

ISO 22000 Audit Checklist

Template Information

Template ID	iso-22000-audit-checklist
Version	v1.0
Language	English (en)
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Source	https://layeraudit.com
Revision Date	2026-10-27
Description	Description: This comprehensive ISO 22000 audit checklist converted using SafetyCulture is composed of 5 sections - Management responsibility and resources, Planning and realization of safe products, Validation, Verification, and Improvement of Food Safety Management System (FSMS). This checklist helps evaluate if the organization has implemented, established and maintained an effective FSMS. It also ensures control over outsourced processes that may affect end product conformity. Use SafetyCulture to generate on the spot reports and assign urgent corrective actions to appropriate team members or vendors.

Audit Information (to be completed during audit)

Audit Date	
Auditor	
Area / Department	
Escort	

Instructions

1. This template contains 326 check items. Record results in the 'Checklist' worksheet.
2. The source does not define fixed pass/fail options. Fill in results according to your own criteria (e.g. Pass / Fail / N.A.).
3. Scores, conclusions and signatures are entered manually in the 'Scoring & Sign-off' worksheet.
4. For photos or other evidence, enter the evidence number in the 'Notes / Evidence No.' column and archive photos by number.
5. Check item numbers are renumbered consecutively. The mapping to the source rows is recorded in '编号对应表.xlsx' in the delivery package.

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No.	Section	Check Item	Result	Notes / Evidence No.
1	General Requirements	Has the organization established, documented and implemented an effective food safety management system in accordance with the requirements of ISO 22000 standard?		
2	General Requirements	Is the FSMS maintained and updated?		
3	General Requirements	Is the scope of the FSMS defined?		
4	General Requirements	Are the products or product categories, processes and production sites that are addressed by the food safety management system specified by scope?		
5	General Requirements	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 the organization do not, directly or indirectly, harm the consumer?		
6	General Requirements	Are the appropriate information - regarding safety issues related to the products - communicated throughout the food chain?		
7	General Requirements	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?		
8	General Requirements	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?		
9	General Requirements	Has the organization ensured control over the outsourced processes that may affect end product conformity?		
10	General Requirements	Is the control of such outsourced processes identified and documented within the FSMS?		
	General	Does the FSMS documentation include:		
11	General	a) Documented statements of a food safety policy and related objectives?		
12	General	b) Documented procedures and records required by ISO 22000 standard?		
13	General	c) Documents needed by the organization to ensure the effective development, implementation and updating of the food safety management system?		
14	Control of documents	Are the documents - which are required by the food safety management system - controlled?		
15	Control of documents	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?		
	Control of documents	Does a documented procedure exist to define the controls needed:		
16	Control of documents	a) To approve documents for adequacy prior to issue?		
17	Control of documents	b) To review and update as necessary and re-approve documents?		
18	Control of documents	c) To ensure that changes and the current revision status of documents are identified?		
19	Control of documents	d) To ensure that relevant versions of applicable documents are available at points of use?		
20	Control of documents	e) To ensure that documents remain legible and readily identifiable?		
21	Control of documents	f) To ensure that relevant documents of external origin are identified and their distribution controlled?		
22	Control of documents	g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?		
23	Control of records	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?		
24	Control of records	Do records remain legible, readily identifiable and retrievable?		
25	Control of records	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?		
	Control of records	Please proceed to Section 5.		
26	Management commitment	Is top management able to provide evidence of its commitment to the development and implementation of the food safety management system?		
	Management commitment	Is top management able to provide evidence that the effectiveness of the food safety management system is continually improved by:		

