JFS-B Standard [Requirements for Organizations]

Ver. 1.1

Japan Food Safety Management Association

July 14, 2017

1. Introduction

1.1 JFS-B Standard

This JFS-B Standard (hereinafter referred to as "this Standard") is a food safety management standard developed by Japan Food Safety Management Association (JFSM) and is intended to assist organizations to improve their activities on manufacturing safe food products. In addition, this Standard can also be utilized for internal and external audits to verify and evaluate the safety of the food production processes of the organization*. This Standard includes HACCP 7 principles and 12 steps.

* 'Organization' refers to a business entity to whom the requirements of this Standard apply. In the manufacturing sector, it refers to a business operator, group or individual who manufactures food products.

1.2 Scope of Application

This Standard applies to the "food manufacturing sector (E)" and to the "manufacturing sector of chemical products (including biochemical products) (L)" as follows:

Food Manufacturing Sector (E)

- El Processing of perishable animal products
- Ell Processing of perishable plant products
- EIII Processing of perishable animal and plant products (mixed products)
- EIV Processing of ambient stable products

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

- L Production of chemical products (including biochemical products).
 - (Production of additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids).

"Chemical products (including biochemical products)" herein refer to those related to food.

** Code "EI" to "EIV" and "L" are cited from GFSI Benchmarking Requirements.

1.3 Structure of this Standard

This Standard consists of three elements, namely, Food Safety Management Systems (FSM), Hazard Analysis and Critical Control Point (HACCP), and Good Manufacturing Practice (GMP).

This Standard only specifies common requirements for the manufacturing sector, and does not cover individual hygiene requirements for each product. Organizations shall use information appropriate for the organization (e.g. laws and regulations on food safety, standards specified by the relevant industry group) in addition to the requirements stipulated in this Standard. Furthermore, organizations are advised to refer to JFS Standards Interpretation of the Requirements and JFSM Guidelines.

1.4 Exclusion from Application of Requirements

All the requirements in this Standard shall be applied in principle. However, in case any of the requirements in this Standard is not able to apply for reasons arising from the business scale, business form and so on of an organization, the organization shall provide a document which indicates proof of non-applicability with explanations demonstrating the proper maintenance of food safety management.

1.5 Check List

At the end of this leaflet, there is a check list for organizations to complete to see if they are operating in accordance with the requirements of this Standard. Organizations are advised to complete this check list.

One of 5 boxes (conformity, minor nonconformity, major nonconformity, critical nonconformity, N/A) should be checked. There is also a space to write comments.

2. Requirements I

I Food Safety Management Systems (FSM)

| Number | Clause name | Requirements |
|------------------------|----------------|---|
| FSM 2 | Food Safety | Top management shall have a clear, concise, documented food |
| | Policy | safety policy which states how the organization ensures safety of the |
| | | product. |
| FSM 4 | Тор | Top management shall establish a communication structure which |
| | Management | enables directing, reporting and consulting. |
| | Responsibility | Top management shall appoint person(s) responsible for the food |
| | | safety management. |
| FSM 5 | Тор | Top management shall provide job descriptions (policies of dividing |
| | Management | duties) for workers involved with food safety and make these fully |
| | Commitment | known to workers. In addition, top management shall keep |
| | | evidence of job description having been made fully known. |
| FSM 7 | Resource | Top management shall ensure to provide resources (manpower, |
| | Management | goods and capital) necessary to implement the organization's food |
| | | safety practice (Hazard Control (HACCP) and Good Manufacturing |
| | | Practices (GMP)) in accordance with this Standard. |
| FSM 8 | Document | The organization shall have a documented procedure to control |
| and Record documents a | | documents and records to prepare, maintain and keep them in order |
| | Control | to control the process for ensuring food safety and demonstrate the |
| | | effective operation. |
| | | Records determined necessary to demonstrate implementation of |
| | | food safety management shall be retained properly. |
| FSM 10 | Procedures | The organization shall design its products and manufacturing |
| | and | processes taking into account all relevant safety requirements. The |
| | Instructions | organization shall establish an 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. |
| FSM 12 | Nonconformity | The rules shall be established and implemented to ensure that raw |
| | Control | materials and ingredients (including packaging materials), partially |
| | | processed products, work in progress, products being reprocessed, |
| | | reworks, and finished products which may possibly be unsafe shall |
| 501/10 | | not be used or delivered. |
| FSM 13 | Corrective | The procedure of corrective actions (to correct nonconformity, |
| | Action | identify the causes of nonconformity and eliminate them) shall be |

