Summary of comparison and revision of JFS-C Standard Document Guideline (Ver.3.1 Edit.1.0/Ver.3.2 Edit.1.0)

JFS-C V3.1 Edit.1.0: JFS-C Standard Document Ver.3.1 Guideline Edit.1.0 JFS-C V3.2 Edit.1.0: JFS-C Standard Document Ver.3.2 Guideline Edit.1.0

Red text: Main additions, corrections, etc.

JFS-C V3.1 Edit.1.0

Introducti on JFS-C V3.2 Edit.1.0 Introducti on

Number	Item		Explanatory text etc.	Number	Item		Explanatory text etc.	Summary of major revisions
	Scope of	Table 1:Reference	The GFSI Benchmarking Requirements version 2020.1 PART I		Scope of	Table 1:Reference	The GFSI Benchmarking Requirements version 2024 PART I	•Alignment with "The GFSI
1.2	Application			1.2	Application			Benchmarking Requirements version
1.2	, ppileacion			112	, application			2024″
	Structure of		The Standard Document is consistent with the benchmark requirement		Structure of	-	The Standard Document is consistent with the benchmark requirement version	•Alignment with "The GFSI
	JFS-C		version 2020.1 (*3 nereatier, BR 2020.1) published by GFSI in June 2020.		JFS-C		2024 (*3 hereafter, BR 2024) published by GFSI in December 2024. On the	Benchmarking Requirements Version
1 3	standard		On the other hand, since BR 2020.1 adopts ISO22000:2018 (*4) in its scope	13	standard		other hand, since BR 2024 adopts ISO22000:2018 (*4) in its scope structure	2024″
1.5	document		structure and numbering structure, this Standard Document has a structure	1.5	document		and numbering structure, this Standard Document has a structure consistent	1
	document		consistent with both the scope structure and numbering structure.		document		with both the scope structure and numbering structure.	1
			(*3) GFSI "The GFSI Benchmarking Requirements version 2020.1"				(*3) GFSI "The GFSI Benchmarking Requirements version 2024"	•Alignment with "The GFSI
								Benchmarking Requirements version
								2024″
				-				Addition of itom numbers due to
			PLAN (FSM) @ DO (FSM) @ FSM 1@ Top Management Responsibility@ FSM 7@ Food defense@				PLAN (FSM) # DO (FSM) # FSM 1# Top Management Responsibility# FSM 7# Food defense#	•Addition of item numbers due to
			FSM 2-4 Steps Cultured FSM 8-4 Food Fraud Prevention				FSM 2-9 Top Management Commitment and Food Safety FSM 8-1 Food Fraud Prevention	alignment with "The GFSI
			FSM 4# Compliance with food safety laws FSM 11# Procedures and Instructions#				FSM 4/P Compliance with food safety laws? FSM 11# Procedures and Instructions?	Benchmarking Requirements version
			FSM 5 [®] Food Safety Management System and General Requirements [®] FSM 14.1 [®] Traceability [®]				FSM 5 Food Safety Management System and General Requirements FSM 14.1 Traceability	2024″
			FSM 6- Food Safety Policy and Goals- FSM 15- Product development- FSM 9 1- Documentation procedures- FSM 16- Allergen Management-				FSM 6 ^{ad} Food Safety Policy and Goals ^{ad} FSM 15 ^{ad} Product development ^{ad} FSM 9.1 ^{ad} Documentation procedures ^{ad} FSM 16 ^{ad} Allergen Management ^{ad}	1
			FSM 9.2 Control and storage of documented FSM 17 Control of Measuring and Monitoring				FSM 9.2 Control and storage of documented information FSM 17 Control of Measuring and Monitoring Devices Specification Control of Purchased or Provided	1
			FSM 10-4 Specification Control of Purchased or Provided FSM 19.1-4 Analysis and Testing				FSM 10 ²⁰ Items and Services ²⁰ FSM 19.1 ²⁰ Analysis and Testing ²⁰	1
		(Item number	ESM 12 Becourse Management 1 ESM 19 21 Environmental Monitoring for Food			(Item number	FSM 12. ² Resource Management ² FSM 19.2 ⁴ Manufacturing ²	1
		classification in the	FSM 12/2 Resource management FSM 19.2 Manufacturing FSM 13.1 ^a Purchasing FSM 22.1 ^a Serious Incident Management			classification in the	FSM 13.10 Purchasing FSM 19.30 Cleaning and Disinfection Program FSM 13.20 Supplier Performance FSM 22.10 Serious Incident Management	1
		table)	FSM 13.2 ⁻³ Supplier Performance- ³ FSM 23.2 ⁻³ Product Release- ⁴			table)	FSM 13.3 Outsourcing FSM 23.2 Product Release Image: State	1
			FSM 13.3 ^a Outsourcing ^a FSM 24 ^a Identification of honconforming products ^a				Product labeling (B-to-C products) PSM 24 of nonconforming products	1
			FSM 18.1 ^o Product labeling (B-to-C products) ^o CHECK (FSM) Performance evaluation ^o Product labeling ^o Product labeling ^o				FSM 18.2 ^o (B-to-B products, work in progress, semi- Fisiched and units)	1
			FSM 18.2 ^a (B-to-B products, work in progress, semi- finished products)← FSM 3+ Management Review←				FSM 23.1 Management of product specifications FSM 3 Management Review	1
			FSM 23.1-9 Management of product specifications FSM 14.2-9 Traceability verification FSM 23.1-9 Charge memory of the specification of the specification FSM 14.2-9 Traceability verification				FSM 26 ^a Change management ^a FSM 14.2 ^a Traceability verification ^a FSM 20 ^a Internal Audit ^a Internal Audit ^a	1
			FSM 20+** Internal Audit** FSM 20+** Internal Audit** FSM 20+** Internal Audit**				FSM 21 Complaint Handling FSM 22.2 Verification of food incident response manual	1
			FSM 22.24 Verification of food incident response manual 4				ei ACT (FSM) Improvementei ei ESM 25:41	1
			← ACT (FSM) Improvement⊷ FSM 25 ← Corrective Action⊷	1			FSM 25P Corrective Action FSM 27P Utilization of Kaizen suggestions from	1 1
			FSM 274 Utilization of Kaizen suggestions from				Figure 1 Conceptual diagram of two PDCA cycles in the JFS-C Standard Document	1 1
			Figure 1 Conceptual diagram of two PDCA cycles in the JFS-C Standard Document Food Safety Management System				Food Safety Management System	
			The food safety management system established by each food business		150.0		The food safety management system established by each food business	•Additional corrections to the
	JFS-C		organization differs depending on many factors such as industry, business		JFS-C		organization differs depending on many factors such as industry, business	notation
1 4	Standard		category, business scale, and social background. This guideline is intended to	1 4	Standard		category, products, business scale, and social background. This guideline is	1
1.4	Document		be used as a reference for each organization to build a food safety	1.4	Document		intended to be used as a reference for each organization to build a food safety	1
	Guideline		management system suited to their own needs.		Guideline		management system suited to their own needs.	1
FSM	-			FSM		-		
Number	Item	Requirements	Concepts and specific examples	Number	Item	Requirements	Concepts and specific examples	Summary of major revisions
FSM 2	Тор	Top management	1. Top management is responsible for the establishment, implementation, and	FSM 2	Тор	Top management	1.Top management is responsible for maintaining a positive food safety culture	 Alignment with "The GFSI
	Managemen	shall show	maintenance of the food safety management system and demonstrates its		Managemer	shall demonstrate	and for establishing, implementing, maintaining and continually improving the	Benchmarking Requirements version
	t	evidence of its	commitment to the establishment, implementation, and maintenance of the		t	evidence of its	food safety management system, and demonstrates its commitment to	2024″
	Commitmen	commitment to	system through the implementation of the following:		Commitmer	commitment to	establishing direction, engaging personnel and providing sufficient resources	1
	t and Food	building,	1) Develop a food safety policy.		t and Food	establish direction,	through the implementation of the following:	1
	Safety	implementing,	2) Communicate to employees in a timely manner the importance of		Safety	engage personnel,	1) Develop a food safety policy.	1
	Culture	maintaining and	compliance with laws, standards, social norms, and rules set by the		Culture	and provide	2) Communicate to employees in a timely manner the importance of	1
		continually	organization.			sufficient resources	compliance with laws, standards, social norms, and rules set by the	1
		improving its food	3) Review the food safety management system in a timely manner.			to maintain a	organization.	1
		safety	Provide necessary resources in a timely manner.			positive food safety	3) Review the food safety management system in a timely manner.	1
		management	5) Ensure that employees are aware of factors that can influence food			culture and develop	4) Provide necessary resources including human resources in a timely manner.	1
		systems.	defense and food fraud risks. To this end, establish and maintain a system			and continuously	5) Ensure that employees are aware of factors that can influence food defense	1
			that allows the organization to constantly obtain the following information.			improve food	and food fraud risks. To this end, establish and maintain a system that allows	1
			● All related laws			safety	the organization to constantly obtain the following information.	1
			 Scientific and technological developments 			management	● All related laws	1
			 Industry code of practice 			system shall be	 Scientific and technological developments 	1
			 Other information on food safety and product quality issues, etc. 			provided.	 Industry code of practice 	1
			6) Engage, direct, and support employees to contribute to food safety				• Other information on food safety and product quality issues, etc.	1
			effectiveness.				6) Engage, direct, and support employees to contribute to food safety	1
			7) Set business goals that support food safety.				effectiveness.	1
			8) Provide opportunities and means for all employees involved in food safety	1			7) Set business goals that support food safety.	1
			to provide the organization with potential food safety improvements they				8) Provide opportunities and means for all employees involved in food safety to	1
			discover. (Responding to "Suggestions for improving food safety from				provide the organization with potential food safety improvements they discover.	1
			employees" listed in "FSM 27.")				(Responding to "Suggestions for improving food safety from employees" listed	1
							in "FSM 27.")	1
								1
		This commitment	9) Other matters necessary for the establishment implementation and			The organization	9) Other matters necessary for the establishment implementation and	1
		shall include	maintenance of food safety management systems			shall establish	maintenance of food safety management systems	1
		elements of a food	2. The following is a reference example of food safety culture elements for tor	,		implement and	2. In order to promote improvements through the food safety management	1 1
		safety culture and	management to include in their commitments to promote improvement			maintain an	system, the organization shall establish implement and maintain an	1 1
		this means at a	through the food safety management system (5 Dimonsions)	1		assessment plan to	assessment plan to identify areas for improvement to promote positive action	1 1
		minimum	1) Clarify the vision and mission	1		identify areas for	regarding the food safety culture that the top management commits to The	1 1
		communicating	Is food safety integrated into your business strategy? (including providing	1		improvement to	following are examples of the elements (5 dimensions)	1 1
		with employees	resources and other support)	1		drive a positivo	1) Clarify the vision and mission	1 1
		responding to	Does the company provide direction and objective goals to employees and	1		hehavior in its food	Is food safety integrated into your business strategy? (including providing	1 1
	1	Kaizen suggostions	clearly state what is expected of them?			safety culture. This	resources and other support)	(I
	1	training to improve	Does it provide messaging with leadership to employees?			assessment plan	Does the company provide direction and objective goals to employees and	1 1
		food safety and	2) Conduct outreach to the people	1		shall include at a	clearly state what is expected of them?	1 1
	1	assessing the	Have the necessary stakeholders been clarified and the governance structure			minimum	Does it provide messaging with leadershin to employees?	1 1
		performance of	clarified?	1		communicating	2) Conduct outreach to the people	1 1
		food safety	Do you communicate with employees on site? (e.g., by holding meetings)	1		with employees	Have the necessary stakeholders been clarified and the governance structure	1 1
	1	activities. In	Is there an organization in place for learning and training?			responding to	clarified?	(I
	1	addition. these	Does the company have an evaluation system (incentives, rewards			Kaizen suggestions	Do you communicate with employees on site? (e.g., by holding meetings)	1 1
		efforts shall be	recognition, etc.) for actions taken by employees?			training to improve	Is there an organization in place for learning and training?	1 1
		incorporated and	<u>3) Consistency.</u>			food safety, and	Does the company have an evaluation system (incentives, rewards, recognition.	1 1
		implemented in the	Is the top management taking the responsibility seriously as the person who			assessing the	etc.) for actions taken by employees?	1 1
		food safety	is ultimately responsible for the company?			performance of	<u>3) Consistency.</u>	1 1
		management	Are employees' performances properly evaluated?			food safety	Is the top management taking the responsibility seriously as the person who is	1 1
	1	systems of the	Are all processes kept in writing?			activities.	ultimately responsible for the company?	1 1
		entire organization.					Are employees' performances properly evaluated?	1 1
							Are all processes kept in writing?	1 1
						Andton		1 1
			4) Adaptability.				4) Adaptability.	1 1
			normal cultural differences of each employees?			induagement shall	outrey demonstrate rood safety expectations while understanding the personal cultural differences of each employees?	1 1
	1		personal cultural underences of each employees?				Does the company provide prompt feedback on employees offers?	1 1
	1		Is the business model appropriately changed to manage view and a shore			demonstrate a	Is the business model appropriately changed to manage view and as here	1 1
			ne pushess model appropriately changed to manage risks and solve				ns the pushess model appropriately changed to manage risks and solve	1 1
			provents:			to cofe feed	F) Decognize bezerde and ricke	1 1
1			J) Recognize flazatus allu fisks.	1		no sale 1000	Does the company provide rick provention education, such as hypervising basis	1 1