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No.	Section	Check Item	Result	Notes / Evidence No.
27	Management commitment	a) Showing food safety is supported by the business objectives of the organization?		
28	Management commitment	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?		
29	Management commitment	c) Establishing the food safety policy?		
30	Management commitment	d) Conducting management reviews?		
31	Management commitment	e) Ensuring the availability of resources?		
32	Food safety policy	Has top management defined, documented and communicated its food safety policy?		
	Food safety policy	Does top management ensure that the food safety policy:		
33	Food safety policy	a) Is appropriate to the role of the organization in the food chain?		
34	Food safety policy	b) Conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers?		
35	Food safety policy	c) Is communicated, implemented and maintained at all levels of the organization?		
36	Food safety policy	d) Is reviewed for continued suitability?		
37	Food safety policy	e) Adequately addresses communication?		
38	Food safety policy	f) Is supported by measurable objectives?		
	Food safety management system planning	Does top management ensure that:		
39	Food safety management system planning	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?		
40	Food safety management system planning	b) The integrity of the food safety management system is maintained when changes to the food safety management system are planned and implemented?		
41	Responsibility and authority	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?		
42	Responsibility and authority	Is the responsibility assigned to all personnel to report the problems with the food safety management to identified person(s)?		
43	Responsibility and authority	Are there designated personnel with defined responsibility and authority to initiate and record actions?		
	Food safety team leader	Has top management appointed a food safety team leader who, irrespective of other responsibilities, shall have responsibility and authority:		
44	Food safety team leader	a) To manage a food safety team and organize its work?		
45	Food safety team leader	b) To ensure relevant training and education of the food safety team member?		
46	Food safety team leader	c) To ensure that the food safety management system is established, implemented, maintained and updated?		
47	Food safety team leader	d) To report to the organization's top management on the effectiveness and suitability of the food safety management system?		
	Food safety team leader	NOTE: The responsibility of the food safety team leader may include liaison with external parties on matters relating to the food safety management system.		
	External communication	Has the organization established, implemented and maintained effective arrangements for communicating with:		
48	External communication	a) Suppliers and contractors?		
49	External communication	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?		
50	External communication	c) Statutory and regulatory authorities?		
51	External communication	d) Other organizations that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system?		

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No.	Section	Check Item	Result	Notes / Evidence No.
52	External communication	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?		
53	External communication	Are records of communications maintained?		
54	External communication	Are the food safety requirements - from statutory and regulatory authorities and customers – available?		
55	External communication	Are there designated personnel with defined responsibility and authority to communicate externally any information concerning food safety?		
56	External communication	Is information obtained through external communication included as input to system updating and management review?		
57	Internal communication	Has the organization established, implemented and maintained effective arrangements for communicating with personnel on issues having an impact on food safety?		
	Internal communication	Has the organization ensured that the food safety team is informed in a timely manner of changes, including but not limited to the following:		
58	Internal communication	a) Products or new products?		
59	Internal communication	b) Raw materials, ingredients, and services?		
60	Internal communication	c) Production systems and equipment?		
61	Internal communication	d) Production premises, location of equipment, and surrounding environment?		
62	Internal communication	e) Cleaning and sanitation programmes?		
63	Internal communication	f) Packaging, storage and distribution systems?		
64	Internal communication	g) Personnel qualification levels and/or allocation of responsibilities and authorizations?		
65	Internal communication	h) Statutory and regulatory requirements?		
66	Internal communication	i) Knowledge regarding food safety hazards and control measures?		
67	Internal communication	j) Customer, sector, and other requirements that the organization observes?		
68	Internal communication	k) Relevant inquiries from external interested parties?		
69	Internal communication	l) Complaints indicating food safety hazards associated with the product?		
70	Internal communication	m) Other conditions that have an impact on food safety?		
71	Internal communication	Does the food safety team ensure that above mentioned information is included in the updating of the food safety management system?		
72	Internal communication	Does top management ensure that relevant information is included as input to the management review?		
73	Emergency preparedness and response	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?		
74	General	Does top management review the organization's food safety management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?		
75	General	Does this review include assessing opportunities for improvement and the need for changes to the food safety management system, including the food safety policy?		
76	General	Are records from management reviews maintained?		
	Review input	Does the input to management review include information about:		
77	Review input	a) Follow-up actions from previous management reviews?		
78	Review input	b) Analysis of results of verification activities?		
79	Review input	c) Changing circumstances that can affect food safety?		
80	Review input	d) Emergency situations, accidents and withdrawals?		
81	Review input	e) Reviewing results of system-updating activities?		
82	Review input	f) Review of communication activities, including customer feed-back?		
83	Review input	g) External audits or inspections?		
84	Review input	Are the data presented in a manner that enables top management to relate the information to stated objectives of the food safety management system?		
	Review output	Does the output from the management review include any decisions and actions related to:		
85	Review output	a) Assurance of food safety?		