| | | documented and implemented in the event that any nonconformities occur. |
|--------|-------------|---|
| | | |
| FSM 14 | Product | Appropriate product specifications shall be prepared in conformity |
| | Release | with the requirements, laws and customer requirements and suitable |
| | | procedures for product release (shipment) shall also be stipulated |
| | | and implemented. |
| FSM 15 | Purchasing | 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. |
| FSM 16 | Supplier | The organization shall establish, implement and maintain procedures |
| | Performance | for the evaluation, approval and continual monitoring of suppliers |
| | | which have an effect on food safety. The results of evaluations, |
| | | investigations and follow-up actions shall be recorded. |
| FSM 18 | Complaint | A control system shall be established, implemented and maintained |
| | Handling | for controlling complaints and related data from customers and |
| | | consumers in order to find, correct and control defects in food safety |
| | | activities. |
| FSM 20 | Serious | An incident response manual*** shall be established and |
| | Incident | implemented in the event of an incident and maintained being valid |
| | Management | any time. Product withdrawal and product recall procedures 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. |
| | | *** A manual for proper response and control in order to prevent |
| | | incidents from getting worse when food safety problems occur. |

| Control of Measuring and Monitoring Devices | The organization shall identify the methods for measurement of parameters critical to ensure food safety, identify the measuring and monitoring devices required, and carry out calibrations of these devices by a method traceable to the national, international or equivalent standard. |
|---|--|
| Food Defense | Risks of intentional food contamination caused by workers or persons outside the organization shall be identified, evaluated and prioritized. The organization shall determine and implement measures to mitigate or eliminate the risks. |
| Product Labeling | All products shall have information that allow customers and consumers to handle, display, store, prepare and use the product in safe ways. In addition, procedures to provide correct information displayed or attached shall be established and implemented. |
| Traceability | A traceability system shall be established which identifies: a) manufacturing lot, b) connections between raw materials and ingredients (including packaging materials) and manufacturing lot and 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. |
| Analysis of Input Materials | The process environments and foods (e.g. raw materials and ingredients, and finished products) which potentially have effects on food safety shall be appropriately tested. It is recommended that tests are conducted in compliance with ISO 17025. |
| | Measuring and Monitoring Devices Food Defense Product Labeling Traceability |

II Hazard Control (HACCP)

| Number | Clause Name | Requirements |
|---------------|-------------------|--|
| НАССР | HACCP Team | A HACCP team shall be assembled with competent staff. |
| Step 1 | Assembly | |
| HACCP | Product | Product specifications shall be documented. |
| Step 2 | Description | 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. |
| НАССР | Identification of | Intended use of product and target consumers shall be |
| Step 3 | Intended Use | clearly described in written document. |
| НАССР | Construction of | The flow diagram that covers all steps in the operation shall |
| Step 4 | Flow Diagram | be constructed. |
| НАССР | On-site | The flow diagram shall be verified whether it correctly reflects |
| Step 5 | Confirmation of | the existing process steps of the operation. |
| | Flow Diagram | |
| НАССР | Hazard Analysis | The HACCP team shall list all hazards that are likely to occur |
| Step 6 | | in each process steps, conduct an analysis, and identify any |
| (Principle 1) | | necessary means to control them. Hazards shall include |
| | | allergens where required. |
| НАССР | Critical Control | Critical Control Points (CCPs) shall be determined. |
| Step 7 | Points | |
| (Principle 2) | | |
| НАССР | Establishment of | Critical limit(s) shall be specified for each CCP. |
| Step 8 | Critical Limits | |
| (Principle 3) | | |
| НАССР | Monitoring | Monitoring procedures shall be established for each CCP. |
| Step 9 | System | |
| (Principle 4) | | |
| НАССР | Corrective | A procedure of corrective actions (correction, investigation |
| Step 10 | Actions | and removal of root cause) shall be established for deviations |
| (Principle 5) | | from a critical limit. |

| НАССР | Verification | Verification procedures shall be established to confirm | |
|---------------|---------------|--|--|
| Procedure 11 | | whether the defined handling (HACCP Plan) is carried out as | |
| (Principle 6) | | 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. | |
| НАССР | Documents and | Necessary documents shall be prepared and maintained. | |
| Procedure 12 | Records | Necessary records shall be taken and retained. | |
| (Principle 7) | | | |

