturing line, information about incident in other organization or regulatory revision. Periodical review is also possible.

FSM 7 Resource Management

[A/B standards]

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.

[C standard]

Top management shall determine and provide, in a timely manner, the qualified resources (including suitably qualified personnel) needed to implement, maintain and improve the food safety management system.

The requirement of A, B and C Standards are basically the same.

The Standard requires the top management to recognize the importance of ensuring food safety and to provide necessary resources in a timely manner. "Human resources, goods and capital" in A/B Standard are listed as typical examples of resources, and other resources such as information and intellectual property are also included.

"In a timely manner" is simply important in this requirement. Timing is sometimes crucial in provision of resources, and in order to make speedy decision, FSM 7 requires the top management to provide.

FSM 8 Record Control / Document and Record Control

[A standard] Record Control

Records determined necessary to demonstrate implementation of food safety management shall be kept accessible.

[B standard] 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.

[C standard] Document and Record Control

The organization shall prepare documents and keep records to demonstrate that the organization's operations and activities comply with the requirements of this Standard.

The organization shall have a written procedure to control and maintain the documents and records and make the documents and records readily accessible when needed.

In order to ensure effective operations and control of food safety processes and management, the retention period of the documents and records shall be set complying with, if any, the regulatory and customer requirements.

"Document and record control" is an important element in management system. A, B and C Standards require different levels of control since the assumed management levels of the Standard users are not the same.

"Document" includes information and medium containing information (including not only letters written on paper but also drawing, chart, image, sound and electronic medium containing information), for instance, record, written specification, written procedure, written flow, report, standard. "Record" means document that describes the achieved result and provides evidence of the organization's activities.

A Standard focuses on management and control in work place, therefore, "record determined necessary to demonstrate implementation of food safety management" is only required to be kept and retained.

"Record determined necessary to demonstrate implementation of food safety management" in A/B Standards has purpose to demonstrate proper management to the second and third parties as well as to utilize for management and control within the organization. What to be recorded is decided by the organization.

"Retained properly" means that record is not only kept for a given period, but also accessible when needed. To "retain" includes the meaning of avoiding degradation and loss of document including record. Retention time is decided by the organization itself considering the period of products on shelf and expiry date.

Band C Standards require not only record control but also document control.

Record is a type of document. The way of controlling document depends on the type of documents, therefore, document control may be decided for each document group not comprehensively.

Requirements on document control procedure in B and C Standards are the same.

FSM 9 Specification Control of Purchased or Provided Items and Services

[C standard]

For all purchased or provided inputs and services (including raw materials and ingredients, utilities and services (e.g. electricity, water, transportation, maintenance)) that have an effect on the safety of final product, the organization shall ensure that documented specifications are prepared, maintained, securely retained and readily accessible when needed.

FSM 9 requires the specification that contains necessary information to ensure food safety in the organization. The documented specification can be the one provided from outside the organization or the one prepared by the organization. Since HACCP Step 2 and 3 require information about the product, it is recommended to consider the requirements in those clauses together.

FSM 10 Procedures and Instructions

[B standard]

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.

[C standard]

The organization shall design the products and production processes taking into account all relevant safety requirements. The organization shall establish, implement and maintain documented procedures and instructions for all processes and operations having an effect on food safety.

Requirements of B and C Standards are basically the same, however, B Standard specifies the way to communicate; B Standard requires to visualize the procedure to relevant workers. The procedures are to be developed considering the requirements of GMP and the result of HACCP study.

Procedures developed are to be documented.

"Relevant safety requirements" required to be considered in product design include hazards which is known to be associated with the product, hazards which is potentially created, increased or introduced during process like manufacturing, storage or transport, requirements of relevant regulations, and requirement which is set in house considering past incident on similar food. Since the safety requirements are also referred in HACCP Step 2, sorting out the requirements considering HACCP Step 2 is helpful. Similar level of attention is to be paid in changing product design, therefore, preparing a procedure for change is recommended.

FSM 11 Internal Audit

[C standard]

The organization shall plan and implement internal audits for the activities covering all the scope of the food safety management system, including the HACCP Plan, Food Defense Plan and Food Fraud

Prevention Plan.

The results of internal audits and corrective actions shall be recorded.

The organization shall specify the competence required for internal auditors and provide training.

FSM 11 requires self-check of activities within the organization through internal audit. FSM 11 also requires corrective action to be taken, in case the result of internal audit requires so. "Competence of internal auditor" is demonstrated by auditor's knowledge, skill, work experience and/or audit experience. As for competence, since there is no applicable criteria for the auditors, each organization needs to make its own criteria to facilitate internal audit and train internal auditors to meet the required criteria. Internal audit includes confirmation of whether the organization's management system complies with the requirements of this Standard and other requirements such as customer and regulatory requirements, and whether the organization's activities follow the procedures defined in the management system. Therefore, internal auditors need to understand the requirements of the Standard and the organization's management system.