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No.	Section	Check Item	Result	Notes / Evidence No.
86	Review output	b) Improvement of the effectiveness of the food safety management system?		
87	Review output	c) Resource needs?		
88	Review output	d) Revisions of the organization's food safety policy and related objectives?		
	Review output	Please proceed to Section 6		
89	Provision of resources	Does the organization provide adequate resources for the establishment, implementation, maintenance and updating of the food safety management system?		
90	General	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?		
91	General	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?		
	Competence, awareness and training	Does the organization:		
92	Competence, awareness and training	a) Identify the necessary competencies for personnel whose activities have an impact on food safety?		
93	Competence, awareness and training	b) Provide training or take other action to ensure personnel have the necessary competencies?		
94	Competence, awareness and training	c) Ensure that personnel responsible for monitoring, corrections and corrective actions of the food safety management system are trained?		
95	Competence, awareness and training	d) Evaluate the implementation and the effectiveness of the actions taken in a), b) and c)?		
96	Competence, awareness and training	e) Ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to food safety?		
97	Competence, awareness and training	f) Ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety?		
98	Competence, awareness and training	g) Maintain appropriate records of training and actions described in b) and c)?		
99	Infrastructure	Does the organization provide the resources for the establishment and maintenance of the infrastructure needed to implement the requirements of ISO 22000 standard?		
100	Work environment	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?		
	Work environment	Please proceed to Section 7.		
101	General	Does the organization plan and develop the processes needed for the realization of safe products?		
102	General	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.		
	Prerequisite programmes (PRPs)	Has the organization established, implemented and maintained PRP(s) to assist in controlling:		
103	Prerequisite programmes (PRPs)	a) The likelihood of introducing food safety hazards to the product through the work environment?		
104	Prerequisite programmes (PRPs)	b) Biological, chemical and physical contamination of the product(s), including cross-contamination between products?		
105	Prerequisite programmes (PRPs)	c) Food safety hazard levels in the product and product processing environment?		
	Prerequisite programmes (PRPs)	Are the PRP(s):		
106	Prerequisite programmes (PRPs)	a) Appropriate to the organizational needs with regard to food safety?		
107	Prerequisite programmes (PRPs)	b) Appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled?		
108	Prerequisite programmes (PRPs)	c) Implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line?		

