ISO 22000 Audit Checklist

UR Startup Inc. / 22 Mar 2023 / Andy Dion

Complete

Score	199 / 326 (61.04%)	Flagged items	3	Actions	0

Client / Site	UR Startup Inc.
Conducted on (Date and Time)	22 Mar 2023 15:42 PST
Inspected by	Andy Dion
Location	Chemin de sous le Clos 16 1232 Confignon Switzerland

Flagged items

3 flagged

Clause 4 / Food Safety Management System / Documentation Requirements / Control of records

Do records remain legible, readily identifiable and retrievable?

No

Some documents need to be reprinted because of they’re faded.

Photo 1

Clause 7 / Planning and realization of safe products / Preliminary steps to enable hazard analysis / Product characteristics / Raw material, ingredients, and product contacted material

c) Origin?

No

Need to clarify what “other” means on the document pertaining to origin.

Clause 8 / Validation, verification, and improvement of the FSMS / FSMS verification / Internal audit

Is it ensured that auditors do not audit their own work?

No

Get external auditors to do the assessment when applicable.

Clause 4	1 flagged, 24 / 25 (96%)
Food Safety Management System	1 flagged, 24 / 25 (96%)
General Requirements	10 / 10 (100%)
Has the organization established, documented and implemented an effective food safety management system in accordance with the requirements of ISO 22000 standard?	Yes
Is the FSMS maintained and updated?	Yes
Is the scope of the FSMS defined?	Yes
Are the products or product categories, processes and production sites that are addressed by the food safety management system specified by scope?	Yes
Are the food safety hazards that may be reasonably expected to occur in relation to products within the scope of the system identified, evaluated and controlled in such manner that the products of theorganization do not, directly or indirectly, harm the consumer?	Yes
Are the appropriate information - regarding safety issues related to the products - communicated throughout the food chain?	Yes
Are the information - concerning development, implementation and updating of the FSMS throughout the organization - communicated to the extent necessary to ensure the food safety required by the ISO 22000 standard?	Yes
Does the organization periodically evaluate FSMS (and update when necessary) to ensure that the system reflects the organization's activities and incorporates the most recent information on the food safety hazards subject to control?	Yes
Has the organization ensured control over the outsourced processes that may affect end product conformity?	Yes
Is the control of such outsourced processes identified and documented within the FSMS?	Yes
Documentation Requirements	1 flagged, 14 / 15 (93.33%)
General	3 / 3 (100%)
Does the FSMS documentation include:	

a) Documented statements of a food safety policy and related objectives?	Yes
b) Documented procedures and records required by ISO 22000 standard?	Yes
c) Documents needed by the organization to ensure the effective development, implementation and updating of the food safety management system?	Yes
Control of documents	9 / 9 (100%)
Are the documents - which are required by the food safety management system - controlled?	Yes
Do the established controls ensure that all proposed changes are reviewed prior to implementation to determine their effects on food safety and their impact on the food safety management system?	Yes
Does a documented procedure exist to define the controls needed:	
a) To approve documents for adequacy prior to issue?	Yes
b) To review and update as necessary and re-approve documents?	Yes
c) To ensure that changes and the current revision status of documents are identified?	Yes
d) To ensure that relevant versions of applicable documents are available at points of use?	Yes
e) To ensure that documents remain legible and readily identifiable?	Yes
f) To ensure that relevant documents of external origin are identified and their distribution controlled?	Yes
g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?	Yes
Control of records	1 flagged, 2 / 3 (66.67%)
Are required records established and maintained in order to provide evidence of conformity to requirements and evidence of the effective operation of the food safety management system?	Yes
Do records remain legible, readily identifiable and	No

retrievable?

Some documents need to be reprinted because of they’re faded.

Photo 1

Does a documented procedure exist in order to define the controls needed for the correction, identification, storage, protection, retrieval, retention time and disposition of records?

Yes

Please proceed to Section 5.