Result of internal audit need to be recorded. FSM 12, FSM 13 and FSM 28 work well to improve or correct the problem found through the audit.

FSM 12 Nonconformity Control

[A/B standards]

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.

[C standard]

The organization shall establish effective procedures to ensure that any product, which does not conform to food safety requirements, is clearly identified, controlled, discarded, reworked, reprocessed and/or corrected to prevent unintended use or delivery.

These procedures shall be documented securely retained and readily accessible when needed.

FSM 12 is intended to apply for all the foods and food-contact materials which have potential impact on food safety and A/B Standard specifies that raw materials and ingredients, partially processed products, and other materials mentioned are covered.

"Partially processed products" mean foods which are not final products but can be sold as products. "Work in progress" means a food which is being processed and cannot be sold as a product. "Products being reprocessed" mean foods which does not conform the specification and are to be processed again to be products. "Reworks" mean foods which is to receive some correction or modification to be products conforming specification.

Nonconformity control is crucial. Although A/B Standard does not require documented procedure, to prepare documented procedure is recommended unless persons involved in nonconformity control surely

comprehend the procedure.

Requirements of C Standard is basically the same as the one of A/B Standard. C Standard additionally requires the documented procedure, and the document is kept always accessible. "Effective procedures" means procedures that can be put into practice and give intended result within the organization.

In case nonconformity is pointed out and corrective action need to be taken, A, B and C Standards require investigation of root cause and taking corrective action following FSM 13.

FSM 13 Corrective Action

[A/B standards]

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.

[C standard]

The organization shall establish procedures for the determination and implementation of corrective action in the event of any nonconformities relating to food safety arising.

In case of deviation or violation, the organization shall identify the root cause, take measures to prevent recurrence, and review the effectiveness for the series of corrective actions.

A/B standards require corrective action to be documented and implemented. The term "corrective action" is used in standards such as ISO 9001, however, concept and target of corrective action are not generally known, therefore, details are given in the parentheses.

Corrective action is required to be documented.

Requirements in A, B and C Standard are basically the same.

"Deviation" and "violation" have basically the same meaning as "nonconformity". The first sentence requires the organization to have a procedure whereas the second sentence requires steps necessary in the procedure. To "confirm the effectiveness" means to confirm that measures to prevent reoccurrence are as intended. The way of confirmation when corrective action is taken is recommended to be planned in advance, at the time that for instance corrective action is taken.

FSM 14 Product Release

[A/B standards]

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.

[C standard]

The organization shall prepare and implement appropriate product release procedures.

FSM 14 requires preparing proper procedure of product release such as checking if the product conforms the specification.

In A/B standard, specification is required to produce food which conforms food safety requirements, statutory and regulatory requirements and customer requirements.

C Standard does not clearly require a specification in FSM 14, however, specifications in HACCP Step 2 have similar meaning to the specifications in A/B Standard and such specifications can be used for release process.

Product release procedure is supposed to have the way to check product safety and to check by persons with authorities over product release.

FSM 15 Purchasing

[B standard]

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.

[C standard]

The organization shall control purchasing processes to ensure that all externally sourced raw materials, ingredients and services (including packaging materials) which have an effect on food safety, conform to requirements.

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.

First sentence of B Standard has basically the same meaning as the one in C Standard and requires a procedure to verify that purchased materials and services complies the specifications developed by the organization.

Second sentence of B Standard requires management of outsourced processes as part of services whereas C Standard has the requirement of "outsourcing" in FSM 17.

While FSM 15 requires management of materials and services, FSM 16 requires evaluation of materials and service providers.

In case of emergency like a natural disaster, purchasing from a supplier that the organization has not had

any business before is allowed after evaluating the facility and verifying that the products complies the required specifications and food safety requirements.

FSM 16 Supplier Performance

[B/C Standards]

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 and investigations, and follow-up actions shall be recorded.

"Supplier" includes subcontractors of processes as well as provider of raw materials and ingredients, packaging materials, and utility like water and electricity.

FSM 16 requires preparation and implementation of procedures to evaluate existing and new suppliers, and to record the evaluation results.

"Follow up" means verification of implementation and effectiveness of improvement made when required through the result of the evaluation.

FSM 17 Outsourcing

[C standard]

The organization shall, where the organization chooses to outsource any process that may affect food safety, shall ensure control over such processes.