DUCS	the company provide risk prevention education, such as by p	loviung
basic	hazard information?	

Are employees involved in activities to prevent near misses? Are hazards verified when they occur and are risks communicated? 3.Fundamental to a well-functioning food safety management system is the establishment and maintenance of a positive food safety culture that recognizes the importance of the actions of all employees involved in providing safe and appropriate food. Therefore, it is advisable that not only top management but also all employees make a commitment. Reference examples are as follows.

(Reference case)

In order to prevent contamination by foreign matter, we will conduct thorough visual checks of the manufacturing process after washing/cleaning and before the start of manufacturing. etc.

	Does the company provide risk prevention education, such as by providing basis
andling.	hazard information?
	Are employees involved in activities to prevent near misses?
	Are hazards verified when they occur and are risks communicated?
	*The Food Communication Project (FCP) site on the Ministry of Agriculture,
	Forestry and Fisheries website (see link below) is also a useful reference.
	https://www.maff.go.jp/j/shokusan/fcp/index.html
	3.Fundamental to a well-functioning food safety management system is the
	establishment and maintenance of a positive food safety culture that recognizes
	the importance of the actions of all employees involved in providing safe and
	appropriate food. Therefore, top management shall ensure that all personnel
	demonstrate a clear commitment to safe food production and handling.
	Reference examples are as follows.
	(Reference case)
	 Personal commitments such as conducting thorough visual checks of the
	manufacturing process after washing/cleaning and before the start of
	manufacturing in order to prevent contamination by foreign matter. etc.
	• Signatures in the record after food safety training at the time of joining the
	organization or at morning meetings, etc.
	 Confirmation of commitment during food safety performance assessment.
	etc.

FSM 7	Food	The organization	1. Food defense means measures to prevent, avoid, and respond to the	FSM 7	Food	The organization	1.Food defense means measures to prevent, avoid, and respond to the	 Alignment with "The GFSI
	Defense	shall document,	intentional contamination of food by persons inside or outside the		Defense	shall document,	intentional contamination of food by persons inside or outside the organization	Benchmarking Requirements versior
		implement, and	organization with physical, chemical, and biological hazards.			implement, and	with physical, chemical, and biological hazards.	2024″
		record assessment	2. In the vulnerability assessment of food defense (analyzing threats and			record assessment	2.In the threat assessment of food defense (analyzing threats and identifying	 Additional corrections to the
		procedures to	identifying weak points), the risks of intentional food contamination described			procedures to	weak points), the risks of intentional food contamination described in 1. are	notation
		identify potential	in 1. are identified, their magnitude is evaluated, and the defensive measures			identify potential	identified, their magnitude is evaluated, and the defensive measures are	
		and overt threats	are formulated as a food defense plan. Since it is difficult to completely			and overt threats	formulated as a food defense plan. In light of the above, appropriate knowledge	
		to hazards of	protect against intentional food contamination because it is a human activity,			to hazards of	and expertise shall be utilized to develop and maintain an effective plan for this	
		intentional food	priorities are determined, documented, implemented, and recorded by			intentional food	assessment. Examples of how this can be utilized include looking at other	
		contamination by	contrasting the contents of each extracted vulnerability with the			contamination by	organizations' case studies posted on government recall sites, past case studies	
		persons within or	management resources that can be invested.			persons within or	within the organization, receiving specialized external training, and obtaining	
		outside the	3. Document and implement procedures for conducting vulnerability			outside the	the participation and advice of external food hygiene experts. Since it is difficult	
		organization and	assessments of facilities.			organization and	to completely protect against intentional food contamination because it is a	
		prioritize response	4.Based on the results of the food defense and facility vulnerability			prioritize response	human activity, priorities are determined, documented, implemented, and	
		to those threats.	assessment, document and implement a food defense plan that includes			to those threats.	recorded by contrasting the contents of each extracted threat with the	
			methods, responsibility and authority, and decision criteria to prevent			Appropriate	management resources that can be invested.	
			intentional food contamination, tampering, etc.			knowledge and	3.Document and implement procedures for conducting threat assessments of	
						expertise shall be	facilities.	
						utilized to develop	4.Based on the results of the food defense and facility threat assessment,	
						and maintain an	document, implement, verify and maintain a food defense plan that includes	
						effective plan for	methods, responsibility and authority, and decision criteria to prevent	
						this assessment.	intentional food contamination, tampering, etc. This food defense threat	
							assessment shall also be checked at intervals determined by the organization,	
							and/or when a new threat is established, and reviewed, if necessary, as a	
							result. The food defense plan shall be revised/updated as necessary and shall	
							be implemented, verified, and maintained.	
		The organization	5. The food defense plan includes the following elements:			The organization	5. The food defense plan includes the following elements:	
		shall document and	1) Personnel from each discipline with food defense responsibilities have			shall document,	1) Personnel from each discipline with food defense responsibilities have been	
		implement a food	been designated			implement, verify	designated	
		defense plan that	2) Have policies and procedures in place to record and control employees,			and maintain a	2) Elave policies and procedures in place to record and control employees,	
		specifies the	contractors, and visitors entering and leaving the facility area			food defense plan	contractors, and visitors entering and leaving the facility area	
		actions that the	3) Elave procedures to ensure the safety of raw materials, utensils,			that specifies the	3) Elave procedures to ensure the safety of raw materials, utensils, containers	
		organization	containers and packaging materials, drugs, and food during storage and			actions that the	and packaging materials, drugs, and food during storage and distribution.	
		implements to	distribution.			organization	4) The site shall be physically secured (security)	
		mitigate or exclude	 The site shall be physically secured (security) 			implements to	5) Have procedures and carry out in place for dealing with discovered or	
		the identified food	5) Have procedures and carry out in place for dealing with discovered or			mitigate or exclude	suspected intentionally contaminated or deteriorated food, packaging, or	
		defense threat.	suspected intentionally contaminated or deteriorated food, packaging, or			the identified food	equipment	
		This plan must	equipment			defense threat.	6) Elave an effective recall program (see FSM 22.1)	
		include GMP and be	6) 田ave an effective recall program (see FSM 22.1)			This plan shall also	7) Provide necessary education and training to personnel in accordance with	
		incorporated into	7) Drovide necessary education and training to personnel in accordance with			be checked at	the food defense plan established by the organization	
		the food safety	the food defense plan established by the organization			intervals	6.Access controls implemented for areas where food defense threats are	
		management	6.Access controls implemented for areas where food defense vulnerabilities			determined by the	identified are also included in the food defense plan. Access controls can include	2
		system.	are identified are also included in the food defense plan. Access controls can			organization, or	guards, ID cards, or systems that limit or record access to authorized	
			include guards, ID cards, or systems that limit or record access to authorized			when a new threat	personnel.	
			personnel.			is established, and		
						reviewed, if		
						necessary, as a		
						result.		
		The organization	7.Reference			The organization	7.Reference	
		shall also establish	1) In addition to monitoring cameras and lock controls, communication			shall also establish	1) In addition to monitoring cameras and lock controls, communication among	
		access controls for	among employees is a deterrent to food protection.			access controls for	employees is a deterrent to food protection.	
		areas where food	2) Excessive reliance on hard measures of food defense may instead damage			areas where food	2) Excessive reliance on hard measures of food defense may instead damage	
-	1	• - • • • • • • • •	The second contraction of the test of the second second second second $\overline{\mathbf{T}}_{i}$		-			-