Clause 5	63 / 63 (100%)
Management responsibility	63 / 63 (100%)
Management commitment	6 / 6 (100%)
Is top management able to provide evidence of its commitment to the development and implementation of the food safety management system?	Yes

Is top management able to provide evidence that the effectiveness of the food safety management system is continually improved by:

a) Showing food safety is supported by the business objectives of the organization?	Yes
b) Communicating to the organization the importance of meeting the requirements of ISO 22000 standard, any relevant statutory and regulatory requirements, as well as customer requirements relating to food safety?	Yes
c) Establishing the food safety policy?	Yes
d) Conducting management reviews?	Yes
e) Ensuring the availability of resources?	Yes
Food safety policy	7 / 7 (100%)
Has top management defined, documented and communicated its food safety policy?	Yes

Does top management ensure that the food safety policy:

a) Is appropriate to the role of the organization in the food chain?	Yes
b) Conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers?	Yes
c) Is communicated, implemented and maintained at all levels of the organization?	Yes
d) Is reviewed for continued suitability?	Yes
e) Adequately addresses communication?	Yes
f) Is supported by measurable objectives?	Yes

Food safety management system planning	2 / 2 (100%)

Does top management ensure that:

a) The planning of the food safety management system is carried out to meet the requirements in clause 4.1, as well as the objectives of the organization that support food safety?	Yes
b) The integrity of the food safety management system is maintained when changes to the food safety management system are planned and implemented?	Yes
Responsibility and authority	3 / 3 (100%)
Does top management ensure that the responsibilities, authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety management system?	Yes
Is the responsibility assigned to all personnel to report the problems with the food safety management to identified person(s)?	Yes
Are there designated personnel with defined responsibility and authority to initiate and record actions?	Yes
Food safety team leader	4 / 4 (100%)

Has top management appointed a food safety team leader who, irrespective of other responsibilities, shall have responsibility and authority:

a) To manage a food safety team and organize its work?	Yes
b) To ensure relevant training and education of the food safety team member?	Yes
c) To ensure that the food safety management system is established, implemented, maintained and updated?	Yes
d) To report to the organization's top management on the effectiveness and suitability of the food safety management system?	Yes

NOTE: The responsibility of the food safety team leader may include liaison with external parties on matters relating to the food safety management system.

Communication	25 / 25 (100%)
External communication	9 / 9 (100%)

Has the organization established, implemented and maintained effective arrangements for communicating with:

a) Suppliers and contractors?	Yes
b) Customers or consumers, in particular in relation to product information (including instructions regarding intended use, specific storage requirements and, as appropriate, shelf life), inquiries, contracts or order handling including amendments, and customer feedback including customer complaints?	Yes
c) Statutory and regulatory authorities?	Yes
d) Other organizations that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system?	Yes
Does such communication provide information on food safety aspects (especially to known food safety hazards that need to be controlled by other organizations in the food chain) of the organization's products that may be relevant to other organizations in the food chain?	Yes
Are records of communications maintained?	Yes
Are the food safety requirements - from statutory and regulatory authorities and customers – available?	Yes
Are there designated personnel with defined responsibility and authority to communicate externally any information concerning food safety?	Yes
Is information obtained through external communication included as input to system updating and management review?	Yes
Internal communication	16 / 16 (100%)
Has the organization established, implemented and maintained effective arrangements for communicating with personnel on issues having an impact on food safety?	Yes