Control of such outsourced processes shall be identified, documented and monitored as a part of food safety management system.

In case of emergency, such as a natural disaster, if outsourcing to non-approved service provider, the organization shall assess the non-approved service provider facility, as necessary, and verify the conformity of the products to the given specification in order to ensure food safety.

In terms of outsourcing, FSM 17 requires the organization to consider outsourced process as a part of food safety management. Therefore, the organization is required to apply the management to outsourced process, as if the process were carried out by the organization, and monitor, evaluate and manage such process not to cause risk on food safety to the products.

Outsourced process is to be drawn in the Flow Diagram in HACCP Step 4, if applicable, and control measures for the process are determined through hazard analysis in HACCP Step 6. In addition, supplier evaluation is to be conducted following FSM 16.

Emergency response is the same as mentioned in FSM 15.

FSM 18 Complaint Handling

[B standard]

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.

[C standard]

The organization shall establish, implement and maintain an effective system for the management of complaints and complaint data to properly control and correct defects in food safety activities.

FSM 18 in B Standard is basically the same as the one in C standard. This clause requires development, implementation and maintenance of the system of "Complaint Handling". This complaint handling is intended not only to handle customers and consumers complaints but also to make use of the complaint data for improvement of food safety. In addition to proper management of food safety issue arising out of complaints, FSM 18 requires complaint data accumulation and complaint trend analysis to find out problems in the management system and improve the system. Complaint data required in this clause includes minute problem reports and constructive suggestions as well as complaints. FSM 12 and/or 13 may be applied in handling complaints.

FSM 19 Utilization of Suggestions for Improvement from Workers

[C standard]

The organization shall establish and implement a system to properly utilize suggestions from workers to improve food safety.

C Standard requires a system to improve efficiently based on a sort of Japanese KAIZEN approach. This way of improvement approach has been highly valued in the Japanese industries and is built in to food safety management system. It is one of the core features of this standard.

Suggestions for improvement from workers are not to be implemented without any evaluation as the suggestion may cause negative side effect on food safety. Such suggestions need to be evaluated and validated by the expert(s) before introduction.

KAIZEN, a system developed by Toyota Motor Corporation for productivity improvement, is globally recognized. Requirement in FSM 19 is not fully the same as KAIZEN, however, the style of workplace originated improvement is similar. This way of approach has been used by a number of Japanese corporations so that the workers at workplace deal with the situation voluntarily and properly.

Through the introduction of the workplace originated improvement, the workers are able to enlighten themselves and promote motivation, and it is effective to bring the cycle of improvement on food safety.

To encourage workers to give suggestions is a key to activate this approach.

FSM 20 Serious Incident Management

[A/B Standard]

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.

[C Standard]

The organization shall establish, implement and maintain an effective incident management procedure. The incident management procedure shall be regularly tested for all products it supplies and cover planning for product withdrawal and product recall as required.

The effectiveness of the incident management procedure shall be verified at least once a year, and the results shall be recorded.

The first sentence of A/B Standard has the same meaning as in C Standard.

"Incident" in this clause can be defined as "having provided products with food safety hazards", however, the organization needs to define the range of the "incident". Consumer complaint may turn to be an "incident" depending on the situation.

The difference between product "withdrawal" and "recall" in this clause is:

"Withdrawal" is applied to products that have been already delivered out of the organization, however not yet sold to the consumers, or products that are within the step of distribution. "Recall" is used for the products that have already been sold or provided to the consumers.

"Tested" in A/B Standard has the similar meaning to the word "verified" in C Standard.

Mock recall (or practice recall) based on the manual or incident management procedure is required regularly since there is often a case that the recall process does not work effectively nor work as intended even the organization has a written procedure.

Verification of the recall procedure required in C Standard can be carried out through not only a practical incident training but also in review of response against the actual incident or recall.

FSM 21 Control of Measuring and Monitoring Devices

[A standard]

The measuring and monitoring equipment and devices to ensure food safety shall be calibrated with statutorily required methods or equivalent methods.

[B/C standard]

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.

FSM 21 requires calibration of measuring and monitoring equipment and devices used to ensure food safety. Calibration is performed to verify the accuracy of devices under test with comparing the measurement value of the devices to the ones delivered by standard with known accuracy. Calibration method is to be either regulatory method or the equivalent. "Equivalent" method in A Standard and "equivalent standard" in B/C Standards are mentioned in addition as some devices are not covered by regulations. In case there is no standard, the organization needs to demonstrate the effectivity of the method of calibration to achieve the required accuracy.

FSM 21 is applied for the measuring and monitoring devices which has an impact on food safety.