III Good Manufacturing Practice (GMP)

| Number | Clause Name | Requirements |
|--------|--|--|
| GMP 2 | Site Management | All the establishment within the premises shall be maintained according to appropriately established criteria. |
| GMP 3 | Design, Construction and Layout of Facilities, Equipment and Production | The site, buildings, and facilities and equipment in the plant shall be maintained to enable controlling the risk of product contamination caused by external and internal environments and manufacturing flows. |
| GMP 4 | | Specifications of manufacturing and storage areas shall meet the intended purpose of use. Control measures to prevent contamination and dew 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. |
| GMP 5 | Devices and Tools | Devices and tools shall be suitably designed for the intended uses and shall be used, maintained and stored so as to minimize food safety risks. |
| GMP 6 | Maintenance | A system of planned maintenance covering all items of equipment which are critical to product safety shall be established. |
| GMP 7 | Staff Facilities | Staff facilities shall be designed and used so as to minimize food safety risks including allergen. |
| GMP 8 | Identification and Control of Contamination Risks | All potential hazards encountered at any stage of the production process (from the receiving 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. |

| Number | Clause Name | Requirements |
|--------|----------------------|---|
| | Cross-contamination | Procedures to prevent contamination and cross- |
| | | contamination shall be established for raw materials |
| | | and ingredients (including packaging materials), |
| GMP 9 | | 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. |
| | Stock Management | A system to use raw materials and ingredients |
| | | (including packaging materials), partially processed |
| | | products, work in progress, products being |
| GMP 10 | | reprocessed, reworks, and finished products to be |
| | | used 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. |
| | Housekeeping, | Housekeeping and cleaning shall be carried out |
| | Cleaning and Hygiene | throughout all the process steps and stages, and an |
| GMP 11 | | appropriate hygiene level shall be maintained at all |
| | | times by disinfecting where necessary. Cleaning |
| | | tools, detergents and disinfectants shall be suitable for |
| | | their intended use and stored appropriately. |
| | Water and Ice | Quality standards classified by applications shall be |
| | Management | established for water (including steam and ice; the |
| | | same applies hereafter) used in food manufacturing, |
| | | and the quality of water shall be regularly monitored |
| GMP 12 | | and recorded. |
| | | Water added to food and water that potentially comes |
| | | into contact with food shall be potable. |
| | | Facilities, equipment and procedures used for |
| | | handling water shall ensure to prevent contamination. |
| | Waste Management | Adequate systems for segregation, collection and |
| | | disposal of waste shall be established. |
| | | Locations and containers for placing waste shall be |
| GMP 13 | | controlled to prevent attraction of pests or growth of |
| | | harmful organisms and microorganisms. The traffic |
| | | line of waste shall be established so as to prevent |
| | | cross-contamination into food. |

| Number | Clause Name | Requirements | |
|--------|---|---|--|
| GMP 14 | Pest Control | Food safety risks caused by insects, rodents and bird in the site or in the facilities shall be controlled (inspections and follow up actions shall be taken if necessary). In the cases where chemicals are used, handling procedures shall be established so as not to affect food. | |
| GMP 15 | Transport | A documented system shall be established to ensure that containers and vehicles, including outsourced 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 those packed, and fresh in final packaging) are suitable for the intended use, maintained in good repair and clean. | |
| GMP 16 | Personal Hygiene and Health Management | Documented appropriate personal hygiene criteria for workers shall be established and implemented. The requirements shall include hand washing methods and frequency, health status confirmation methods, rules on working wear 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. | |
| GMP 17 | Training | A system shall be in place to ensure that 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. | |

JFS-B Standard (Ver. 1.1) Self-check List

Select one of 5 boxes in the "Observations" column.

Conformity: Requirement fully satisfied.