Has the organization ensured that the food safety team is informed in a timely manner of changes, including but not limited to the following:

a) Products or new products?	Yes
b) Raw materials, ingredients, and services?	Yes
c) Production systems and equipment?	Yes

d) Production premises, location of equipment, and surrounding environment?	Yes
e) Cleaning and sanitation programmes?	Yes
f) Packaging, storage and distribution systems?	Yes
g) Personnel qualification levels and/or allocation of responsibilities and authorizations?	Yes
h) Statutory and regulatory requirements?	Yes
i) Knowledge regarding food safety hazards and control measures?	Yes
j) Customer, sector, and other requirements that the organization observes?	Yes
k) Relevant inquiries from external interested parties?	Yes
l) Complaints indicating food safety hazards associated with the product?	Yes
m) Other conditions that have an impact on food safety?	Yes
Does the food safety team ensure that above mentioned information is included in the updating of the food safety management system?	Yes
Does top management ensure that relevant information is included as input to the management review?	Yes
Emergency preparedness and response	1 / 1 (100%)
Has top management established, implemented and maintained procedures to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain?	Yes
Management review	15 / 15 (100%)
General	3 / 3 (100%)
Does top management review the organization's food safety management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?	Yes
Does this review include assessing opportunities for improvement and the need for changes to the food safety management system, including the food safety policy?	Yes

Are records from management reviews maintained?	Yes
Review input	8 / 8 (100%)

Does the input to management review include information about:

a) Follow-up actions from previous management reviews?	Yes
b) Analysis of results of verification activities?	Yes
c) Changing circumstances that can affect food safety?	Yes
d) Emergency situations, accidents and withdrawals?	Yes
e) Reviewing results of system-updating activities?	Yes
f) Review of communication activities, including customer feed-back?	Yes
g) External audits or inspections?	Yes
Are the data presented in a manner that enables top management to relate the information to stated objectives of the food safety management system?	Yes
Review output	4 / 4 (100%)

Does the output from the management review include any decisions and actions related to:

a) Assurance of food safety?	Yes
b) Improvement of the effectiveness of the food safety management system?	Yes
c) Resource needs?	Yes
d) Revisions of the organization's food safety policy and related objectives?	Yes

Please proceed to Section 6

Clause 6	12 / 12 (100%)
Resource management	12 / 12 (100%)
Provision of resources	1 / 1 (100%)
Does the organization provide adequate resources for the establishment, implementation, maintenance and updating of the food safety management system?	Yes
Human resources	9 / 9 (100%)
General	2 / 2 (100%)
Are the food safety team and the other personnel carrying out activities having an impact on food safety, competent on the basis of appropriate education, training, skills and experience?	Yes
Are there available records of agreement or contracts defining the responsibility and authority of external experts, where the assistance of external experts is required for the development, implementation, operation or assessment of the food safety management system?	Yes
Competence, awareness and training	7 / 7 (100%)
Does the organization:	
a) Identify the necessary competencies for personnel whose activities have an impact on food safety?	Yes
b) Provide training or take other action to ensure personnel have the necessary competencies?	Yes
c) Ensure that personnel responsible for monitoring, corrections and corrective actions of the food safety management system are trained?	Yes
d) Evaluate the implementation and the effectiveness of the actions taken in a), b) and c)?	Yes
e) Ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to food safety?	Yes
f) Ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety?	Yes
g) Maintain appropriate records of training and actions	Yes

described in b) and c)?	
Infrastructure	1 / 1 (100%)
Does the organization provide the resources for the establishment and maintenance of the infrastructure needed to implement the requirements of ISO 22000 standard?	Yes
Work environment	1 / 1 (100%)
Does the organization provide the resources for the establishment, management and maintenance of the work environment needed to implement the requirements of ISO 22000 standard?	Yes

Please proceed to Section 7.

Clause 7	1 flagged, 52 / 177 (29.38%)
Planning and realization of safe products	1 flagged, 52 / 177 (29.38%)
General	2 / 2 (100%)
Does the organization plan and develop the processes needed for the realization of safe products?	Yes
Does the organization implement, operate and ensure the effectiveness of the planned activities and any changes to those activities? Note: This includes PRP(s) as well as operational PRP(s) and/or the HACCP plan.	Yes
Prerequisite programmes (PRPs)	24 / 24 (100%)
Has the organization established, implemented and maintained PRP(s) to assist in controlling:	
a) The likelihood of introducing food safety hazards to the product through the work environment?	Yes
b) Biological, chemical and physical contamination of the product(s), including cross-contamination between products?	Yes
c) Food safety hazard levels in the product and product processing environment?	Yes
Are the PRP(s):	
a) Appropriate to the organizational needs with regard to food safety?	Yes
b) Appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled?	Yes
c) Implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line?	Yes
d) Approved by the food safety team?	Yes
Does the organization identify statutory and regulatory requirements related to the above?	Yes
Does the organization consider and utilize appropriate information, when selecting and/or establishing PRP(s)?	Yes
Does the organization consider the following (when establishing PRP(s)):	