		The organization shall establish and implement procedures for responding to possible intentional contamination of product.	 prove the actions of employees in the event of a food accident. 3) Ebod defense is not limited to physical measures of the facility; internal attacks from interested parties must also be anticipated. Ensuring that there are no short-term workers or disgruntled or disgruntled workers is particularly useful. 4) Almechanism for examining trends in social cases, cases of other companies in the same industry, prevention cases, and predictive signs is required. 8. For specific examples of food defense, please refer to the following. (1), (2), and (3) are applicable in Japan.) 1) Ministry of Health, Labour and Welfare "Guidelines for Food Defense Measures (for Food Production Plants)" (Draft revised in 2019) 2) Ministry of Health, Labour and Welfare "Guidelines for Food Protection Measures for Large-Scale Events (Manufacturing Plants)" (Revision 2) 3) Ministry of Agriculture, Forestry and Fisheries "Voluntary Action Plan for Enhancing Confidence in the Food Industry" Guidance for Formulation -Five Basic Principles - (Revised January 2016) (Basic Principle 2) Establish compliance awareness (Principle 3) Basis of proper hygiene and quality control (Basic Principle 5) Efforts to collect, communicate, and disclose information 4) EDA "Food Defense Mitigation Strategies Database (FDMSD)". https://www.cfsanappsexternal.fda.gov/scripts/fooddefensemitigationstrateg es/index.cfm 	i		The organization shall establish and implement procedures for responding to possible intentional contamination of product.	 the actions of employees in the event of a food accident. 3) Ebod defense is not limited to physical measures of the facility; internal attacks from interested parties must also be anticipated. Ensuring that there are no short-term workers or disgruntled or disgruntled workers is particularly useful. 4) Almechanism for examining trends in social cases, cases of other companies in the same industry, prevention cases, and predictive signs is required. 8. For specific examples of food defense, please refer to the following. (1), (2), and (3) are applicable in Japan.) 1) Ministry of Health, Labour and Welfare "Guidelines for Food Defense Measures (for Food Production Plants)" (Draft revised in 2019) 2) Ministry of Health, Labour and Welfare "Guidelines for Food Protection Measures for Large-Scale Events (Manufacturing Plants)" (Revision 2) 3) Ministry of Agriculture, Forestry and Fisheries "Voluntary Action Plan for Enhancing Confidence in the Food Industry" Guidance for Formulation -Five Basic Principles - (Revised January 2016) (Basic Principle 2) Establish compliance awareness (Principle 3) Basis of proper hygiene and quality control (Basic Principle 4) Establish systems for appropriate hygiene and quality control (Basic Principle 5) Efforts to collect, communicate, and disclose information 4) EDA "Food Defense Mitigation Strategies Database (FDMSD)". https://www.cfsanappsexternal.fda.gov/scripts/fooddefensemitigationstrategies / index.cfm 	
SM 8	Food Fraud Prevention	The organization shall document, implement, and record assessment procedures to identify potential and overt food fraud vulnerabilities such as tampering with records and labeling of products and intentional dilution, and prioritize food fraud mitigation measures.	 "Food fraud" refers to intentional acts committed primarily for economic reasons, such as tampering for the purpose of cost reduction or misrepresentation of good quality. Examples include dilution, substitution, concealment, fraudulent labeling, function enhancement by unauthorized means, counterfeiting, etc. Among these, this requirement covers food fraud as it relates to food safety. Examples of food fraud related to food safety include the following: Melamine contamination of powdered milk made in China in 2008 Ebrse meat contamination of beef-based food products sold in Ireland in 2013 (contamination of veterinary drugs) Methods to "identify potential and actual falsification of records and labeling and intentional dilution of products" include the following: 	FSM 8	Food Fraud Prevention	The organization shall document, implement, and record assessment procedures to identify potential and overt food fraud vulnerabilities such as tampering with records and labeling of products and intentional dilution, and prioritize food fraud mitigation measures. Appropriate knowledge and expertise shall be utilized to develop and maintain an effective plan for this assessment.	 "Food fraud" refers to intentional acts committed primarily for economic reasons, such as tampering for the purpose of cost reduction or misrepresentation of good quality. Examples include dilution, substitution, concealment, fraudulent labeling, function enhancement by unauthorized means, counterfeiting, etc. Among these, this requirement covers food fraud as it relates to food safety. Examples of food fraud related to food safety include the following: Melamine contamination of powdered milk made in China in 2008 Ebrse meat contamination of beef-based food products sold in Ireland in 2013 (contamination of veterinary drugs) Methods to "identify potential and actual falsification of records and labeling and intentional dilution of products" include the following: Rèfer to past or currently developing cases of food fraud in the supply chain. The organization will have a process in place for accessing cases of fraud. Such information can be obtained, for example, from Industry Associations Government Sources Private information centers Information systems established by the organization in the FSM2 Izlentify in what situations food fraud can occur. It is also effective to assume food fraud in each production flow as follows: Fraud uning manufacture Fraud in products after shipment (including resale of discarded defective products as food)	 Alignment with "The GFSI Benchmarking Requirements version 2024" Additional corrections to the notation
		The organization shall develop a documented plan that specifies the measures the organization implements to mitigate the identified threats of food fraud. This plan shall cover the GMP and shall be incorporated into the food safety management system.	 3. Supply chains are becoming more complex, extending overseas, and the risk of food fraud is increasing. "Assessing vulnerability" means analyzing what types of food fraud are likely to occur and how likely they are to occur due to external and internal factors in the context of such changes in the environment surrounding the organization. Vulnerability assessors need to understand the potential food fraud risks, which includes knowledge of the raw materials used in the field and the concept of vulnerability assessment described above. Vulnerability assessment is conducted from two perspectives: product/supplier. Examples of vulnerability assessment steps include: 1) Clarify the raw materials and their specifications related to the food products handled. 2) Estimate what are the events that could cause fraud (what kind of fraud could occur). 3) Estimate the magnitude of risk for any possible fraud that may occur. 4) Estimate the magnitude of the impact of fraud on food safety. 5) Prioritize vulnerabilities by risk and magnitude of impact. 			The organization shall document, implement, verify and maintain a plan that specifies the measures the organization implements to mitigate the identified threats of food fraud. This plan shall also be checked at intervals determined by the organization, or when new vulnerabilities are recognized, and reviewed, if necessary, as a result.	 3. Supply chains are becoming more complex, extending overseas, and the risk of food fraud is increasing. "Assessing vulnerability" means analyzing what types of food fraud are likely to occur and how likely they are to occur due to external and internal factors in the context of such changes in the environment surrounding the organization. Vulnerability assessors need to understand the potential food fraud risks, which includes knowledge of the raw materials used in the field and the concept of vulnerability assessment described above. Vulnerability assessment is conducted from two perspectives: product/supplier. In light of the above, appropriate knowledge and expertise shall be utilized to develop and maintain an effective plan for this assessment. Examples of how this can be utilized include looking at other organizations' case studies posted on government recall sites, past case studies within the organization, receiving specialized external training, and obtaining the participation and advice of external food hygiene experts. Examples of vulnerability assessment steps include: 1) Clarify the raw materials and their specifications related to the food products handled. 2) Estimate what are the events that could cause fraud (what kind of fraud could occur). 3) Estimate the magnitude of risk for any possible fraud that may occur. 4) Estimate the magnitude of the impact of fraud on food safety. 5) Prioritize vulnerabilities by risk and magnitude of impact. 	