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

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

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

 \Box N/A: Requirement not applied.

| | | Number / Clause Name / Requirements | Observations | Remarks |
|-------------|---|--|---|---------|
| FSI | FSM 2 Food Safety Policy | | 🗌 Conformity 🔄 Minor Nonconformity 🗌 Major Nonconformity 📄 Critical Nonconformity 📄 N/A | |
| | Top management shall have a clear, concise, documented food safety policy which states how the organization ensures safety of the product. | | | |
| FSI | М 4 Тор Ма | nagement Responsibilty | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| con | sulting. | t shall establish a communication structure which enables directing, reporting and | | |
| тор | managemen | t shall appoint person(s) responsible for the food safety management. | | |
| | Guideline | FSM 4-1 Does the organization have an up-to-date chart which describes organizational structure? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | FSM 4-2 Does the organization have a communication system in place for directing, reporting and consulting? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| Top safe | FSM 5 Top Management Commitment 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. | | □ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A | |
| | Guideline | FSM 5-1 Are the responsibilities for product safety and compliance clearly defined, documented, and communicated to the workers? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | FSM 5-2 Is there record or displayed information which demonstrates communication with the workers? | | |

| FSM 7 Resou | Irce Management | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
|--|---|---|--|
| implement the o | nt shall ensure to provide resources (man power, goods and capital) necessary to organization's food safety practice (Hazard Control (HACCP) and Good Manufacturing) in accordance with this Standard. | | |
| Guideline | FSM 7-1 Is there evidence that top management is committed to provide the resources necessary to implement and comply with the food safety program? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| FSM 8 Docum | ent and Record Control | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
| operation, and r The procedure s records. | a shall have documented procedure to control documents, which enables effective ecords, which demonstrates conformity and effectiveness of the organization's activity. hall include ways to prepare and maintain documents, and ways to keep and retain ined necessary to demonstrate implementation of food safety management shall be y. | | |
| Guideline | FSM 8-1 Does the organization have records to support the compliance with the food safety management system which covers the regulatory and customer requirements applied? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 8-2 Does the organization have record retention period that complies with regulatory and customer requirements? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 8-3 Does the organization have written document control procedures in place, and implement the procedure effectively? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| FSM 10 Proce | edures and Instrucructions | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🗍 Critical Nonconformity 🗌 N/A | |
| 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. | | | |
| Guideline | FSM 10-1 Does the organization have detailed procedures in place and implement the procedures effectively for all processes and operations that affect food safety? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 10-2 Are the procedures clearly communicated to relevant workers? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| The pac | rules shall be aging materia | onformity Control established and implemented to ensure that raw materials and ingredients (including als), partially processed products, work in progress, products being reprocessed, reworks, ucts which are potentially unsafe shall not be used or delivered. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
|------------|---------------------------------|---|---|
| | Guideline | FSM 12-1 Does the organization have documented procedure in place to identify and manage all nonconformity of raw materials (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| | | FSM 12-2 Is the control of nonconforming materials carried out by competent personnel? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| The | procedure of | cctive Action corrective action (to correct nonconformity, identify the causes of nonconformity and shall be documented and implemented in the event that any nonconformities occur. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| | | FSM 13-1 Does the organization have documented procedure in place to investigate nonconformities and prevent recurrence? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| | | FSM 13-2 Does the organization specify root cause and take corrective action to prevent recurrence, on the incident related to raw materials and ingredients, finished product or procedure of manufacturing process. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |

| FSM 14 Prod | uct Release | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
|--|---|---|--|
| intrusion into bui | g inspection, prevention of infestation and removal of pests) of the growth in building and Iding shall be implemented to minimize the food safety risks caused by insects, rodents, pests in the site or the facilities. | | |
| Guideline | FSM 14-1 Are the specifications defined for all raw materials and ingredients, additives, packaging materials, products being reprocessed, reworks and finished products? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 14-2 Does the organization have written specifications which complies with relevant food safety, regulatory and customer requirements? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 14-3 Does the organization have a system in place to communicate changes of written specifications of products to personnel in and out of the organization on update? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 14-4 Is there a designated person responsible for controlling specifications? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 14-5 Does the organization have a procedure in place to confirm if the releasing products conform the written specification? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 14-6 Does the organization have a written procedure in place for releasing products? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| FSM 15 Purc | hasing | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
| ingredients, supp purchasing requi In case the proce processes shall b control to the su In case of emerg Under such situa | or purchasing shall be established and implemented. Externally sourced raw materials and blies and services which have potential effect on food safety shall conform to all the rements of the organization. esses which have potential effect on food safety are outsourced, the control of the be properly implemented with specifications or contracts providing the requirements for pplier, or by other ways. gency, such as a natural disaster, purchasing from non-approved suppliers is allowed. tion, in order to ensure food safety, the organization shall assess the non-approved and verify the conformity of the products to the given specification. | | |
| Guideline | FSM 15-1 Do purchased material and services conform current written specifications and contracts? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