B and C Standards require calibration of devices, and in advance the following:

- a) to identify the method for parameter measurement that is essential to ensure food safety;
- b) to specify necessary measuring and monitoring devices.

Specifying devices is assumed to be required in A Standard, therefore, A, B and C Standards are basically the same. In B and C Standards, requirement of this clause is related to the one in HACCP Step 9.

FSM 22 Food Defense

[B standard]

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.

[C standard]

The organization shall establish a documented assessment procedure to identify threats of food defense and prioritize food defense measures, implement and record the evaluation result.

The organization shall develop a documented plan that specifies the measures the organization implements to mitigate the identified threats of food defense.

The plan (Food Defense Plan) shall cover GMP and shall be incorporated into the food safety management system.

FSM 22 in B Standard has basically the same meaning as the one in C Standard.

"Food defense" means measures to protect the organization from intentional attack on food supply chain for the purpose of ruining the reputation of product or manufacturer, harming to consumers' health, or bringing social disorder. Intentional attack made by persons both in and out of the organization need to be taken into account.

To "identify threats of food defense and prioritize food defense measures" in C Standard means to prepare the procedure to identify the probability of intentional food contamination, to evaluate the risks identified, to

record the result of risk assessment, to specify the measures to the response against each risk, and to prioritize the introduction of defense measures based on the vulnerability.

Based on the priority determined, the organization is required to plan and implement mitigation measures.

With respect to the measures of food defense, looking into past incidents is helpful to identify mitigation measures against the threats specified.

Impact of risk depends on the social environment of the country or region where the site locates, therefore, risk assessment of the site needs to be suitable to the country or region.

Since food defense measures have some relationship to several GMP requirements, such relations and interactions need to be taken into account on developing GMP and food defense system. Furthermore, food defense needs to be a part of food safety management system.

FSM 23 Product Labeling

[B standard]

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.

[C standard]

The organization shall ensure that all product bears or is accompanied by information to enable the safe handling, display, storage, preparation and use of the product including allergens in the food supply chain or by consumer. The finished product shall be labelled according to the applicable food regulations in the intended country of sale.

Procedures to ensure the correct information on the product shall be established and implemented.

FSM 23 in B and C Standards are basically the same. It is important to comply with regulation of country or region which products are targeted. FSM 23 requires not only to comply with such regulation but also a procedure to avoid mislabeling. In addition, product description required in HACCP Step 2 also includes product labeling.

FSM 24 Traceability

[A standard]

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 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.

[B standard]

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.

[C standard]

The organization shall establish, implement and maintain appropriate procedures and systems to ensure:

- a) identification of any outsourced raw materials and ingredients (including packaging materials), products, services and outsourced processes;
- b) product identification that includes, as a minimum, the name and location of the producer;
- c) identification of batches, partially processed products, work in progress, products being reprocessed, reworks, finished products, and packaging materials throughout the production process;
- d) records of purchaser and delivery destination for all products supplied.

The procedures and systems shall be verified at least once a year, and the results shall be recorded.

"Purchaser" in FSM 24 basically means a purchaser that is one step downstream of food chain and does not necessarily mean the food chain down to the consumer. "Purchaser" includes, for instance, wholesaler or retailer which sells delivered products. The products are not always delivered directly to purchasers and

sometimes delivered to warehouse designated by the purchaser. In order to respond quickly when food safety incident occurs, FSM 24 requires recognizing not only present owner of the product but also "delivery destination" where products are actually held.

In principle with respect to purchased materials and ingredients, purchaser at least one step upstream in food chain needs to be traceable.

"Partially processed products", "work in progress", "products being reprocessed", and "reworks" are the same as the explanation mentioned in FSM12.

While A Standard requires development of traceability system, B and C Standards require verification of the system, such as trace test, at least once a year to confirm the effectiveness.

"Product identification" in b) is only in C Standard. "Producer" means the organization and it is intended to ensure that consumer or customer is able to contact immediately with the organization when a problem is found. "Product identification" means labeling or accompanied document containing information on producer and others.

FSM 25 Analysis of Input Materials

[B standard]

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.

[C standard]

The organization shall establish and implement a system to ensure analysis of input raw materials and ingredients (including water) that have an effect on food safety. The inspection shall be conducted in compliance with ISO 17025 or equivalent standards.

B and C Standards require analysis of raw materials and ingredients, including water and ice, which affect food safety. Analysis for quality control may be excluded in this clause. "The process environments and foods which potentially have effects on food safety" in B Standard includes analysis of not only on raw materials and ingredients but also on manufacturing processes and products.