			 4.Based on the results of the vulnerability assessment, a management plan to reduce food fraud shall be developed after conducting an evaluation of current control measures related to food fraud. The plan shall clearly identify priorities. The following methods can be used as means to reduce food fraud: 1) Conduct appropriate monitoring in response to vulnerabilities 2) Verification of origin and labeling 3) Specification Management 4) Conduct supplier audits 5) Enalytical testing 6) Use of anti-counterfeiting technology 7) Collect whistleblower testimonials from within the organization. 5.Examples of methods include the following: 1) Add fraud to the scope when conducting second-party audits. 2) Request that suppliers monitor their supply chains. 3) Change the origin/supplier of raw materials to one where there is no precedent for fraud. 4) Strengthen controls in situations where fraud practices are likely to occur (extremely low prices from suppliers used below market prices, soaring raw material prices, tight supply, frequent advance shipment times, sudden increases in order volumes, and understaffed production systems). 5) Edd fraud vulnerability to the frequency of analysis/testing. 6) Review the supplier's financial situation. 6.Organizations are required to clarify the scope of the above food fraud prevention plan and incorporate and operate it into their food safety management system. 7.The food fraud vulnerability assessment shall be reviewed at least annually and/or whenever significant changes occur. The food fraud, reduction plan will be revised/updated as needed. 8.Please refer to the following for concepts on fraud prevention. (1) is the scope of application in Japan.) 1) The "FCP's Focus on Collaboration," which was created by the Food Communication Project (FCP) launched by the Ministry of Agriculture, Forestry and Fisheries (M				 4.Based on the results of the vulnerability assessment, a management plan to reduce food fraud shall be developed after conducting an evaluation of current control measures related to food fraud. The plan shall clearly identify priorities. The following methods can be used as means to reduce food fraud: 1) Conduct appropriate monitoring in response to vulnerabilities 2) Værification of origin and labeling 3) Especification Management 4) Conduct supplier audits 5) Enalytical testing 6) Uise of anti-counterfeiting technology 7) Collect whistleblower testimonials from within the organization. 5.Examples of methods include the following: 1) Add fraud to the scope when conducting second-party audits. 2) Request that suppliers monitor their supply chains. 3) Change the origin/supplier of raw materials to one where there is no precedent for fraud. 4) Strengthen controls in situations where fraud practices are likely to occur (extremely low prices from suppliers used below market prices, soaring raw material prices, tight supply, frequent advance shipment times, sudden increases in order volumes, and understaffed production systems). 5) Edd fraud vulnerability to the frequency of analysis/testing. 6) Review the supplier's financial situation. 6.Organizations are required to clarify the scope of the above food fraud prevention plan and incorporate and operate it into their food safety management system. 7.Food fraud reduction plan will be revised/updated as needed. Food fraud vulnerability assessment shall be revised/and reviewed, if necessary, as a result. Food fraud reduction plan shall be revised/updated as necessary and shall be implemented, verified, and maintained. 8.Please refer to the following for concepts on fraud prevention. (1) is the scope of application in japan.) 1) The "FCP's Focus on Collaboration," which was created by the Food Commun	
FSM 10	Specification Control of Purchased or Provided Items and Services	For all purchased or provided input items and services (including raw materials and ingredients (including containers and packaging materials), equipment and tools, utilities, and services (e.g. electricity, water, transportation, maintenance)) that have an affect on the safety of final product, the organization shall ensure that documented specifications are prepared, maintained, securely retained and readily accessible when needed. The organization shall evaluate the risks and set the confirmation items (confirmation of inspection certificate, condition, temperature, display, etc.) on	 Maintain documentation of specifications for goods, equipment, tools, utilities, and services that the organization procures from external sources. Specifications requested by the organization for purchased goods, etc., or obtained from suppliers, etc., are evaluated within the organization to ensure that they are appropriate and intended. Li is important to maintain and control the specifications stored as documents so that they can be used as needed for verification at the time of acceptance. The organization shall assess the inherent risks of the items it purchases or receives supplies from and establish checks upon acceptance (e.g., inspection certificates, condition, temperature, labeling, etc.), as well as establish procedures for these checks. Anherent risks include, for example, the following hazards: Ta dign where temperature control is not properly implemented: histamine accumulation This requirement calls for attention to hazard factors in purchased products based on the product characteristics handled by the organization. S.If externally procured goods, equipment, tools, utilities, or services do not conform to specifications can include: Statement of compliance with laws and regulations Clustomer requirements (food safety is the subject of this standard) Blandling of specifications (e.g., frequency, timing, etc.) Whether on not to re-consign and its conditions, etc. Browlab inspection lems that conform to specification and a certificate of inspection (also called Certification of Puellement a review process for this information, including the frequency of periodic reviews. Bardling of specifications (e.g., frequency, timing, etc.) Whether or not to re-consign and its conditions, etc. Browling also cal	FSM 10	Specificatio n Control of Purchased or Provided Items and Services	For all purchased or provided input items and services (including raw materials and ingredients (including containers and packaging materials), equipment and tools, utilities, and services (e.g. electricity, water, transportation, maintenance)) that have an effect on the safety of final product, the organization shall ensure that documented specifications are prepared, maintained, securely retained and readily accessible when needed. Microbiological, physical, chemical and allergenic specifications shall be based on appropriate scientific principles. The organization shall evaluate the risks and set the confirmation items (confirmation of inspection certificate, condition, temperature, display, etc.) on the items to be purchased or provided. In addition, the organization shall define and implement a review process that includes the handling of changes in specifications and the frequency of regular reviews.	 Maintain documentation of specifications for goods, equipment, tools, utilities and services that the organization procures from external sources. Specifications requested by the organization for purchased goods, etc., or obtained from suppliers, etc., are evaluated within the organization to ensure that they are appropriate and intended. Microbiological, physical, chemical and allergenic specifications shall be based on appropriate scientific principles. It is important to maintain and control the specifications stored as documents so that they can be used as needed for verification at the time of acceptance. The organization shall assess the inherent risks of the items it purchases or receives supplies from and establish checks upon acceptance (e.g., inspection certificates, condition, temperature, labeling, etc.), as well as establish procedures for these checks. If ground beef requiring adequate heat: enterohemorthagic E. coli O-157 If aredfish where temperature control is not properly implemented: histamine accumulation This requirement calls for attention to hazard factors in purchased products based on the product characteristics handled by the organization. If externally procured goods, equipment, tools, utilities, or services do not conform to specifications, procedures shall also be established to ensure that they are not misused. Procedures should be documented as necessary. G.In addition to specific requirements for goods, equipment, tools, utilities, and services, specifications can include: Statement of compliance with laws and regulations Ustormer requirements (food safety is the subject of this standard) Bandling of specification changes Review of specification changes Review of specification items that conform to superifications and a certificate of inspection (laso called Certification of Quality or Certification of Analysis)<!--</th--><th>Alignment with "The GFSI Benchmarking Requirements version 2024"</th>	Alignment with "The GFSI Benchmarking Requirements version 2024"
НАССР				FSM 19.3	Cleaning and Disinfection Program	The organization shall establish, implement, and maintain a cleaning and disinfection program. The Cleaning and disinfection Program shall include measures to verify the effectiveness of this program.	 1.FSM 19.3 requires the establishment, implementation, maintenance and verification of effectiveness of the cleaning and disinfection program, while GMF 8 requires specific implementation details for housekeeping, cleaning, sterilization, and disinfection. 2.The cleaning and disinfection program shall clarify the areas to be covered, the method and frequency of work, the detergents and tools to be used, the method for confirming effectiveness, the method for recording, etc. 3.For details on implementation procedures, etc., refer to GMP8. 	•Alignment with "The GFSI Benchmarking Requirements version 2024"
HACCP Step 1	HACCP team assembly and identificatio n of the scope of application	HACCP team shall be assembled with competent staff, and the scope of application of the HACCP system and applicable GMPs shall be identified. The scope shall be documented what products and processes are covered by which HACCP plan.	1.By forming the HACCP team with people with as many specialized skills as possible from the manufacturing/processing department, quality assurance/quality control department, and the maintenance department responsible for the maintenance and preservation of facilities and machinery used in manufacturing, it is possible to eliminate blind spots in hazard analysis and facilitate communication. The HACCP team leader (food safety officer) should be a food hygiene officer or food hygiene manager who has knowledge of the product and specialized skills, and knowledge of the product and specialized skills, and knowledge of the product's characteristics and processes, furthermore, has strong communication skills and is able to summarize opinions within the organization. When the Food Safety Officer and the HACCP team leader are different personnel, it is necessary to ensure that they communicate with each other. 2.Depending on the size of the business, there are many cases in which various tasks are performed holding multiple positions, and for this reason, the top management himself may be the team leader, or one person may be responsible for all food safety-related actions, etc. However, it is important to try to ensure the cooperation of employees within the organization to the extent possible. 3.If the number of employees is small, the team does not necessarily need to be composed of several people. It is also possible to use outside resources. 4.If the organization lacks in-house knowledge or expertise, it can be also effective to receive external training or to obtain the participation and advice of external food hygiene experts.	HACCP Step 1	HACCP team assembly and identificatio n of the scope of application	The organization shall assemble the HACCP team with competent staff to identify the scope of the HACCP system and the applicable GMPs. The scope shall be documented what products and processes are covered by which HACCP plan. Additionally, appropriate knowledge and expertise shall be utilized in developing an effective HACCP system.	 By forming the HACCP team with people with as many specialized skills as possible from the manufacturing/processing department, quality assurance/quality control department, and the maintenance department responsible for the maintenance and preservation of facilities and machinery used in manufacturing, it is possible to eliminate blind spots in hazard analysis and facilitate communication. The HACCP team leader (food safety officer) should be a food hygiene officer or food hygiene manager who has knowledge of the product and specialized skills, and knowledge of the product's characteristics and processes, furthermore, has strong communication skills and is able to summarize opinions within the organization. When the Food Safety Officer and the HACCP team leader are different personnel, it is necessary to ensure that they communicate with each other. Depending on the size of the business, there are many cases in which various tasks are performed holding multiple positions, and for this reason, the top management himself may be the team leader, or one person may be responsible for all food safety-related actions, etc. However, it is important to try to ensure the cooperation of employees within the organization to the extent possible. If the number of employees is small, the team does not necessarily need to be composed of several people. It is also possible to utilize outside resources. If the organization lacks in-house knowledge or expertise, it can be also effective to receive external training or to obtain the participation and advice of external food hygiene experts. 	• Supplementary correction of notation