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

| FSM 20 Serie | ous Incident Management | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
|-------------------------------------|---|---|--|
| manual detailing Product withdra | t response procedures shall be established and implemented in the event of an incident. A g these procedures shall be kept up to date. wal and product recall procedure shall be included in the manual if necessary. as of the incident response manual shall be tested on products supplied by the organization year. | | |
| Guideline | FSM 20-1 Does the organization have a written incident response manual to report incidents, withdraw products and recall products? Is a test or practice based on the manual done and the manual reviewed more than once a year? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 20-2 Are incident records kept and assessed to establish severity and consumer risks? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 20-3 Does the organization have capability of withdrawal and recall of products affected by an incident? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 20-4 Does the organization have a plan to enhance effective communication to customers, consumers and regulatory authorities by designating a person responsible to provide information? | Conformity I Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| FSM 21 Cont | trol of Measuring and Monitoring Devices | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🗌 Critical Nonconformity 🗌 N/A | |
| identify the mea | n shall identify the methods for measurement of parameters critical to ensure food safety, isuring and monitoring devices required, and carry out calibration of these measuring and ces by a method traceable to a national, international or equivalent standard. | | |
| Guideline | FSM 21-1 Are measuring and monitoring devices critical to food safety and regulatory requirements reliable? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 21-2 Are measuring and monitoring devices critical to food safety identified, calibrated and traceable to national, international or other recognized standards? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 21-3 Are appropriate actions taken and recorded in case the measuring and monitoring devices are found to be out of specified limits? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| FSM 22 Food Defense | | Conformity I Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|--|---|---|--|
| Guideline | FSM 22-1 Does the organization identify potential risks of intentional food contamination and analyze the risks? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 22-2 Does the organization identify vulnerable points in intentional product tampering or contamination in the process, and take measures to mitigate the vulnerability? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | FSM 22-3 Does the organization have a procedure in place to deal with products which is suspected to be intentionally contaminated? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| All products shall and use the prod | uct Labeling have information that allow customers and consumers to handle, display, store, prepare uct in safe ways. edures to ensure the product to provide correct information shall be established and | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| FSI | M 24 Trace | ability | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
|--|--|---|---|--|
| raw proo The Rec • I or s • I rew | materials and cessing and dis system shall ords of the system dentification of ervices. dentification of orks, finished | tem shall be established which identifies: a) manufacturing lot, b) connections between d ingredients (including packaging materials) and manufacturing lot, c) information on stribution. be verified at least once a year. stem shall include the following: of any outsourced raw materials and ingredients (including packaging materials), products of batches, partially processed products, work in progress, products being reprocessed, I products, and packaging throughout the production process. rchaser and delivery destination for all products released. | | |
| | Guideline | FSM 24-1 Does the organization have a written procedure for traceability in place for each product including identification of product, raw materials and ingredients, and outsourced materials and services? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | FSM 24-2 Is the traceability system effective including partially processed products, work in progress, products being reprocessed and reworks? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | FSM 24-3 Are products traceable (i.e. all the materials are identified and records are kept) through all processes from purchasing raw materials and ingredients to storage and release. | Conformity D Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | FSM 24-4 Does the organization verify the effectiveness of traceability system more than once a year, review the system as necessary, and retain the records? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| The pote | process envir entially have e | rsis of Input Materials ronments and foods (e.g. raw materials and ingredients, and finished products) which effects on food safety shall be appropriately tested. It is recommended that tests are pliance with ISO 17025. | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🗍 Critical Nonconformity 🗌 N/A | |
| | Guideline | FSM 25-1 Does the organization have a procedure for analysis to ensure that products conforms all the specified requirements including food safety, regulatory and customer requirements for a determined period? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | FSM 25-2 Does the organization use appropriate methods for analysis which provide valid results for food safety? (e.g. procedure conforming ISO 17025 and/or methods recognized by the industry) | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| HACCP Step 1 | HACCP Team Assembly | Conformity C Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|--------------------------------------|--|---|--|
| A HACCP team s | hall be assembled with competent staff. | | |
| Guideline | HACCP 1-1 Does a multi-disciplinary team with different responsibilities carry out the tasks described in HACCP Steps 2 to 12 in this check list? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| Product specifica The document sh | Product Description tions shall be described documented. hall describe all product information necessary to conduct hazard analysis. CCP system shall be defined per product or product group and per process line or process | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🗍 Critical Nonconformity 🗌 N/A | |
| Guideline | HACCP 2-1 Does the organization identify all the regulatory and customer requirements relevant to the product or the product group? Does the product or the product group conform the requirements? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | HACCP 2-2 Does the organization have complete product specifications for all the products and product groups covering raw materials and ingredients, packaging materials, finished products, and storage and distribution conditions? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| HACCP Step 3 | Identification of Intended Use | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🗍 Critical Nonconformity 🗌 N/A | |
| The intended use | of product and target consumers shall be clearly described in written document. | | |
| Guideline | HACCP 3-1 Is the intended use of the product described, and are the target consumers identified? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | Construction of Flow Diagram n that covers all steps in the operation shall be constructed. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| Guideline | HACCP 4-1 Does the organization have a flow diagram describing all the process steps of product manufacturing and processing? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | On-site Confirmation of Flow Diagram | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| Guideline | HACCP 5-1 Is an on-site verification carried out to make the flow diagram accurately reflect the existing process? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