a) Construction and layout of buildings and associated utilities?	Yes
b) Layout of premises, including workspace and employee facilities?	Yes
c) Supplies of air, water, energy and other utilities?	Yes
d) Supporting services, including waste and sewage disposal?	Yes
e) The suitability of equipment and its accessibility for cleaning, maintenance, and preventative maintenance?	Yes
f) Management of purchased materials (e.g. raw materials, ingredients, chemicals, and packaging), supplies (e.g. water, air, steam, and ice), disposals (e.g. waste and sewage) and handling of products (e.g. storage and transportation)?	Yes
g) Measures for the prevention of cross-contamination?	Yes
h) Cleaning and sanitizing?	Yes
i) Pest control?	Yes
j) Personal hygiene?	Yes
k) Other aspects as appropriate?	Yes
Is verification of PRP(s) planned?	Yes
Are PRP(s) modified as necessary?	Yes
Are records of verifications and modifications maintained?	Yes
Do documents specify how activities included in the PRP(s) are managed?	Yes
Preliminary steps to enable hazard analysis	1 flagged, 26 / 39 (66.67%)
General	2 / 2 (100%)
Are all relevant information - needed to conduct the hazard analysis - collected, maintained, updated and documented?	Yes
Are the records related to hazard analysis maintained?	Yes
Food safety team	3 / 3 (100%)
Has a food safety team been appointed?	Yes

Do the members of the food safety team provide a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system? Note: This includes, but need not be limited to, the organization's products, processes, equipment and food safety hazards within the scope of the food safety management system.	Yes
Are records - that demonstrate that the food safety team has the required knowledge and experience - maintained?	Yes
Product characteristics	1 flagged, 18 / 19 (94.74%)
Raw material, ingredients, and product contacted material	1 flagged, 9 / 10 (90%)

Are all raw materials, ingredients and product-contact materials described in documents to the extent needed to conduct the hazard analysis, including the following, as appropriate:

a) Biological, chemical, and physical characteristics?	Yes
b) Composition of formulated ingredients, including additives and processing aids?	Yes
c) Origin?	No

Need to clarify what “other” means on the document pertaining to origin.

d) Method of production?	Yes
e) Packaging and delivery methods?	Yes
f) Storage conditions and shelf life?	Yes
g) Preparation and/or handling before use or processing?	Yes
h) Food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses?	Yes
Does the organization identify statutory and regulatory food safety requirements related to the raw materials, ingredients and product-contact materials?	Yes
Are the descriptions kept up-to-date including, when required?	Yes
Characteristics of end products	9 / 9 (100%)

Are the characteristics of end products described in documents to the extent needed to conduct the hazard analysis, including information on the following, as appropriate:

a) Product name or similar identification?	Yes
b) Composition?	Yes
c) Biological, chemical and physical characteristics relevant to food safety?	Yes
d) Intended shelf life and storage conditions?	Yes
e) Packaging?	Yes
f) Labeling relating to food safety and/or instructions for handling, preparation, and usage?	Yes
g) Method(s) of distribution?	Yes
Does the organization identify statutory and regulatory food safety requirements related to the characteristics of end products?	Yes
Are the descriptions kept up-to-date including, when required?	Yes
Intended use	3 / 3 (100%)
Are the intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product considered and described in documents to the extent needed to conduct the hazard analysis?	Yes
Are groups of users and, where appropriate, groups of consumers identified for each product, and consumer groups are known to be especially vulnerable to specific food safety hazards considered?	Yes
Are the descriptions kept up-to-date including, when required?	Yes
Flow diagrams, process steps, and control measures	0 / 12 (0%)
Flow diagrams	0 / 10 (0%)
Are flow diagrams prepared for the products or process categories covered by the food safety management system?	
Do flow diagrams provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards?	
Are flow diagrams clear, accurate and sufficiently detailed?	