HACCP Step 2	Product Description	Product specifications shall be documented. The document shall describe all product information necessary to conduct hazard analysis. Scope of the HACCP system shall be defined per product or product group and per process line or process location. This system should be systematic and comprehensive and take into account legal and regulatory requirements related to food safety.	 S.The HACCP team shall identify the scope of the HACCP system and appropriate GMPs (PRPs in ISO 22000). Examples of documentation of products and processes covered by the HACCP plan include inclusion in product manuals. G.The main roles of the HACCP team, other than the above No.5, are as follows: Perparation of HACCP Plan Establishment of GMP Establishment of GMP Batablishment of GMP Brapiration of HACCP system and GMP verification Every amendment or change of the HACCP plan based on verification results Brapiration of changes in raw materials, product composition, manufacturing processes, etc. and review of HACCP plans accordingly Review, improve, or modify HACCP plans as needed based on new food hygiene information Reponse to external inspections The HACCP team is responsible for managing food safety efforts within the organization. In order to clarify the characteristics of the product, describe the specifications and characteristics of the final product, divided into necessary items, as follows: Specifically, for the final product, describe the name and type of product, the intended use/purpose of additives and standards for use, form of packaging, units and quantities, materials of containers and packaging, expiration date or best before date and storage method, distribution method, internal targets for controlling hazards in the product, including the standard criteria specified by the recipient. End facilities that manufacture multiple products, it can be effective to group food stogether for purposes of developing HACCP plans, depending on similar characteristics and processing steps. Eladicities that manufacture multiple products, it can be effective to group food stogether for purposes of developing HACCP plans, depending on similar characteristics and processing steps. 	HACCP Step 2	Product Description	The organization shall document product specifications. The document shall describe all product information necessary to conduct hazard analysis. Scope of the HACCP system shall be defined per product or product group and per process line or process location. This system should be systematic and comprehensive and take into account legal and regulatory requirements related to food safety.	 S.The HACCP team shall identify the scope of the HACCP system and appropriate GMPs (PRPs in ISO 22000). Examples of documentation of products and processes covered by the HACCP plan include inclusion in product manuals. G.The main roles of the HACCP team, other than the above No.5, are as follows: Preparation of AACCP Plan Etablishment of GMP Preparation of sanitation standard operating procedures Education and training for personnel in charge of HACCP plan implementation Implementation of HACCP system and GMP verification Review, amendment or change of the HACCP plan based on verification results Education of changes in raw materials, product composition, manufacturing processes, etc. and review of HACCP plans accordingly Review, improve, or modify HACCP plans as needed based on new food hygiene information Response to external inspections The HACCP team is responsible for managing food safety efforts within the organization. 1.In order to clarify the characteristics of the product, describe the specifications and characteristics of the final product, divided into necessary items, as follows: Specifically, for the final product, describe the names of raw materials, names of additives and standards for use, form of packaging, units and quantities, materials of containers and packaging, expiration date or best before date and storage method, distribution method, internal targets for controlling hazards in the product (Ingredient standards for bacteria specified by the recipient. If acilities that manufacture multiple products, it can be effective to group foods together for purposes of developing HACCP plans, depending on similar characteristics and processing steps. If alellergens are included, or if there may be cross-contact of allergens in the same facility, this shall also be noted. 	•No change to the guideline
HACCP Step 3	Identificatio n of Intended Use	Intended use of the product and target users (consumers) shall be clearly described in a written document.	 The intended use (method of use) and intended users (consumers) of the product shall be described in the document as follows: Clarify the methods of consumption and use of the food and the target consumers. Particular attention shall be paid to the content, especially in the case of vulnerable health consumers, young children, and the elderly. If the intended use includes cases where the product requires cooking with heat or where precautions after opening the package, the necessary information shall be stated. If shall clearly state what the risks are if the intended use is not followed and misused. For foods intended for susceptible populations, a high level of assurance that the food is safe can require enhanced process controls, more frequent monitoring, product testing to verify the effectiveness of controls, or other activities. 	HACCP Step 3	Identificatio n of Intended Use	The organization shall clearly describe intended use of the product and target users (consumers) in a written document.	 The intended use (method of use) and intended users (consumers) of the product shall be described in the document as follows: Clarify the methods of consumption and use of the food and the target consumers. Particular attention shall be paid to the content, especially in the case of vulnerable health consumers, young children, and the elderly. If the intended use includes cases where the product requires cooking with heat or where precautions after opening the package, the necessary information shall be stated. If shall clearly state what the risks are if the intended use is not followed and misused. For foods intended for susceptible populations, a high level of assurance that the food is safe can require enhanced process controls, more frequent monitoring, product testing to verify the effectiveness of controls, or other activities. 	•No change to the guideline
HACCP Step 4	Construction of Flow Diagram	The flow diagram that covers all steps in the operation shall be constructed.	1. For a series of manufacturing or processing processes from receipt of raw materials to shipment of the final product, a flow diagram shall be prepared to show the operations of each process along the flow. This shall include any applicable rework. The same flow diagram can be used for a group of products manufactured using similar processing steps. 2. The flow diagram is used as the basis for evaluating the likelihood of occurrence, increase, decrease, survival, or contamination of a hazard factor when conducting a hazard factor analysis. 3. The flow diagram is used as the basis for evaluating the likelihood of occurrence, increase, decrease, survival, or contamination of a hazard factor when conducting a hazard factor analysis. 3. The flow diagram Shall be accurate and detailed enough to perform a hazard analysis. Creating a flow diagram. 4. The flow diagram shall be created according to the following procedure: 1) Biefly list all processes and operations from receipt of raw materials to shipment of final products and applicable rework. 2) The listed raw materials and processes shall be enclosed in a frame, the frames are connected with arrows, and the process is numbered in order. For raw materials, food additives, water and packaging materials used, gas (only if used), and other materials that come into contact with the product shall be also written down, and these shall be written in a box in the same row, and arrows shall be connected to the process in wilk they are used. 3) The the process, if there are processes with pass/fail judgment, reprocess hey mother and raws that it can be controlled. 5) The process being outsourced shall also be clearly stated so that it can be controlled. 5) The process being outsourced shall also be clearly stated so that it can be controlled. 5. We drawings of the facility showing the outline of each process and the planar and three-dimensional layout of the facility, it is possible to identify	HACCP Step 4	Constructio n of Flow Diagram	The organization shall construct the flow diagram that covers all steps in the operation.	LiFor a series of manufacturing or processing processes from receipt of raw materials to shipment of the final product, a flow diagram shall be prepared to show the operations of each process along the flow. This shall include any applicable rework. The same flow diagram can be used for a group of products manufactured using similar processing steps. 2. The flow diagram is used as the basis for evaluating the likelihood of occurrence, increase, decrease, survival, or contamination of a hazard factor when conducting a hazard factor analysis. 3. The flow diagram shall be accurate and detailed enough to perform a hazard analysis. [Creating a flow diagram] 4. The flow diagram shall be created according to the following procedure: 1) Briefly list all processes and operations from receipt of raw materials to shipment of final products and applicable rework. 2) The listed raw materials and processes shall be enclosed in a frame, the frames are connected with arrows, and the process is numbered in order. For raw materials, food additives, water and packaging materials used, gas (only if used), and other materials that come into contact with the product shall be allow arrows shall be connected to the process in which they are used. 3) In the course of raw material processing, if waste is generated or it becomes a processed raw material to be used in other products, it shall be clearly stated. 5) The process being outsourced shall also be clearly stated. 5. By drawings of the facility, showing the outline of each process and the planar and three-dimensional layout of the facility, it is possible to identify process key points and areas where cross-contamination is possible, which can aid in hazard analysis. Fue fuences fuences from the facility, it is possible to identify process key points and areas where cross-contamination is possible, which can aid in hazard in hazard in the same fuence fuence for the process in the facility is the foremation in the same fuence for the same fuence foremation is possible, wh	•No change to the guideline
HACCP Step 5	On-site Confirmatio n of Flow Diagram	The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.	 1.A person with sufficient knowledge of the process shall verify on-site that the process is clearly defined in the flow diagram so that the hazard analysis in HACCP Step 6 (Principle 1) can be sufficiently performed. At that time, the on-site verification shall be performed as follows, while checking against the site layout diagram: 1) At the site, verification shall be carried out step by step from the upstream process, to check that appropriate processes are shown, including temporary storage of products and management of semi-finished products. 2) If a process or activity is inconsistent with the flow diagram at the site, check with the responsible person for the correct control method and correct the documentation. 3) Werification shall be observing the work during various work periods to ensure that the flow diagram matches the work. 	HACCP Step 5	On-site Confirmatio n of Flow Diagram	The organization shall verify the flow diagram whether correctly reflects the existing process steps of the operation.	 1.A person with sufficient knowledge of the process shall verify on-site that the process is clearly defined in the flow diagram so that the hazard analysis in HACCP Step 6 (Principle 1) can be sufficiently performed. At that time, the onsite verification shall be performed as follows, while checking against the site layout diagram: 1) At the site, verification shall be carried out step by step from the upstream process, to check that appropriate processes are shown, including temporary storage of products and management of semi-finished products. 2) If a process or activity is inconsistent with the flow diagram at the site, check with the responsible person for the correct control method and correct the documentation. 3) Werification shall be observing the work during various work periods to ensure that the flow diagram matches the work. 	•No change to the guideline