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

| HACCP Step 11 (Principle 6) Verification Verification procedures shall be established to confirm (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended. Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process. | | dures shall be established to confirm defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are ded. be carried out considering the design of equipment, change in processing method and | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|--|--|--|---|--|
| | Guideline | HACCP 11-1 Are verification procedures established? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | HACCP 11-2 Are the verification procedures implemented effectively? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | HACCP Step 12 (Principle 7) Documents and Records Necessary documents shall be prepared and maintained. Necessary records shall be taken and retained. | | Conformity I Minor Nonconformity I Major Nonconformity I Critical Nonconformity N/A | |
| | Guideline | HACCP12-1 Are records and documents controlled to implement HACCP plan? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | HACCP12-2 Are all the procedures for HACCP-related record and document control implemented effectively? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 2 Site Management An appropriate standard for all grounds within the site shall be established and maintained. | | Conformity I Minor Nonconformity I Major Nonconformity I Critical Nonconformity N/A | |
| | Guideline | GMP 2-1 Are the surrounding areas of the facilities always controlled and kept free of hygienic problems? For instance, is vegetation periodically trimmed or mowed? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| risk | site, building | n, Construction and Layout of Facilities, Equipment and Production , and facilities and equipment in the plant shall be maintained to enable the control of the ontamination caused by the external and internal environment, and by the manufacturing | □ Conformity □ Minor Nonconformity □ Major Nonconformity □ Critical Nonconformity □ N/A | |
|------|----------------------------------|---|---|--|
| | Guideline | GMP 3-1 Are the facilities designed, constructed, layouted suitable to maintain and clean? | Conformity D Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 3-2 Is the lighting adequate in brightness and color to prevent mistake? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 3-3 Is the drainage system designed and controlled to minimize potential risks of product contamination? Are the floor and catch basin sloped to facilitate water flow and cleaning? | Conformity D Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| Proc | ifications of ı edures to cor | facturing and Storage Areas Specifications, and Utility Management manufacturing and storage areas shall meet the intended purpose. ntrol contamination and condensation shall be established and implemented, as necessary, as air, compressed air and other gases which may come into contact with food. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | Guideline | GMP 4-1 Is the boiler compound, a chemical agent for steam boiler, approved for food manufacturing use? Is the boiler designed to prevent contamination of the compound? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | Guidelinit | GMP 4-2 Are air conditioning and/or ventilation systems designed and constructed, if necessary, to prevent air contamination? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| Devices and to | ices and Tools ols shall be suitably designed for the intended uses and shall be used, maintained and stored ize food safety risks. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
|--|---|---|
| | GMP 5-1 Are the devices and tools designed to facilitate cleaning, sanitizing, maintenance and drainage? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| Guideline | e GMP 5-2 Are the food contact surfaces durable, easy to maintain, clean, sanitize and monitor, and made of materials that withstand cleaning materials and methods? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| GMP 6 Mair A system of pla be established. | anned maintenance covering all items of equipment which are critical to product safety shall | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 📄 Critical Nonconformity 📄 N/A |
| Guideline | GMP 6-1 e Does the organization have written procedure for maintenance of all equipment which have impact on food safety? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| | GMP 6-2 Is the maintenance procedure effectively implemented? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| | GMP 6-3 Does the maintenance procedure requires hygienic and clearance criteria for all maintenance activities? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |
| | GMP 6-4 Are all the materials used in maintenance appropriate for intended use? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A |