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No.	Section	Check Item	Result	Notes / Evidence No.
109	Prerequisite programmes (PRPs)	d) Approved by the food safety team?		
110	Prerequisite programmes (PRPs)	Does the organization identify statutory and regulatory requirements related to the above?		
111	Prerequisite programmes (PRPs)	Does the organization consider and utilize appropriate information, when selecting and/or establishing PRP(s)?		
	Prerequisite programmes (PRPs)	Does the organization consider the following (when establishing PRP(s)):		
112	Prerequisite programmes (PRPs)	a) Construction and layout of buildings and associated utilities?		
113	Prerequisite programmes (PRPs)	b) Layout of premises, including workspace and employee facilities?		
114	Prerequisite programmes (PRPs)	c) Supplies of air, water, energy and other utilities?		
115	Prerequisite programmes (PRPs)	d) Supporting services, including waste and sewage disposal?		
116	Prerequisite programmes (PRPs)	e) The suitability of equipment and its accessibility for cleaning, maintenance, and preventative maintenance?		
117	Prerequisite programmes (PRPs)	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)?		
118	Prerequisite programmes (PRPs)	g) Measures for the prevention of cross-contamination?		
119	Prerequisite programmes (PRPs)	h) Cleaning and sanitizing?		
120	Prerequisite programmes (PRPs)	i) Pest control?		
121	Prerequisite programmes (PRPs)	j) Personal hygiene?		
122	Prerequisite programmes (PRPs)	k) Other aspects as appropriate?		
123	Prerequisite programmes (PRPs)	Is verification of PRP(s) planned?		
124	Prerequisite programmes (PRPs)	Are PRP(s) modified as necessary?		
125	Prerequisite programmes (PRPs)	Are records of verifications and modifications maintained?		
126	Prerequisite programmes (PRPs)	Do documents specify how activities included in the PRP(s) are managed?		
127	General	Are all relevant information - needed to conduct the hazard analysis - collected, maintained, updated and documented?		
128	General	Are the records related to hazard analysis maintained?		
129	Food safety team	Has a food safety team been appointed?		
130	Food safety team	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.		
131	Food safety team	Are records - that demonstrate that the food safety team has the required knowledge and experience - maintained?		
	Raw material, ingredients, and product contacted material	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:		
132	Raw material, ingredients, and product contacted material	a) Biological, chemical, and physical characteristics?		
133	Raw material, ingredients, and product contacted material	b) Composition of formulated ingredients, including additives and processing aids?		

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No.	Section	Check Item	Result	Notes / Evidence No.
134	Raw material, ingredients, and product contacted material	c) Origin?		
135	Raw material, ingredients, and product contacted material	d) Method of production?		
136	Raw material, ingredients, and product contacted material	e) Packaging and delivery methods?		
137	Raw material, ingredients, and product contacted material	f) Storage conditions and shelf life?		
138	Raw material, ingredients, and product contacted material	g) Preparation and/or handling before use or processing?		
139	Raw material, ingredients, and product contacted material	h) Food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses?		
140	Raw material, ingredients, and product contacted material	Does the organization identify statutory and regulatory food safety requirements related to the raw materials, ingredients and product-contact materials?		
141	Raw material, ingredients, and product contacted material	Are the descriptions kept up-to-date including, when required?		
	Characteristics of end products	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:		
142	Characteristics of end products	a) Product name or similar identification?		
143	Characteristics of end products	b) Composition?		
144	Characteristics of end products	c) Biological, chemical and physical characteristics relevant to food safety?		
145	Characteristics of end products	d) Intended shelf life and storage conditions?		
146	Characteristics of end products	e) Packaging?		
147	Characteristics of end products	f) Labeling relating to food safety and/or instructions for handling, preparation, and usage?		
148	Characteristics of end products	g) Method(s) of distribution?		
149	Characteristics of end products	Does the organization identify statutory and regulatory food safety requirements related to the characteristics of end products?		
150	Characteristics of end products	Are the descriptions kept up-to-date including, when required?		
151	Intended use	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?		
152	Intended use	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?		
153	Intended use	Are the descriptions kept up-to-date including, when required?		
154	Flow diagrams	Are flow diagrams prepared for the products or process categories covered by the food safety management system?		
155	Flow diagrams	Do flow diagrams provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards?		
156	Flow diagrams	Are flow diagrams clear, accurate and sufficiently detailed?		
	Flow diagrams	Do flow diagrams, as appropriate, include the following:		
157	Flow diagrams	a) The sequence and interaction of all steps in the operation?		
158	Flow diagrams	b) Any outsourced processes and subcontracted work?		