ISO 17025 is a standard which defines requirements for testing and calibration laboratories. Accreditation body accredits the testing and calibration laboratories based on ISO 17025. B Standard recommends organization to comply with ISO 17025 for analysis which have impact on food safety. C Standard requires organization to conduct analysis which comply with ISO 17025 or the equivalent. It does not mean ISO 17025 certification is necessary. The analysis is not necessarily certified if the compliance to the standard is confirmed. The analysis can be conducted by either in-house laboratory or outsourced laboratory. Analysis which is designated by regulatory body and carried out by the public institute can be considered as equivalent to the ISO 17025 certified analysis.

In case the analysis is conducted by the in-house laboratory, at least the followings are required:

- a) to use official method or the equivalent;

- b) to have documented procedures;
- c) to be conducted by the trained laboratory staff;
- d) to use calibrated devices;
- e) to ensure traceability of the results (e.g. proficiency test).

FSM 26 Food Fraud Prevention

[C standard]

The organization shall establish a documented assessment procedure to identify the food fraud vulnerability such as potential falsification of product record, mislabeling and intentional dilution of product, and to prioritize food fraud mitigation measures, implement the procedure, and record the result.

The organization shall develop a documented plan that specifies the measures the organization implements to mitigate the identified threats of food fraud.

The plan (Food Fraud Mitigation Plan) shall cover the GMP and shall be incorporated into the food safety management system.

"Food fraud" basically means economically motivated intentional act for cost reduction or economical gain. Manipulation of origin or shelf life, substitution or dilution with cheaper ingredient are examples of food fraud. FSM 26 mainly covers food fraud which has impact on food safety.

The way to "identify food fraud vulnerability such as potential falsification" is to prepare a procedure to identify possible food fraud act referring to the past fraud cases, evaluate the vulnerability (magnitude of the impact and probability), prioritize the mitigation measures, and document all steps in the procedures.

The target of food fraud mitigation measures are to include falsification of raw materials and ingredients, fraudulent activity in manufacturing process, and falsification of delivered products (including the resale of disposed defective products as food).

Considering the result of the evaluation, food fraud mitigation needs to be planned and introduced based on the vulnerability or priority. To design prevention measures, it is helpful to refer to the past food fraud incidents.

FSM 27 Verification Activities and Results Analysis

[C standard]

The organization shall verify the implementation status of FSM, GMP and HACCP, and analyze the results of verification activities. Results of analysis and follow up activities shall be recorded in proper manner. These results shall be reported to top management at the management review.

To "verify" means to confirm if the activity complies with the requirement, and if the planned activity is carried out effectively.

In order to ensure the verification process, to prepare verification plan, including purpose, method, frequency and responsibility, is essential.

The activities concerning FSM, HACCP and GMP are to be included as the target of the verification plan.

To "analyze the result of verification activities" means to systematically evaluate the result of each

verification result and give the information as follows:

- a) if the overall performance achieves the intended objectives;
- b) if the management system needs update or improvement;
- c) if there is no trend which has negative impact on food safety such as occurrence of the series of nonconformities.

"Follow up activities" mean the activities to confirm the effectiveness of improvement, such as correction and corrective actions, triggered by verification result and/or verification analysis result.

The results of analysis of verification and follow up activities need to be recorded and reported to top management at the management review.

FSM 28 Food Safety Management System Updating

[C standard]

Top management shall ensure continual update of the organization's food safety management system.

In order to achieve the continual update, the organization shall review the organization's food safety management system at planned intervals, and record the result.

The organization shall report the system updating activities to top management at the management review.

FSM 28 works together with FSM 6, 11 and 27, and requires to utilize the result of analysis in FSM 27 (corresponds to the part of "Check" in PDCA cycle) to promote continual improvement.

FSM 29 Allergen Management

[C standard]

The organization shall develop and implement an allergen management plan for all food manufacturing facilities.

The plan shall include a risk assessment of allergen cross-contamination and control measures to implement to reduce or eliminate the risk of cross-contamination.

All finished products intentionally or potentially containing allergenic materials shall be labelled according to the allergen labelling regulations in the country of manufacture and the country of destination.

FSM 29 requires identifying allergen that needs to be controlled and making a plan including procedures to control identified allergen.

Control measures to reduce or eliminate cross-contamination risks including, for instance, separate manufacturing line, thorough cleanup on switching products, way of storage appropriate for each product, the order of production starting from fewer to more allergens, equipment dedicated to each allergen status, ensuring identification and control of partially processed products, work in progress and recalled products and wearing dedicated work clothes. As allergen may cause serious health damage, it is required to conduct risk analysis, develop a procedure to control the risk and implement management procedures

considering laws and regulations of countries involved.