								1.5.4.1.1
IACCP	Hazard	The HACCP team	1. Hazard analysis is to identify potential hazards to be controlled by the	НАССР	Hazard	The organization	1. Hazard analysis is to identify potential hazards to be controlled by the HACCP • Modification of Haza	ard Matrix
step 6	Analysis	shall list all the	HACCP plan, determining critical hazards, and clarifying control measures for	Step 6	Analysis	shall list all the	plan, determining critical hazards, and clarifying control measures for each Examples	
Principle 1)		hazards that are	each critical hazard. For this purpose, information is first collected on	(Principle 1)		hazards that are	critical hazard. For this purpose, information is first collected on potential	
		reasonably likely to	potential hazards and the conditions under which they can occur throughout			reasonably likely to	hazards and the conditions under which they can occur throughout the entire	
		occur in each	the entire process from raw materials, manufacturing and processing,			occur in each	process from raw materials, manufacturing and processing, storage and	
		process steps.	storage and distribution to consumption, and the likelihood of occurrence of			process steps.	distribution to consumption, and the likelihood of occurrence of the hazards and	
		Potential hazards in	the hazards and the severity of the hazards when they do occur are			Potential hazards in	the severity of the hazards when they do occur are identified.	
		each process shall	identified.			each process shall	1) Elazards shall be specific and shall explain the cause or reason for their	
		be identified, the	1) Elazards shall be specific and shall explain the cause or reason for their			be identified, the	presence. The potential misuse of the product by potential consumers that	
		critical hazards	presence. The potential misuse of the product by potential consumers that			critical hazards	would make the food unsafe, as well as any unintended uses that could be	
		shall be identified,	would make the food unsafe, as well as any unintended uses that could be			shall be identified,	known from known cases, shall also be considered.	
		and all measures to	known from known cases, shall also be considered.			and all measures to	2) Elazards should also be identified and considered whenever possible.	
		control them must	2) Elazards should also be identified and considered whenever possible.			control them must	Examples are provided below:	
		be considered.	Examples are provided below:			be considered.	(In the case of metallic foreign bodies, which are physical hazards)	
		Hazards shall	(In the case of metallic foreign bodies, which are physical hazards)			Hazards shall	A certain part A in the manufacturing process is subject to routine	
		include allergens, if	• A certain part A in the manufacturing process is subject to routine			include allergens, if	maintenance, but it has been missing in the past, and since there is a possibility	
		necessary.	maintenance, but it has been missing in the past, and since there is a			necessary.	that it may get mixed into the product in the future and cause injury to	
			possibility that it may get mixed into the product in the future and cause			,	consumers who eat it, it is identified as a major hazard and management	
			injury to consumers who eat it, it is identified as a major hazard and				measures are required.	
			management measures are required.				•On the other hand, a certain part B in the manufacturing process is managed	
			\bullet On the other hand, a certain part B in the manufacturing process is				through daily maintenance, and there have been no cases in the past of it being	
			managed through daily maintenance, and there have been no cases in the				missing and contaminating the product, so it is considered to be controlled	
			past of it being missing and contaminating the product, so it is considered to				through general hygiene management and is not identified as a significant	
			be controlled through general hygiene management and is not identified as a				hazard.	
			2.By conducting a Hazard Analysis, an appropriate management system can				2.By conducting a Hazard Analysis, an appropriate management system can be	
			be created for the facility according to the frequency of possible hazards and				created for the facility according to the frequency of possible hazards and the	
			the severity of the consequences.				severity of the consequences.	
			3. The actual process of hazard analysis is to first list, by raw material and				3. The actual process of hazard analysis is to first list, by raw material and	
			process, the hazards in the final product that can lead to health hazards				process, the hazards in the final product that can lead to health hazards when	
			when eaten.				eaten.	
			4.Following the flow diagram from raw materials to final products, identify				4.Following the flow diagram from raw materials to final products, identify raw	
			raw materials and processes that can lead to the occurrence of hazards,				materials and processes that can lead to the occurrence of hazards, narrow	
			narrow down important hazards in terms of the frequency of occurrence of				down important hazards in terms of the frequency of occurrence of hazards in	
			hazards in each process and the severity of the results, prepare the Hazard				each process and the severity of the results, prepare the Hazard Analysis Sheet	
			Analysis Sheet that lists the causes of occurrence (contamination,				that lists the causes of occurrence (contamination, proliferation, survival,	
			proliferation, survival, contamination, etc.) and the control measures to				contamination, etc.) and the control measures to control them.	
			control them.				5. When preparing the Hazard Analysis Sheet, it is necessary for all members of	
			5. When preparing the Hazard Analysis Sheet, it is necessary for all members				the HACCP team to share their expertise and knowledge, and to discuss and	
			of the HACCP team to share their expertise and knowledge, and to discuss				summarize these findings.	
			and summarize these findings.					
							(Steps to prepare the Hazard Analysis Sheet)	
			(Steps to prepare the Hazard Analysis Sheet)				6. The steps for creating the Hazard Analysis Sheet are explained using the	
			6. The steps for creating the Hazard Analysis Sheet are explained using the				"Example Hazard Analysis Worksheet" given in the International Commission on	
			"Example Hazard Analysis Worksheet" given in the International Commission				Food Standards (CODEX) Committee's General Principles of Food Safety CXC 1-	
			on Food Standards (CODEX) Committee's General Principles of Food Safety				1969, Rev.2022.	
			CXC 1-1969, Rev.2022.					
			Example of Hazard Factor Analysis Worksheet (Prenared from Codex General Principles of Food Hygiane 2020, Japan Food				Example of Hazard Factor Analysis Worksheet (Prenared from Codey Conarel Principles of Food Hygiana 2020), Japan Food	
			Sanitation Association 2021 First Edition Figure 2)				Sanitation Association 2021 First Edition Figure 2)	
			(1) column (2) column (3) column (4) column (5) column Raw Materials / Identify hazards Do these potential Justify your judgment in column What measures can be applied				(1) column (2) column (3) column (4) column (5) column Raw Materials / Identify hazards Do these potential Justify your judgment in column What measures can be applied	
			Operation works (stage) that are expected to occur or are hazards need to be addressed in the (3). to prevent, eliminate or reduce to an acceptable level the				Operation works that are expected hazards need to be (3). to prevent, eliminate or reduce (stage) to occur or are addressed in the to an acceptable level the	
			likely to increase HACCP plan? (If rated "0": Indicate the basis for hazards? the judgment and the cause of the				likely to increase HACCP plan? (If rated "0": Indicate the basis for hazards?	
		1	B: Biological (Yes or No) bazardous factor. (Specify the means to control			1	B - Biological (Ves or No) bazardous factor (Specify the means to control	

	P: Physical	reason(s) for the rating.)	column (3)).
	В:		
	C:		
	P:		
	В:		
	C:		
	P:		
	В:		
	C:		
	P:		

×(If rated "x": Indicate the

the hazards rated as critical in

[Step 1] (Column (1) of "Example of Hazard Analysis Worksheet") List raw materials and manufacturing and processing processes according to the flow diagram.