| | | acilities II be designed and used so as to minimize food safety risks. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|--------------------|----------------------------------|--|---|--|
| | Guideline | GMP 7-1 Does the organization have changing room located to enable personnel handling food to move to the production areas in such a way that cleanliness of their workwear is kept? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 7-2 Does the organization have hygienically designed toilets that are sufficiently isolated from food handling areas? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 7-3 Does the organization provide adequate numbers, locations and means of hygienic hand washing facilities? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 7-4 Are canteens and designated areas for food and drink storage and consumption apart from manufacturing, packaging and storage areas? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| GM | P8 Identi | fication and Control of Contamination Risks | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
| mat (e.g Bas | erials and ing . chemicals, a | rds encountered at any stage of the production process (from the reception of raw redients to the release of products) including physical (e.g. metal fragments), chemical illergens), and biological (e.g. micro-organisms) shall be listed. necessary control methods, procedures and criteria for contamination risks shall be | | |
| | Guideline | GMP 8-1 Does the organization have physical barriers or effective procedures in place to eliminate potential hazard of physical, chemical or biological contamination or minimize the hazard to acceptable level? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| ingredients (inclu | event contamination and cross-contamination shall be established for raw materials and ding packaging materials), partially processed products, work in progress, products being orks and finished products, covering all aspects of food safety including micro-organisms, | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|--------------------|---|--|--|
| Guideline | GMP 9-1 Confo Does the organization have a procedure of cross-contamination prevention which includes identification of the potentially hazardous areas due to flows of workers and materials in food manufacturing, and preparation of prevention plan? | rmity 🔲 Minor Nonconformity 🗌 Major Nonconformity 📄 Critical Nonconformity 🗌 N/A | |
| | GMP 9-2 Does the organization identify all the allergens that need to be controlled in products or processes through risk assessment? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 9-3 On specifying allergens to be controlled, are specifications, including regulatory and customer requirements, taken into consideration? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 9-4 Does the organization have a procedure to prevent cross-contamination in handling raw materials and ingredients including packaging materials, and products including partially processed products, work in progress, products being reprocessed, reworks, and finished products? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 9-5 Does the organization have a written procedure of allergen control which includes method of cleaning to remove undeclared allergens and to prevent cross-contamination, and method of verification? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 9-6 Is the product labeling of allergens that are based on risk assessment appropriate? | | |