Do flow diagrams, as appropriate, include the following:

a) The sequence and interaction of all steps in the operation?

b) Any outsourced processes and subcontracted work?

c) Where raw materials, ingredients, and intermediate products enter the flow?

d) Where reworking and recycling take place?

e) Where end products, intermediate products, byproducts, and waste are released or removed?

Does the food safety team verify the accuracy of the flow diagrams by on-site checking?

Are verified flow diagrams maintained as records?

Description of process steps and control measures 0 / 2 (0%)

Are the existing control measures process parameters and/or the rigorousness with which they are applied, or the procedures that may influence food safety, described to the extent needed to conduct the hazard analysis?

Are external requirements (e.g. regulatory authorities ore costumes) that may impact the choice or rigorousness of the control measures described and updated?

Hazard analysis 0 / 30 (0%)

General 0 / 1 (0%)

Does the food safety team conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required?

Hazard identification and determination of acceptable levels 0 / 12 (0%)

Are all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities identified and recorded?

Is the identification based on:

a) The preliminary information and data collected in preliminary steps to enable hazard analysis?

b) Experience?

c) External information including, to the extent possible, epidemiological and other historical data?

d) Information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products, and the food at consumption?

Are the step(s) (from raw materials, processing, and distribution) - at which each food safety hazard may be introduced – indicated?

Is the consideration - when identifying the hazards - given to:

a) The steps preceding and following the specified operation?

b) The process equipment, utilities/services, and surroundings?

c) The preceding and following links in the food chain?

Are the acceptable level of the food safety hazard in the end product determined (whenever possible) for each of the food safety hazards identified?

Does the determined level take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data?

Are the justification for, and the result of, the determination of the acceptable level of the food safety hazard recorded?

Hazard assessment 0 / 4 (0%)

Is a hazard assessment conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe food and whether its control is needed to enable the defined acceptable levels to be met?

Is each food safety hazard evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence?

Is the methodology used for the hazard described?

Are the results of the food safety hazard assessment recorded?

Selection and assessment of control measures	0 / 13 (0%)

Is an appropriate combination of control measures selected (based on the hazard assessment), which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels?

Is each of the selected control measures reviewed with respect to its effectiveness against the identified food safety hazards?

Is each selected control measure categorized as to whether it needs to be managed through operational PRP(s) or by the HACCP plan, using a logical approach that includes assessments with regard to the following:

a) Its effect on identified food safety hazards relative to the strictness applied?

b) Its feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrective actions)?

c) It is placed within the system relative to other control measures?

d) The likelihood of failure in the functioning of a control measure or significant processing variability?

e) The severity of the consequence(s) in the case of failure in its functioning?

f) Whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s)?

g) Synergistic effects (i.e. interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects)?

Are control measures - categorized as belonging to the HACCP plan – implemented?

Are other control measures implemented as operational PRPs?

Are the methodology and parameters - used for this categorization - described in documents?

Are the results of the assessment recorded?

Establishing the operational prerequisite programmes (PRPs)	0 / 7 (0%)

Are the operational PRPs documented?

Are the operational PRPs included the following information for each programme:

a) Food safety hazard(s) to be controlled by the programme?

b) Control measure(s)?

c) Monitoring procedures that demonstrate that the operational PRPs are in place?

d) Corrections and corrective actions to be taken if monitoring shows that the operational PRPs are not in control?

e) Responsibilities and authorities?

f) Record(s) of monitoring?