Write the same numbers along the flow diagram for materials that come in contact with the product, such as main raw materials, secondary raw materials, water used, and packaging materials, as well as for the manufacturing and processing processes.

Perform the hazard analysis of all raw materials used in the food product. This can be done in two ways:

1)Methods to analyze hazards related to raw materials in the process of receiving raw materials

2)Methods to conduct hazard analysis separately for raw materials and processes

This guideline describes the method in 1).

C: Chemical

[Step 2] (Column (2) of "Example of Hazard Analysis Worksheet") List potential hazards originating from raw materials and manufacturing and processing processes.

Hazards shall be described specifically. For example, instead of "food poisoning bacteria," list "Salmonella," "pathogenic E. coli O-157" and so on are enumerated. Also, instead of just "metal fragments," describe the source of contamination and the reason for their presence, such as "contamination from metal foreign bodies derived from broken blades from crushing," "pieces of kitchen knives," etc.

[Step 3] (Column (3) of "Example of Hazard Analysis Worksheet") Based on the frequency of occurrence (likelihood of occurrence) and the severity of the consequences (the extent of damage if they occur) of the listed hazards, evaluate whether or not they are significant hazards that shall be reduced/eliminated from the food to guarantee the safety of the final product.

When conducting a Hazard Analysis to determine critical hazards, consider the following whenever possible:

1) Elazards related to the type of food to be produced and processed, including ingredients and processes (e.g., results of hazard surveys or sampling and testing in the food chain, recall cases, information from scientific literature or epidemiological data)

2) 🖾 kelihood of a hazard occurring in the absence of additional controls, taking into account GMP (PRP in ISO22000)

3) Entequency of occurrence and severity of consequences of adverse health effects due to hazards in food in the absence of controls

4) Identified acceptable levels of hazards in the food (e.g., based on regulations, intended uses, and scientific information)

5) Mature of the facility and machinery and equipment in which the food is produced

6) Survival or growth of pathogenic microorganisms
 7) Generation or persistence of toxins (e.g., mold toxins).

7) Generation or persistence of toxins (e.g., mold toxins), chemicals (e.g., pesticides, veterinary drugs, allergens) or physical hazards (e.g., glass, metals) in food

8) Potential for food to become unsafe as a result of its intended use, and/or mishandling of the product by the consumer

P: Physical	reason(s) for the rating.)	column (3)).
В:		
C:		
Р:		
В:		
C:		
Р:		
В:		
C:		
P:		

×(If rated "x": Indicate the

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2) Enkelihood of a hazard occurring in the absence of additional controls, taking into account GMP (PRP in ISO22000)

3) Enequency of occurrence and severity of consequences of adverse health effects due to hazards in food in the absence of controls

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5) Mature of the facility and machinery and equipment in which the food is produced

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7) Generation or persistence of toxins (e.g., mold toxins), chemicals (e.g., pesticides, veterinary drugs, allergens) or physical hazards (e.g., glass, metals) in food

8) Potential for food to become unsafe as a result of its intended use, and/or mishandling of the product by the consumer

5 1 7

9) Conditions leading to the above

For the evaluation of hazards in Step 3, recommend using a matrix table of "frequency of occurrence" and "severity of results" as shown below, and entering the numbers into the hazard analysis sheet. There are various examples of matrix tables created, and it is advisable to adopt one in consideration of the target product, manufacturing process, etc. However, this does not apply to cases that can be clearly evaluated with "yes/no".

			Severity of Results							
			0 I		Π	Ш	IV			
			not (verb- negating suffix; may indicate question or invitation with rising intonation)	complaint	recall	serious illness	lethal			
	4	Often Occurs	risk risk		Serious risk	Serious risk	Serious risk			
	3	Occasionally Occurs	OK to manage	risk	risk	Serious risk	Serious risk			
frequency of occurrence	2	Occurred at other companies Has occurred at other companies	OK to manage	OK to manage	risk	risk	Serious risk			
	1	No information on other companies There is no	OK to manage	OK to manage	OK to manage	risk	risk			
	0	unthinkable	OK to manage	OK to manage	OK to manage	OK to manage	OK to mana			

How to read the matrix

major risk	It is an extremely high risk, suggesting the potential to become a significant source of harm, which would likely be controlled by control measures that would be CCPs under HACCP Procedure 7, Principle 2.
risk	The current control measures are likely to be inadequate, indicating the need to add some means to strengthen and enforce the current GMP (General Sanitation Management Program).
OK to manage	The current means of management is adequate to manage the situation.

9) **C**onditions leading to the above

For the evaluation of hazards in Step 3, recommend using a matrix table of "frequency of occurrence" and "severity of results" as shown below, and entering the numbers into the hazard analysis sheet. There are various examples of matrix tables created, and it is advisable to adopt one in consideration of the target product, manufacturing process, etc. However, this does not apply to cases that can be clearly evaluated with "yes/no".

An example	of t	he concept o	f the likelihood (of an enumerate	ed cause of harn	n and the magnit	tude of damage			
(Based on "Ri	sk A	ssessment Ha	ndbook", METI 2	2011.6)						
	Severity of Results									
			а	b	С	d	е			
			Not	Complaint	Recall	Serious	Lethal			
	E	Often Occurs	15	19	22	24	25			
	D	Occasionally Occurs	10	14	18	21	23			
frequency of occurrence	C at other companies		6	9	13	17	20			
	В	No information in other companies	3	5	8	12	16			
	А	Unthinkable	1	2	4	7	11			
How to r	ead	d the matri	x							
20~25		It is an signifi measu	n extremely hi cant source of res that woul	gh risk, sugg ⁻ harm, which d be CCPs un	esting the po would likely der HACCP Pi	tential to bec be controlled rocedure 7, P	come a l by control rinciple 2.			
12~19 The current control measures are likely to be inadequate, indicating the need to add some means to strengthen and enforce the current GMP (General Sanitation Management Program).It is highly likely that it will be managed under GMP4.										
1~11 The current means of management is adequate to manage the situation.										

[Step 4] (Column (4) of "Example of Hazard Analysis Worksheet") In this step, for significant hazards marked with \bigcirc or Yes in [Step 3] ((3) in the "Example of Hazard Analysis Worksheet"), identify the factors causing the hazard and describe the basis for the decision in column (4). For those hazards marked with X or No in column (3), describe the basis for judgment. [Step 5] (Column (5) of "Example of Hazard Analysis Worksheet") For each hazard rated as critical, identify control measures to ensure the safety of the final product. The following is an example of a hazard evaluation (Step 3) and a hazard analysis sheet.

Consider which control measures to apply to each critical hazard, as multiple control measures may be needed to control one hazard. For example, to control Listeria monocytogenes, heat treatment may be required to kill viable organisms in the food, and environmental cleaning and disinfection can be required to prevent contamination from the processing environment after heating.

It can be possible to control multiple hazards through specific control measures. For example, if Salmonella spp. and E. coli O-157 are present in a food, heat treatment can control both hazards.

*Reference examples of the Hazard Analysis Sheet are as follows. Source: Ministry of Health, Labour and Welfare website (http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000098735.html)

Example of Hazard Analysis Shee

HACCP

Step 7

(Principle 2) Points

Critical

Control

Critical Control

be determined.

Points (CCPs) shall

[Step 4] (Column (4) of "Example of Hazard Analysis Worksheet")

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Example of Hazard Analysis Shee