This requirement does not appear in A/B Standard, however, the organization is to consider allergens as hazard and develop a way of control in GMP 8 and GMP 9 in A Standard, HACCP, GMP 8 and GMP 9 in B Standard.

FSM 30 Environmental Monitoring for Food Manufacturing

[C standard]

The organization shall develop and implement a risk-based environmental monitoring program which includes all high-care and high-risk areas.

To identify and introduce control measures in manufacturing process, HACCP Steps 6 and 7 (Principles 1 and 2) play important role. FSM 30 requires to specify risk of contamination from processing environment rather than in process itself, and to develop monitoring program including verification. "High-care and high-risk areas" includes work places which manufacture product consumed without heating, and work places which handle unpackaged sterilized product. An example of the environmental monitoring is a test for environmental pathogens in such work places.

II Hazard Analysis and Critical Control Point (HACCP)

- Requirements of HACCP are based on the annex to "General principle of food hygiene", or so called Codex HACCP.
- As for the detail and interpretation of requirements of HACCP in this Standard, Codex HACCP and other reference documents are published and are helpful.
- A Standard is designed for the entities which have not been familiar with or have not introduced food safety management system yet. It is important to arrange the information on product and process in order to ensure food safety, and the arrangement corresponds to HACCP Steps 1 to 5. HACCP Steps 1 to 5 are also added in the requirements of A Standard to prepare the introduction of HACCP system in future.
- Guidelines for A, B and C Standards provide viewpoints and specific examples of HACCP 12 Steps.

Reference: Codex Alimentarius Commission, "General principle of food hygiene" CAC/RCP 1-1969, Rev. 4 (2003).

HACCP Step 1 HACCP Team Assembly

[A standard] HACCP Team Assembly (Food Safety Team)

A HACCP team (food safety team) shall be assembled by competent staff.

[B/C standards] HACCP Team Assembly

A HACCP team shall be assembled with competent staff.

HACCP Step 2 Product Description

[A standard]

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.

[B/C standards]

Product specifications shall be 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.

HACCP Step 3 Identification of Intended Use

[A/B/C standards]

Intended use of the product and target consumers shall be clearly described in a written document.

HACCP Step 4 Construction of Flow Diagram

[A/B/C standards]

The flow diagram that covers all steps in the operation shall be constructed.

HACCP Step 5 On-site Confirmation of Flow Diagram

[A/B/C standards]

The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.

HACCP Step 6 (Principle 1) Hazard Analysis

[B/C standards]

The HACCP team shall list all of the hazards that are reasonably likely to occur in each process steps, conduct an analysis, and identify any necessary measures to control them. Hazards shall include allergens where required.

HACCP Step 7 (Principle 2) Critical Control Points

[B/C standards]

Critical Control Points (CCPs) shall be determined.

HACCP Step 8 (Principle 3) Establishment of Critical Limits

[B/C standards]

Critical limit(s) shall be stipulated for each CCP.

HACCP Step 9 (Principle 4) Monitoring System

[B/C standards]

Monitoring procedures shall be established for each CCP.

HACCP Step 10 (Principle 5) Corrective Actions

[B/C standards]

A procedure of corrective actions (correction, and investigation and removal of root cause) shall be established for deviations from a critical limit.

HACCP Step 11 (Principle 6) Verification

[B/C standards]

Verification procedures shall be established to confirm whether the defined handling (HACCP Plans) is carried out as specified and to judge whether it is necessary to modify the defined handling.

Verification shall be carried out considering the design of equipment, change in processing method and technology development in the manufacturing process.

HACCP Step 12 (Principle 7) Documents and Record

[B/C standards]

Necessary documents shall be prepared and maintained.

Necessary records shall be taken and retained.

III Good Manufacturing Practice (GMP)

GMP 1 Facility Environment

[C standard]

The site shall be located and maintained so as to prevent contamination and enable the production of safe products.

C Standard has a requirement on conditions surrounding the site. Although site location is important for the organization that intends to implement food safety, A/B Standard does not have this requirement to avoid over burden for small and medium sized entities.

When the organization builds a new site for food manufacturing, the organization is to assess the location and confirm that there is no hazard which potentially affects the food safety. For existing site, GMP 1 does not necessarily require the relocation of the facility, in case the site does not comply with this requirement. Hazards which come from surrounding area of the site need to be considered comparing with the control measures which the organization takes. When the organization has or implements adequate measures relative to the hazards, the location can be considered as the place where "production of safe products" is enabled. In introducing the control measures against hazards from the surrounding areas, it is required to be able to explain what the hazards that need control are, what measures are taken to control the hazards, and that hazards are adequately controlled.