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No.	Section	Check Item	Result	Notes / Evidence No.
159	Flow diagrams	c) Where raw materials, ingredients, and intermediate products enter the flow?		
160	Flow diagrams	d) Where reworking and recycling take place?		
161	Flow diagrams	e) Where end products, intermediate products, byproducts, and waste are released or removed?		
162	Flow diagrams	Does the food safety team verify the accuracy of the flow diagrams by on-site checking?		
163	Flow diagrams	Are verified flow diagrams maintained as records?		
164	Description of process steps and control measures	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?		
165	Description of process steps and control measures	Are external requirements (e.g. regulatory authorities ore costumes) that may impact the choice or rigorousness of the control measures described and updated?		
166	General	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?		
167	Hazard identification and determination of acceptable levels	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?		
	Hazard identification and determination of acceptable levels	Is the identification based on:		
168	Hazard identification and determination of acceptable levels	a) The preliminary information and data collected in preliminary steps to enable hazard analysis?		
169	Hazard identification and determination of acceptable levels	b) Experience?		
170	Hazard identification and determination of acceptable levels	c) External information including, to the extent possible, epidemiological and other historical data?		
171	Hazard identification and determination of acceptable levels	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?		
172	Hazard identification and determination of acceptable levels	Are the step(s) (from raw materials, processing, and distribution) - at which each food safety hazard may be introduced – indicated?		
	Hazard identification and determination of acceptable levels	Is the consideration - when identifying the hazards - given to:		
173	Hazard identification and determination of acceptable levels	a) The steps preceding and following the specified operation?		
174	Hazard identification and determination of acceptable levels	b) The process equipment, utilities/services, and surroundings?		
175	Hazard identification and determination of acceptable levels	c) The preceding and following links in the food chain?		
176	Hazard identification and determination of acceptable levels	Are the acceptable level of the food safety hazard in the end product determined (whenever possible) for each of the food safety hazards identified?		
177	Hazard identification and determination of acceptable levels	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?		
178	Hazard identification and determination of acceptable levels	Are the justification for, and the result of, the determination of the acceptable level of the food safety hazard recorded?		

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No.	Section	Check Item	Result	Notes / Evidence No.
179	Hazard assessment	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?		
180	Hazard assessment	Is each food safety hazard evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence?		
181	Hazard assessment	Is the methodology used for the hazard described?		
182	Hazard assessment	Are the results of the food safety hazard assessment recorded?		
183	Selection and assessment of control measures	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?		
184	Selection and assessment of control measures	Is each of the selected control measures reviewed with respect to its effectiveness against the identified food safety hazards?		
	Selection and assessment of control measures	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:		
185	Selection and assessment of control measures	a) Its effect on identified food safety hazards relative to the strictness applied?		
186	Selection and assessment of control measures	b) Its feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrective actions)?		
187	Selection and assessment of control measures	c) It is placed within the system relative to other control measures?		
188	Selection and assessment of control measures	d) The likelihood of failure in the functioning of a control measure or significant processing variability?		
189	Selection and assessment of control measures	e) The severity of the consequence(s) in the case of failure in its functioning?		
190	Selection and assessment of control measures	f) Whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s)?		
191	Selection and assessment of control measures	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)?		
192	Selection and assessment of control measures	Are control measures - categorized as belonging to the HACCP plan – implemented?		
193	Selection and assessment of control measures	Are other control measures implemented as operational PRPs?		
194	Selection and assessment of control measures	Are the methodology and parameters - used for this categorization - described in documents?		
195	Selection and assessment of control measures	Are the results of the assessment recorded?		
196	Establishing the operational prerequisite programmes (PRPs)	Are the operational PRPs documented?		
	Establishing the operational prerequisite programmes (PRPs)	Are the operational PRPs included the following information for each programme:		
197	Establishing the operational prerequisite programmes (PRPs)	a) Food safety hazard(s) to be controlled by the programme?		
198	Establishing the operational prerequisite programmes (PRPs)	b) Control measure(s)?		
199	Establishing the operational prerequisite programmes (PRPs)	c) Monitoring procedures that demonstrate that the operational PRPs are in place?		
200	Establishing the operational prerequisite programmes (PRPs)	d) Corrections and corrective actions to be taken if monitoring shows that the operational PRPs are not in control?		
201	Establishing the operational prerequisite programmes (PRPs)	e) Responsibilities and authorities?		