| GMP 1 | 0 Stock | Management | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
|--------------------------------|---|---|---|--|
| products order ar | s, work in nd within t | raw materials and ingredients (including packaging materials), partially processed progress, products being reprocessed, reworks, and finished products in a designated he defined expiry period shall be established and these materials shall be stored under ons to avoid contamination and deterioration. | | |
| Gu | uideline | GMP 10-1 Does the organization have facilities to store raw materials and ingredients, partially processed products, work in progress, products being reprocessed, reworks and finished products without contamination and deterioration due to in appropriate temperature, relative humidity or other factors? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| Houseke steps ar necessa | GMP 11 Housekeeping, Cleaning and Hygiene Housekeeping and cleaning shall be carried out following the documented criteria throughout all the process steps and stages, and an appropriate hygiene level shall be maintained at all times by disinfecting where necessary. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended use and stored appropriately. | | Conformity I Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| Gu | uideline | GMP 11-1 Does the organization have a procedure in place for housekeeping, cleaning and hygiene? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 11-2 Are the devices, equipment and tools used for cleaning and sanitizing kept clean and stored in designated areas? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 11-3 Are chemicals for cleaning and sanitizing identified and stored in the designated areas? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 11-4 Are cleaning and sanitizing carried out by trained or competent workers? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| GM | P12 Wate | r and Ice Management | 🗌 Conformity 🔲 Minor Nonconformity 🗌 Major Nonconformity 🔲 Critical Nonconformity 🗌 N/A | |
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| sam and Wate | 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. | | | |
| | Guideline | GMP 12-1 Does the organization periodically test water for food manufacturing to verify the quality conforms to the regulation? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 12-2 Does the organization have a written procedure to control waters for each purpose such as water added into food or water not come into contact with food such as cooling water? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| GMI | P 13 Wast | e Management | Conformity 🗌 Minor Nonconformity 🗌 Major Nonconformity 🗍 Critical Nonconformity 🗌 N/A | |
| Loca harn | Adequate systems for segregation, collection and disposal of waste shall be established. Locations and containers for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro-organisms. The traffic line of waste shall be established so as to prevent cross- contamination into food. | | | |
| | Guideline | GMP 13-1 Does the organization have a suitable procedure in place for the storage and removal of waste (including inedible by-products)? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 13-2 Does the organization periodically verify the result of waste control including the implementation of the procedure? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 13-3 To prevent cross-contamination between waste and food, is waste stored not to affect food safety? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| Foo (ins | MP 14 Pest Control od safety risk caused by insects, rodents and birds in the site or in the facilities shall be controlled ispection and follow up action shall be taken if necessary). the cases where chemicals are used, handling procedures shall be established so as not to affect food. | | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|-------------|--|---|---|--|
| | Guideline | GMP 14-1 Does the organization identify pests targeted through experience, scientific data and information of product characteristics, and establish an effective pest control plan? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 14-2 Does the organization monitor periodically if pests are controlled effectively? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 14-3 In case monitoring indicates infestation of pests and suggest control, does the organization prepare a plan to remove pests which does not have impact on food safety and facility operation? Does a competent or qualified personnel implement the plan? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 14-4 Does the organization have a procedure to treat pests with chemical and to restart production following the treatment? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| A do veh part (inc | IP 15 Transport ocumented system shall be established to ensure that containers and vehicles, including contracted out icles, used for the transportation of raw materials and ingredients (including packaging materials), tially processed products, work in progress, products being reprocessed, reworks, and finished products duding packed, fresh product in final packaging) are suitable for the intended use, maintained in good air and clean. | | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|-----------------------------|--|---|---|--|
| | Guideline | GMP 15-1 Does the organization have a procedure to make containers and vehicles, which are used for transportation of raw materials and ingredient (including packaging material), and products (partially processed products, work in progress, products being reprocessed, reworks and finished products) suitable to the purpose, well maintained, and kept clean and hygienic? Is the procedure implemented effectively? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 15-2 Are the containers or vehicles equipped with temperature or relative humidity control if the products require? Are the measuring instruments in transport vehicles verified periodically, and the records kept? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| GMP 16 Pers | ional Hygiene and Health Management | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|--|---|---|--|
| requirements sha rules on workwe methods and pre | propriate personal hygiene criteria for workers shall be established and implemented. The all include hand washing methods and frequency, health status confirmation methods, ar and shoes, methods of entry to and exit from the production area, food handling evention of foreign material contamination. ents shall be made known to workers, and shall also apply to contractors and visitors on. | | |
| Guideline | GMP 16-1 Do the organization's criteria for personal hygiene comply with legal and regulatory requirements? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 16-2 Are the personal hygiene criteria applied and communicated to all the workers including contractors and visitors? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 16-3 Does the organization have a procedure to announce to workers including contractors and visitors to take an action to prevent spread of infectious diseases and pathogen contamination into food. | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 16-4 Does the organization have a procedure to report to the top management and/or persons in charge of food safety/production, as necessary, about a suspected worker of infection, and to keep the worker away from food handling areas? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 16-5 Do workers including contractors and visitors change, as necessary, workwear and footwear which is clean, intact and suitable to the purpose? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | GMP 16-6 Does the organization have a rule of laundering and/or switching workwear? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |

| A sy HAC A sy Trai | CP) and pract stem shall be | ing e in place to ensure all workers are adequately trained on food safety principles (including tices, commensurate with the worker's activity. e established to ensure all workers are adequately instructed and supervised. ure all workers to be aware of the roles in food safety and the significance of the | Conformity I Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
|-----------------------------|--------------------------------|--|---|--|
| | Guideline | GMP 17-1 Does the organization provide training to all workers, including new members, to obtain necessary competence and knowledge for each specific role in food handing, and is it recorded? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 17-2 Does the organization have a plan for taininig in place and the plan is implemented effectively? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 17-3 Is the HACCP training plan implemented? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 17-4 Is training record kept properly and available? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |
| | | GMP 17-5 Is a refresher training plan documented and implemented? | Conformity Minor Nonconformity Major Nonconformity Critical Nonconformity N/A | |