GMP 2 Site Management

[A/B/C standards]

All grounds within the site shall be maintained according to appropriately established criteria.

GMP 2 requires the establishment and the implementation of rules to control the site or ground in A, B and C Standards. Procedures for cleaning and pest control, such as taking care of vegetation and avoiding formation of standing water are included.

"Appropriately established criteria" mean criteria to take care of the site or ground adequate to avoid any food safety issue. This criteria include requirements of regulations, and also requirements specified by the organization itself to ensure food safety.

GMP 3 Design, Construction and Layout of Facilities, Equipment and Production

[A/B standards]

Site, building, and facility and equipment in the plant shall be maintained to enable controlling the risk of product contamination caused by external and internal environment and manufacturing flow.

[C standard]

Site, building, and facility and equipment in the plant shall be designed, laid out, constructed and

maintained to enable controlling the risk of product contamination caused by external and internal environment and manufacturing flow.

"Facility" in GMP 3 includes constructions such as production lines, roads and fences, and "equipment" includes piping and large machinery that are not usually relocated. While C Standard requires measures including capital investment if necessary, A/B Standard focuses on soft-ware based measures including the ideas from workers to minimize contamination risks.

GMP 4 Manufacturing and Storage Areas Specifications, and Utility Management

[B/C standards]

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.

To "meet the intended purpose" means to comply with the requirements specifications such as cleanliness and/or temperature in product manufacturing and storage areas to ensure and maintain food safety.

GMP 5 Devices and Tools

[B/C standards]

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.

"Suitably designed for the intended use" means to comply with requirements in specifications such as temperature setting or range of heating/cooling devices and/or easiness of cleaning in product manufacturing and storage areas to ensure maintain food safety.

GMP 6 Maintenance

[B/C standards]

A system of planned maintenance covering all items of equipment which are critical to product safety shall be established.

"Maintenance" includes corrective maintenance (i.e. temporary and permanent repairs) and preventive maintenance.

GMP 7 Staff Facilities

[A standard]

Staff facilities shall be used so as to minimize food safety risks.

[B/C standards]

Staff facilities shall be designed and used so as to minimize food safety risks including allergen.

Staff facilities include, for instance, shoe lockers, changing rooms, canteens, and toilets. B and C Standards refer to "design", however, it does not necessarily mean that facilities are to be newly introduced, however, means that existing facilities are to be improved as well. Food safety risks include allergens.

GMP 8 Identification and Control of Contamination Risks / Physical, Chemical and Biological Product Contamination Risks

[A/B standards] 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.

[C standard] Physical, Chemical and Biological Product Contamination Risks

Appropriate facilities and procedures shall be established to control the risks of physical, chemical (including allergen) and biological contamination of product.

A, B and C Standards require ways to identify contamination risks including allergens, and to control the risks identified.

Identification and control of contamination risks in GMP 8 are closely related to identification of risks and control measures in HACCP Step 6 (Principle 1). Since A Standard does not include HACCP Step 6, GMP 8 is applied to control contamination risks. B and C Standards require Hazard Analysis in accordance with HACCP Step 6 (Principle 1), and determine CCP. Hazards which are not determined as CCP are controlled under GMP 8.

GMP 9 Cross-Contamination/Segregation and Cross-Contamination

[A/B standards] 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 microorganisms, chemicals and allergens.

[C standard] Segregation and 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.

Requirements of A, B and C Standards are basically the same. "Partially processed products", "work in progress", "products being reprocessed" and "reworks" are the same as those in FSM 12.

"Cross-contamination" means that the source of contaminant happens to come into contact directly or indirectly with the product caused by the material flow crossing or coming close to each other.

GMP 10 Stock Management

[A/B/C standards]

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.

"Defined expiry period" is a time frame that a material is storable under given condition such as temperature and usually set by the producer based on clear evidence. "Proper conditions to avoid contamination and deterioration" means the conditions that products are to be stored to keep the quality required in specifications.

GMP 11 Housekeeping, Cleaning and Hygiene

[A/B/C standards]

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.

GMP 11 requires cleanliness and good hygiene adequate to produce foods, and it is preferable to achieve with the support of GMP 3, 4 and 5, that is, easy-to-clean building, facilities, devices and tools rather than this clause alone.

To be "suitable for their intended use" means that cleaning tools, cleaning agents and disinfectants do not pose hazards in addition to the effectiveness of cleaning.

GMP 12 Water and Ice Management

[A/B standards]

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.