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No.	Section	Check Item	Result	Notes / Evidence No.
202	Establishing the operational prerequisite programmes (PRPs)	f) Record(s) of monitoring?		
203	HACCP plan	Is the HACCP plan documented?		
	HACCP plan	Is the HACCP plan included the following information for each identified critical control point (CCP):		
204	HACCP plan	a) Food safety hazard(s) to be controlled at the CCP?		
205	HACCP plan	b) Control measure(s)?		
206	HACCP plan	c) Critical limit(s)?		
207	HACCP plan	d) Monitoring procedure(s)?		
208	HACCP plan	e) Corrections and corrective action(s) to be taken if critical limits are exceeded?		
209	HACCP plan	f) Responsibilities and authorities?		
210	HACCP plan	g) Record(s) of monitoring?		
211	Identification of critical control points	Are CCP(s) identified for the control measures identified, for each hazard that is to be controlled by the HACCP plan?		
212	Determination of critical limits for CCP(s)	Are critical limits determined for the monitoring established for each CCP?		
213	Determination of critical limits for CCP(s)	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?		
214	Determination of critical limits for CCP(s)	Are critical limits measurable?		
215	Determination of critical limits for CCP(s)	Are the rationale for the chosen critical limits documented?		
216	Determination of critical limits for CCP(s)	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?		
217	System for the monitoring of critical control points	Is a monitoring system established for each CCP to demonstrate that the CCP is in control?		
218	System for the monitoring of critical control points	Are all scheduled measurements or observations - relative to the critical limit(s) - included in the monitoring system?		
	System for the monitoring of critical control points	Does the monitoring system consist of relevant procedures, instructions, and records that cover the following:		
219	System for the monitoring of critical control points	a) Measurements or observations that provide results within an adequate time frame?		
220	System for the monitoring of critical control points	b) Monitoring devices used?		
221	System for the monitoring of critical control points	c) Applicable calibration methods?		
222	System for the monitoring of critical control points	d) Monitoring frequency?		
223	System for the monitoring of critical control points	e) Responsibility and authority related to monitoring and evaluation of monitoring results?		
224	System for the monitoring of critical control points	f) Record requirements and methods?		
225	System for the monitoring of critical control points	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?		
226	Actions when monitoring results exceed critical limits	Are planned corrections and corrective actions - to be taken when critical limits are exceeded - specified in the HACCP plan?		

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No.	Section	Check Item	Result	Notes / Evidence No.
	Actions when monitoring results exceed critical limits	Do the actions ensure that:		
227	Actions when monitoring results exceed critical limits	a) The cause of nonconformity is identified?		
228	Actions when monitoring results exceed critical limits	b) The parameter(s) controlled at the CCP is (are) brought back under control?		
229	Actions when monitoring results exceed critical limits	c) Recurrence is prevented?		
230	Actions when monitoring results exceed critical limits	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	Does the organization update the following information in operational PRP(s) and/or the HACCP plan, if necessary:		
231	Updating of preliminary information and documents specifying the PRPs and the HACCP plan	a) Product characteristics?		
232	Updating of preliminary information and documents specifying the PRPs and the HACCP plan	b) Intended use?		
233	Updating of preliminary information and documents specifying the PRPs and the HACCP plan	c) Flow diagrams?		
234	Updating of preliminary information and documents specifying the PRPs and the HACCP plan	d) Process steps?		
235	Updating of preliminary information and documents specifying the PRPs and the HACCP plan	e) Control measures?		
236	Updating of preliminary information and documents specifying the PRPs and the HACCP plan	Are the HACCP plan and the procedures and instructions specifying the PRP(s) amended, if necessary?		
237	Verification planning	Does verification planning define the purpose, methods, frequencies, and responsibilities for the verification activities?		
	Verification planning	Do the verification activities confirm that:		
238	Verification planning	a) The PRP(s) are implemented?		
239	Verification planning	b) Input to the hazard analysis is continually updated?		
240	Verification planning	c) The operational PRP(s) and the elements within the HACCP plan are implemented and effective, d) hazard levels are within identified acceptable levels?		
241	Verification planning	e) Other procedures required by the organization are implemented and effective?		
242	Verification planning	Is the output of verification planning in a form suitable for the organization's method of operations?		
243	Verification planning	Are verification results recorded and communicated to the food safety team?		
244	Verification planning	Are verification results provided on such way to enable the analysis of the results of the verification activities?		