Establishing the HACCP plan 0 / 28 (0%)

HACCP plan 0 / 8 (0%)

Is the HACCP plan documented?

Is the HACCP plan included the following information for each identified critical control point (CCP):

a) Food safety hazard(s) to be controlled at the CCP?

b) Control measure(s)?

c) Critical limit(s)?

d) Monitoring procedure(s)?

e) Corrections and corrective action(s) to be taken if critical limits are exceeded?

f) Responsibilities and authorities?

g) Record(s) of monitoring?

Identification of critical control points 0 / 1 (0%)

Are CCP(s) identified for the control measures identified, for each hazard that is to be controlled by the HACCP plan?

Determination of critical limits forCCP(s)	0 / 5 (0%)
Are critical limits determined for the monitoring established for each CCP?	
Are critical limits established on such a way to ensure that the identified acceptable level of the food safety hazard in the end product is not exceeded?	
Are critical limits measurable?	
Are the rationale for the chosen critical limits documented?	
Are critical limits - based on subjective data (such as visual inspection of product, process, handling, etc.) - supported by instructions or specifications and/or education and training?	
System for the monitoring of critical control points	0 / 9 (0%)
Is a monitoring system established for each CCP to demonstrate that the CCP is in control?	
Are all scheduled measurements or observations - relative to the critical limit(s) - included in the monitoring system?	
Does the monitoring system consist of relevant procedures, instructions, and records that cover the following:	
a) Measurements or observations that provide results within an adequate time frame?	
b) Monitoring devices used?	
c) Applicable calibration methods?	
d) Monitoring frequency?	
e) Responsibility and authority related to monitoring and evaluation of monitoring results?	
f) Record requirements and methods?	
Are the monitoring methods and frequency capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed?	
Actions when monitoring results exceed critical limits	0 / 5 (0%)
Are planned corrections and corrective actions - to be taken	

when critical limits are exceeded - specified in the HACCP plan?

Do the actions ensure that:

a) The cause of nonconformity is identified?

b) The parameter(s) controlled at the CCP is (are) brought back under control?

c) Recurrence is prevented?

Are documented procedures established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated?

Updating of preliminary information and documents specifying the PRPs and the HACCP plan — 0 / 6 (0%)

Does the organization update the following information in operational PRP(s) and/or the HACCP plan, if necessary:

a) Product characteristics?

b) Intended use?

c) Flow diagrams?

d) Process steps?

e) Control measures?

Are the HACCP plan and the procedures and instructions specifying the PRP(s) amended, if necessary?

Verification planning — 0 / 9 (0%)

Does verification planning define the purpose, methods, frequencies, and responsibilities for the verification activities?

Do the verification activities confirm that:

a) The PRP(s) are implemented?

b) Input to the hazard analysis is continually updated?

c) The operational PRP(s) and the elements within the HACCP plan are implemented and effective, d) hazard levels are within identified acceptable levels?

e) Other procedures required by the organization are implemented and effective?

Is the output of verification planning in a form suitable for the organization's method of operations?

Are verification results recorded and communicated to the food safety team?

Are verification results provided on such way to enable the analysis of the results of the verification activities?

Are the affected lots of product handled as potentially unsafe, if system verification is based on testing of end product samples, and where such test samples show lack of conformity with the acceptable level of the food safety hazard?

Traceability system 0 / 4 (0%)

Has the organization established and does it apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing, and delivery records?

Is the traceability system able to identify incoming material from the immediate suppliers and the initial distribution route of the end product?

Are traceability records maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal?

Are records in accordance with statutory and regulatory requirements and customer requirements?

Control of nonconformity 0 / 23 (0%)

Corrections 0 / 8 (0%)

Does the organization ensure that when critical limits for CCP(s) are exceeded or there is a loss of control of operational PRP(s), the end products affected are identified and controlled with regard to their use and release?

Is a documented procedure established and maintained defining:

a) The identification and assessment of affected end products to determine their proper handling?

b) A review of the corrections carried out?