[C standard]

Required quality criteria shall be defined for waters (including steam and ice; the same applies hereinafter) used in food manufacturing, depending upon the intended use, and the quality of water shall be regularly monitored and recorded.

"Monitoring" means test on quality of water sample to confirm the safety of water or suitability for food production. Factors to be monitored and frequency are determined by the organization based on the characteristics of water source, products and applicable regulations.

"Application-dependent quality standards" mean standards which are determined based on the usage of water. For example, cooling water and steam which does not come into direct contact with food are able to have different criteria from the one applied to water added to food.

"Potable" water in A/B Standard and "waters used in food manufacturing" in C Standard are basically the same. In the context of "water that potentially comes into contact with food", indirect contact with foods need to be considered.

GMP 13 Waste Management

[A/B/C standards]

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/microorganisms. The traffic line of waste shall be established so as to prevent cross-contamination into food.

"Pest" means insects, rodents, birds and other harmful animals, and is used the same in GMP 14. Although waste management is generally considered important from the environment conservation point of view, this clause requires management targeting food safety or good hygiene in processing environment. In this clause, inedible by-products are included in waste.

GMP 14 Pest Control

[A/B standards]

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.

[C standard]

A system shall be established to control or eliminate the food safety risks caused by pests in the site or in the facilities.

In case where chemicals are used, a handling procedure shall be established not to affect food.

A/B Standard gives examples of pests for this requirement to understand easily. In A/B Standard, "risks" are classified into growth in building and intrusion into building, and C Standard user needs to address both of these risks although the standard does not specify them. Pest control may include evaluation of facility, development of control plan, introducing control measure and monitoring, and implementation of extermination when needed. Hazard of chemicals also needs to be considered, if the chemicals are used for treatment.

GMP 15 Transport

[A standard]

Containers and vehicles, including contracted out vehicles, used for the transportation of raw materials and ingredients including packaging materials, partially processed products, work in progress, products being reprocessed, reworks and finished products including packed fresh produce in final packaging, shall be suitable for the intended use, maintained and kept clean.

[B standard]

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.

[C standard]

A documented system shall be established to ensure that containers and vehicles, including contracted vehicles, used for the transportation of raw materials and ingredients (including packaging materials), partially processed products, works in progress, products being reprocessed, reworks, and finished products (including packed fresh products in final packaging) are suitable for the intended use, maintained in good repair and clean.

The purpose of GMP 15 is to ensure transportation clean and safe, not to cause any risks on the product. This clause in A Standard requires a process to achieve such purpose, and the clause in B/C Standard requires a system to achieve the purpose. B/C Standard requires a system documented.

GMP 16 Personal Hygiene and Health Management

[A/B standards]

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.

[C standard]

Personal hygiene criteria based on contamination risks due to product characteristics shall be documented and implemented, according to which personnel shall be trained.

The criteria shall include provisions of hand washing and toilet facilities, ways and frequency of hand washing, medical screening procedure to identify conditions impacting food safety, proper protective clothing, rules on the clothing and shoes, rules on accessing production area, ways of food handling, and control measures for foreign materials.

The criteria shall be made fully known, trained and applied to workers, contractors and visitors without exception.

To "implement" in the first sentence of A, B and C Standards mean that workers have been trained and act following the documented hygiene criteria.

GMP 17 Education and Training

[A standard]

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.

[B/C standards]

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.

All workers need to be educated and trained to implement food safety activities following the procedures. Workers who have not received adequate education and training are not allowed to conduct such activities. Since the education for understanding "roles in food safety and the significance of the activities" are helpful to FSM 19 in C Standard and FSM 22 in B and C Standards, such education needs to be provided with

education and training of activities and operations which affects food safety.

GMP 18 Package and Storage of Product

[C standard]

Packaging materials shall be obtained with information of origin, be appropriate for use and be used and stored so as not to be a source of contamination to the product.

Products shall be handled, sorted, graded and packaged in a way to minimize biological, chemical and physical contamination.

Products shall be stored in designated areas and handled under proper condition to minimize contamination.

Products and packaging materials need to be stored in designated areas and controlled properly to prevent contamination. Ways to identify contamination risks which potentially affect food safety during storage, including allergens, and ways to determine control measures against the risks need to be developed.

"Information of origin" means traceable details of used material. In order to ensure food safety, to provide information of origin is important, particularly for material which directly contacts food.

Ways to identify contamination risks and to determine control measures against the identified risks are closely related to risks and control measures in HACCP Step 6 (Principle 1). Hazards which are identified significant are determined as CCP and ways to control are developed under HACCP Step 7 to 12 (Principle 2 to 7). The other hazards are controlled under GMP 8 and this clause.