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No.	Section	Check Item	Result	Notes / Evidence No.
245	Verification planning	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?		
246	Traceability system	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?		
247	Traceability system	Is the traceability system able to identify incoming material from the immediate suppliers and the initial distribution route of the end product?		
248	Traceability system	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?		
249	Traceability system	Are records in accordance with statutory and regulatory requirements and customer requirements?		
250	Corrections	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?		
	Corrections	Is a documented procedure established and maintained defining:		
251	Corrections	a) The identification and assessment of affected end products to determine their proper handling?		
252	Corrections	b) A review of the corrections carried out?		
253	Corrections	Are potentially unsafe products - manufactured under conditions where critical limits have been exceeded - handled?		
254	Corrections	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?		
255	Corrections	Are these products, where necessary, handled?		
256	Corrections	Is the evaluation recorded?		
257	Corrections	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?		
258	Corrective actions	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?		
259	Corrective actions	Are corrective actions initiated when critical limits are exceeded or when there is a lack of conformity with operational PRP(s)?		
260	Corrective actions	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.		
261	Corrective actions	Are corrective actions recorded?		
	General	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		
262	General	a) The food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels?		
263	General	b) The food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain?		
264	General	c) The product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity?		

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No.	Section	Check Item	Result	Notes / Evidence No.
265	General	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?		
266	General	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.		
267	General	Are the controls and related responses and authorization for dealing with potentially unsafe products documented?		
	Evaluation for release	Is each lot of product affected by the nonconformity released as safe only when any of the following conditions apply:		
268	Evaluation for release	a) Evidence other than the monitoring system demonstrates that the control measures have been effective?		
269	Evaluation for release	b) Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended?		
270	Evaluation for release	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	Is the lot of product - which is not acceptable for release - handled (after evaluation) by one of the following activities:		
271	Disposition of nonconforming products	a) Reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels?		
272	Disposition of nonconforming products	b) Destruction and/or disposal as waste?		
	Withdrawals	To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe		
273	Withdrawals	a) Has top management appointed personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal?		
274	Withdrawals	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?		
275	Withdrawals	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?		
276	Withdrawals	Are the cause, extent and result of a withdrawal recorded and reported to top management as input to the management review?		
277	Withdrawals	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)?		
	Withdrawals	Please proceed to Section 8.		
278	General	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?		
	Validation of control measure combinations	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:		
279	Validation of control measure combinations	a) The selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated?		
280	Validation of control measure combinations	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?		
281	Validation of control measure combinations	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?		