Are potentially unsafe products - manufactured under conditions where critical limits have been exceeded - handled?

Are products - manufactured under conditions where operational PRP(s) have not been conformed with - evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety?

Are these products, where necessary, handled?

Is the evaluation recorded?

Are all corrections approved by the responsible person(s), and recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots?

Corrective actions 0 / 4 (0%)

Are data - derived from the monitoring of operational PRPs and CCPs - evaluated by designated person(s) with sufficient knowledge and authority to initiate corrective actions?

Are corrective actions initiated when critical limits are exceeded or when there is a lack of conformity with operational PRP(s)?

Has the organization established and does it maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered?
Note:
These actions include
a) reviewing nonconformities (including customer complaints),
b) reviewing trends in monitoring results that may indicate development towards loss of control,
c) determining the cause(s) of nonconformities,
d) evaluating the need for action to ensure that nonconformities do not recur,
e) determining and implementing the actions needed,
f) recording the results of corrective actions taken, and
g) reviewing corrective actions taken to ensure that they are effective.

Are corrective actions recorded?

Handling of potentially unsafe products 0 / 11 (0%)

General 0 / 6 (0%)

Does the organization handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that

a) The food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels?

b) The food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain?

c) The product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity?

Are all lots of product - that may have been affected by a nonconforming situation - held under control of the organization until they have been evaluated?

Does the organization notify relevant interested parties and initiate a withdrawal, if products that have left the control of the organization are subsequently determined to be unsafe? Note: The term “withdrawal” includes recall.

Are the controls and related responses and authorization for dealing with potentially unsafe products documented?

Evaluation for release 0 / 3 (0%)

Is each lot of product affected by the nonconformity released as safe only when any of the following conditions apply:

a) Evidence other than the monitoring system demonstrates that the control measures have been effective?

b) Evidence shows that the combined effect ofthe control measures for that particular product complies with the performanceintended?

c) The results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned?

Disposition of nonconforming products 0 / 2 (0%)

Is the lot of product - which is not acceptable for release - handled (after evaluation) by one of the following activities:

a) Reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels?

b) Destruction and/or disposal as waste?

Control of nonconformity	0 / 5 (0%)
Withdrawals	0 / 5 (0%)

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe

a) Has top management appointed personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal?

b) Has the organization established and does it maintain a documented procedure for
1) notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
2) handling of withdrawn products as well as affected lots of the products still in stock, and
3) the sequence of actions to be taken?.

Are withdrawn products secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe?

Are the cause, extent and result of a withdrawal recorded and reported to top management as input to the management review?

Does the organization verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. challenge testing, mock withdrawal or practice withdrawal)?

Please proceed to Section 8.

Clause 8	1 flagged, 48 / 49 (97.96%)
Validation, verification, and improvement of the FSMS	1 flagged, 48 / 49 (97.96%)
General	1 / 1 (100%)
Does the food safety team plan and implement the processes needed to validate control measures and/or control measure combinations, and to verify and improve the food safety management system?	Yes
Validation of control measure combinations	4 / 4 (100%)
Does the organization validate (prior to implementation of control measures to be included in operational PRP(s) and the HACCP plan and after any change therein) that:	
a) The selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated?	Yes
b) The control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels?	Yes
Are the control measure and/or combinations thereof modified and re-assessed when the result of the validation shows that one or both of the above elements cannot be confirmed?	Yes
Note: Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.	Yes
Control of monitoring and measuring	12 / 12 (100%)
Is there evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures?	Yes
Are the measuring equipment and methods used:	
a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards? Note: Where necessary to ensure valid results	Yes

b) Adjusted or re-adjusted as necessary?	Yes
c) Identified to enable the calibration status to be determined?	Yes
d) Safeguarded from adjustments that would invalidate the measurement results?	Yes
e) Protected from damage and deterioration?	Yes
Are records of the results of calibration and verification maintained?	Yes
Does the organization assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements?	Yes
Does the organization take action appropriate for the equipment and any product affected, If the measuring equipment is non-conforming?	Yes
Are records of such assessment and resulting actions maintained?	Yes
Is the ability of computer software confirmed to satisfy the intended application when used in the monitoring and measurement of specified requirements?	Yes
Is the confirmation of computer software undertaken prior to initial use and reconfirmed as necessary?	Yes
FSMS verification	1 flagged, 22 / 23 (95.65%)
Internal audit	1 flagged, 8 / 9 (88.89%)