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No.	Section	Check Item	Result	Notes / Evidence No.
282	Validation of control measure combinations	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.		
283	Control of monitoring and measuring	Is there evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures?		
	Control of monitoring and measuring	Are the measuring equipment and methods used:		
284	Control of monitoring and measuring	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		
285	Control of monitoring and measuring	b) Adjusted or re-adjusted as necessary?		
286	Control of monitoring and measuring	c) Identified to enable the calibration status to be determined?		
287	Control of monitoring and measuring	d) Safeguarded from adjustments that would invalidate the measurement results?		
288	Control of monitoring and measuring	e) Protected from damage and deterioration?		
289	Control of monitoring and measuring	Are records of the results of calibration and verification maintained?		
290	Control of monitoring and measuring	Does the organization assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements?		
291	Control of monitoring and measuring	Does the organization take action appropriate for the equipment and any product affected, If the measuring equipment is non-conforming?		
292	Control of monitoring and measuring	Are records of such assessment and resulting actions maintained?		
293	Control of monitoring and measuring	Is the ability of computer software confirmed to satisfy the intended application when used in the monitoring and measurement of specified requirements?		
294	Control of monitoring and measuring	Is the confirmation of computer software undertaken prior to initial use and reconfirmed as necessary?		
	Internal audit	Does the organization conduct internal audits at planned intervals to determine whether the food safety management system:		
295	Internal audit	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?		
296	Internal audit	b) Is effectively implemented and updated?		
297	Internal audit	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?		
298	Internal audit	Are the audit criteria, scope, frequency, and methods defined?		
299	Internal audit	Do the selection of auditors and the conduct of audits ensure objectivity and impartiality of the audit process?		
300	Internal audit	Is it ensured that auditors do not audit their own work?		
301	Internal audit	Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records defined in documented procedure?		
302	Internal audit	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?		
303	Internal audit	Do follow-up activities include the verification of the actions taken and the reporting of verification results?		
304	Evaluation of individual verification results	Does the food safety team systematically evaluate the individual results of planned verification?		
305	Evaluation of individual verification results	Does the organization take action to achieve the required conformity, when verification does not demonstrate conformity with the planned arrangements?		

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No.	Section	Check Item	Result	Notes / Evidence No.
	Evaluation of individual verification results	Does action – taken for achieving the required conformity – include (but is not limited to), review of:		
306	Evaluation of individual verification results	a) Existing procedures and communication channels?		
307	Evaluation of individual verification results	b) The conclusions of the hazard analysis, the established operational PRP(s) and the HACCP plan?		
308	Evaluation of individual verification results	c) The PRP(s)?		
309	Evaluation of individual verification results	d) The effectiveness of human resource management and of training activities?		
310	Analysis of results of verification activities	Does the food safety team analyze the results of verification activities, including the results of the internal audits and external audits?		
	Analysis of results of verification activities	Is the analysis carried out in order		
311	Analysis of results of verification activities	a) To confirm that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the organization?		
312	Analysis of results of verification activities	b) To identify the need for updating or improving the food safety management system?		
313	Analysis of results of verification activities	c) To identify trends which indicate a higher incidence of potentially unsafe products?		
314	Analysis of results of verification activities	d) To establish information for planning of the internal audit programme concerning the status and importance of areas to be audited?		
315	Analysis of results of verification activities	e) To provide evidence that any corrections and corrective actions that have been taken are effective?		
316	Analysis of results of verification activities	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?		
317	Analysis of results of verification activities	Are the results of the analysis and the resulting activities used as an input for updating the food safety management system?		
318	Continual improvement	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 verification activities, - validation of control measure combinations, - corrective actions and - food safety management system updating?		
319	Updating the food safety management system	Does top management ensure that the food safety management system is continually updated?		
320	Updating the food safety management system	Does the food safety team evaluate the food safety management system at planned intervals in order to achieve that FSMS is continually updated?		
321	Updating the food safety management system	Does the team consider whether it is necessary to review the hazard analysis, the established operational PRP(s) and the HACCP plan?		
	Updating the food safety management system	Are the evaluation and updating activities based on:		
322	Updating the food safety management system	a) Input from communication, external as well as internal?		
323	Updating the food safety management system	b) Input from other information concerning the suitability, adequacy, and effectiveness of the food safety management system?		
324	Updating the food safety management system	c) Output from the analysis of results of verification activities?		
325	Updating the food safety management system	d) Output from management review?		
326	Updating the food safety management system	Are system updating activities recorded and reported, in an appropriate manner, as input to the management review?		
	Completion	Recommendation		

ISO 22000 Audit Checklist — Scoring & Sign-off

Sign-off

Inspector's Full name and Signature	
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