Does the organization conduct internal audits at planned intervals to determine whether the food safety management system:

a) Conforms to the planned arrangements, to the food safety management system requirements established by the organization, and to the requirements of this International Standard?	Yes
b) Is effectively implemented and updated?	Yes
Is an audit programme planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits?	Yes
Are the audit criteria, scope, frequency, and methods defined?	Yes

Do the selection of auditors and the conduct of audits ensure objectivity and impartiality of the audit process?	Yes
Is it ensured that auditors do not audit their own work?	No

Get external auditors to do the assessment when applicable.

Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records defined in documented procedure?	Yes
Does the management responsible for the area being audited to ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes?	Yes
Do follow-up activities include the verification of the actions taken and the reporting of verification results?	Yes
Evaluation of individual verification results	6 / 6 (100%)
Does the food safety team systematically evaluate the individual results of planned verification?	Yes
Does the organization take action to achieve the required conformity, when verification does not demonstrate conformity with the planned arrangements?	Yes

Does action – taken for achieving the required conformity – include (but is not limited to), review of:

a) Existing procedures and communication channels?	Yes
b) The conclusions of the hazard analysis, the established operational PRP(s) and the HACCP plan?	Yes
c) The PRP(s)?	Yes
d) The effectiveness of human resource management and of training activities?	Yes
Analysis of results of verification activities	8 / 8 (100%)
Does the food safety team analyze the results of verification activities, including the results of the internal audits and external audits?	Yes

Is the analysis carried out in order

a) To confirm that the overall performance of the system meets the planned arrangements and the food safety	Yes

management system requirements established by the organization?	
b) To identify the need for updating or improving the food safety management system?	Yes
c) To identify trends which indicate a higher incidence of potentially unsafe products?	Yes
d) To establish information for planning of the internal audit programme concerning the status and importance of areas to be audited?	Yes
e) To provide evidence that any corrections and corrective actions that have been taken are effective?	Yes
Are the results of the analysis and the resulting activities recorded and reported, in an appropriate manner, to top management as input to the management review?	Yes
Are the results of the analysis and the resulting activities used as an input for updating the food safety management system?	Yes
Improvement	9 / 9 (100%)
Continual improvement	1 / 1 (100%)
Does top management ensure that the organization continually improves the effectiveness of the food safety management system through the use of: **- communication,** **- management review,** **- internal audit,** **- evaluation of individual verification results,** **- analysis of results of verificationactivities,** **- validation of control measurecombinations,** **- corrective actions and** **- food safety management system updating?**	Yes
Updating the food safety management system	8 / 8 (100%)
Does top management ensure that the food safety management system is continually updated?	Yes
Does the food safety team evaluate the food safety management system at planned intervals in order to achieve that FSMS is continually updated?	Yes
Does the team consider whether it is necessary to review the hazard analysis, the established operational PRP(s) and the HACCP plan?	Yes

Are the evaluation and updating activities based on:

a) Input from communication, external as well as internal?	Yes
b) Input from other information concerning the suitability, adequacy, and effectiveness of the food safety management system?	Yes
c) Output from the analysis of results of verification activities?	Yes
d) Output from management review?	Yes
Are system updating activities recorded and reported, in an appropriate manner, as input to the management review?	Yes

Completion

Recommendation

Inspector's Full name and Signature

Andy Dion
22 Mar 2023 15:54 PST

Media summary

Photo 1