Product name: Catering Bento					Product name: Cate	rering Bento
(1) (2) (3) Is it an important hazar	(4) (5)				(1)	(2) (3) (4) (5)
Ingredients/Process Hazards expected to occur in (1) that needs to be reduced or eliminated from the food supply?	Basis for decision in column (3) Control measures for hazards identified as important in column (3)				Ingredients/Process	katards expected to occur in (1) that needs to be reduced or eliminated as important in column (3)
Refrigerated Organisms: Presence of pathogenic					Refrigerated	Irom the tood supply? Organisms: Presence of pathogenic Organisms: Presence of pathogenic
(Vegetables) Harmful Microorganisms	Contamination is possible due to unconitory bandling during manufacturing and				(Vegetables)	Harmful Microorganisms
Pathogenic Escherichia coli NO	processing, but can be controlled by adhering to hygienic handling of food and					Salmonella spo. Contamination is possible due to unsanitary handling during manufacturing and Pathogenic Escherichia coli NO processing, but can be controlled by adhering to hygienic handling of tood and
Staphylococcus aureus	other products.					Staphylococcus aureus other products.
Clostridium botulinum	Contamination is possible due to unsanitary handling during manufacturing and					Heat-resistant spore bacteria Cotatridium botulinum Contamination is possible due to unsanitary handling during manufacturing and
Welch bacillus	processing, but the bacteria are anaerobic and cannot grow during storage.					Welch bacillus NO processing, but the bacteria are anaerobic and cannot grow during storage.
	Possible contamination due to unhygienic handling during manufacturing and					Possible contamination due to unbyvienic bandling during manufacturing and
Bacillus cereus NO	processing, but can be controlled by adhering to hygienic handling of food and					Bacillus cereus NO processing, but can be controlled by adhering to hygienic handling of food and
	other products.					other products.
Chemical: None						Chemical: None
Physical: Presence of metallic foreign bodies YES	Possible presence of metallic foreign matter due to improper handling during manufacturing and processing Controlled by metal detection (NO.9)					Physical: Presence of metallic foreign bodies YES Possible presence of metallic foreign matter due to improper handling during manufacturing and processing Controlled by metal detection (NO.9)
Product name: Boiled soba noodles					Product name: Boile	
(1) (2) (3)	(4) (5)				(1)	(2) (3) (4) (5)
predients/Process Hazards expected to occur in (1)	Basis for decision in column (3) Control measures for hazards identified				Instandiante (D	that needs to be Real for draining in advance (2) Control measures for hazards identified
reduced or eliminated from the food supply?	as important in column (3)				Ingredients/Process	ss riazards expected to occur in (1) reduced or eliminated reduced or eliminated
Jockwheat Organisms: Presence of pathogenic					Buckwheat	Organisms: Presence of pathogenic
Harmful Microorganisms	May be more contaminated than soil					Harmful Microorganisms
Pathogenic Escherichia coli 6	May be more containinged than soil Can be controlled in the sterilization Can be controlled by Sterilization					Salmonella spp. 6 May be more contaminated than soil Can be controlled in the sterilization Pathogenic Excherichia coll 6 May be more contaminated than soil Can be controlled by Sterilization
Heat-resistant spore bacteria	May be more contaminated than call					Heat-resistant spore bacteria
Welch bacillus 19	Not likely to proliferate since not placed under anaerobic conditions thereafter					Bacillus cereus / May be more contaminated than soil Can be controlled by cooling (NO.33)
	No possibility of proliferation, as the material will not be placed under anaerobic					Weich bacillus 19 Not likely to proiferate since not placed under anaeropic conditions thereafter
Clostridium botulinum 15	conditions thereafter.					Clostridium batulinum 15 No possibility of proliferation, as the material will not be placed under anaerobic conditions thereafter.
Chemical: Residual pesticides 17	Inspection certificate is issued once a year to confirm that the product has					Chemical: Residual pesticides 17 Inspection certificate is issued once a year to confirm that the product has
Physical: Presence of foreign matter	passed the inspection.					passed the inspection. Provide the inspection.
Hard foreign body 13	Can be eliminated by visual check at weighing (NO.14)					Hard foreign body 13 Can be eliminated by visual check at weighing (N0.14)
Metallic foreign body 18	Can be eliminated by visual check at weighing (NO.14)					Metallic foreign body 18 Can be eliminated by visual check at weighing (NO.14)
What are Critical Control Point	ts (CCPs)?	HACCP	Critical	The organization	1.What a	• No change to the guideline
Critical control points (herea	fter referred to as CCPs) are steps at which	Step 7	Control	shall determine	1) Critica	al control points (hereafter referred to as CCPs) are steps at which
ntrol is essential for the manu	afacture of a product in order to reduce or	(Principle 2)	Points	Critical Control	control is	essential for the manufacture of a product in order to reduce or
ninate significant hazards fro	m the food to acceptable levels, they are set			Points (CCPs).	eliminate	significant hazards from the food to acceptable levels, they are set in
processes where deviations c	ould lead to food that can be unsafe, and				processes	s where deviations could lead to food that can be unsafe, and they are
ey are stages with procedures	s or operations that require especially strict				stages wi	ith procedures or operations that require especially strict control.
ntrol.					2) Eor ea	ach hazard that is identified as a significant hazard as a result of the
Eor each hazard that is ident	ified as a significant hazard as a result of the				hazard ar	nalysis, it is always necessary to establish one or more control
azard analysis, it is always nec	essary to establish one or more control				measures	s that can control that hazard.

measures that can control that hazard.

3) Among the control measures for the critical hazards listed in HACCP Step 6 (Principle 1), consider control measures that could serve as CCPs. 4) At CCPs, it is necessary to set permissible limits as described below, conduct monitoring, and take measures such as not allowing products manufactured during the period when the limit was exceeded to be shipped if there is a deviation.

5) CCPs can be needed at multiple stages to control a single hazard. 2. How to determine CCPs - Example of Decision Tree application See the figure below for the procedure / The main points are as follows: 1) The requirements for CCPs are that it can be monitored continuously or with a reasonable frequency using a pre-defined monitoring method, and if the parameter deviates critical limit (CL), production can be stopped immediately and process control can be restored to the original state in a short period of time, and food produced during the period of deviation can be identified and isolated.

2) Only those processes for which significant hazards are identified in the hazard analysis are subject to Decision Tree application.

3) Consider the significance of the hazard (i.e., the likelihood of its occurrence and the severity of the effect of the hazard in the absence of controls) and whether it can be adequately controlled by the GMP. A GMP can be a normal GMP, or it can be a GMP that requires greater attention (e.g., monitoring and recording) to control the hazard (so-called GMP 4.2). (See *) 4) If CCPs were not identified in Q2-Q4, review the process and control measures again and re-conduct the hazard analysis. (See **) 5) Determine whether a control measure at a process where a significant hazard has been identified is used in combination with a control measure at another process to control the same hazard, in which case both processes should be considered CCPs (See ***).

6) If there are no specific and special control measures, the process and control measures should be reviewed again and the hazard analysis shall be re-performed. (See ****)



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			 3.Specific examples of CCPs 1) Examples of CCPs that prevent the occurrence of hazards are as follows: (1)Acceptance of raw materials: Prevention of antimicrobial residues by checking raw material inspection reports submitted by suppliers (2)Cooling: Prevention of pathogen growth through appropriate temperature control (3)Refrigerated storage: Prevention of pathogen growth through appropriate temperature control (4)Weighing of food additives: Prevention of over-additives 2) Examples of CCPs that eliminate hazards include the following: (1)Heating process or sterilization process with chemicals: Sterilization of pathogenic bacteria (2)Metal detection: Detection by detector and elimination of metal fragments 3) Examples of multiple CCPs that control a single hazard are as follows: (1)Control patty thickness and heating time/temperature to kill non-sporeforming pathogenic microorganisms in hamburgers. (2)The heating process can be a CCP to kill vegetative cells of spore-forming pathogens, and the cooling process can also be a CCP to prevent spore germination and growth. If control measures for identified significant hazards do not exist at any stage, the product or manufacturing process should be modified. 				 3.Specific examples of CCPs 1) Examples of CCPs that prevent the occurrence of hazards are as follows: (1)Acceptance of raw materials: Prevention of antimicrobial residues by checking raw material inspection reports submitted by suppliers (2)Cooling: Prevention of pathogen growth through appropriate temperature control (3)Refrigerated storage: Prevention of pathogen growth through appropriate temperature control (4)Weighing of food additives: Prevention of over-additives 2) Examples of CCPs that eliminate hazards include the following: (1)Heating process or sterilization process with chemicals: Sterilization of pathogenic bacteria (2)Metal detection: Detection by detector and elimination of metal fragments 3) Examples of multiple CCPs that control a single hazard are as follows: (1)Control patty thickness and heating time/temperature to kill non-sporeforming pathogenic microorganisms in hamburgers. (2)The heating process can be a CCP to kill vegetative cells of spore-forming pathogens, and the cooling process can also be a CCP to prevent spore germination and growth. If control measures for identified significant hazards do not exist at any stage, the product or manufacturing process should be modified. 	
HACCP Step 8 (Principle 3)	Critical Limits	Validated critical limit(s) shall be stipulated for each CCP.	 <u>What is the Critical Limit (CL)?</u> CL is a monitoring criterion that distinguishes between acceptable and unacceptable conditions of food in relation to the control measures applied as a critical hazard (CCP). A CL can have one or more parameters. Since incorrectly set CL can lead to the occurrence of hazards, they shall be validated based on scientific data and set appropriately. Deviations from the CL require corrective action. The CL shall meet the following conditions: The cl shall meet the following conditions: The cl shall meet the following conditions: The cl shall meet the following conditions:	HACCP Step 8 (Principle 3)	Critical Limits	The organization shall stipulate Validated critical limit(s) for each CCP.	 <u>What is the Critical Limit (CL)?</u> CL is a monitoring criterion that distinguishes between acceptable and unacceptable conditions of a control measure of hazards and is an observable or measurable criterion that distinguishes between acceptable and unacceptable conditions of food in relation to the control measures applied as a critical hazard (CCP). A CL can have one or more parameters. Since incorrectly set CL can lead to the occurrence of hazards, they shall be validated based on scientific data and set appropriately. Deviations from the CL require corrective action. The CL shall meet the following conditions: (1)The most appropriate parameters for ensuring that hazards are prevented, eliminated, controlled or reduced to acceptable levels, and whose value is scientifically proven (2)Criteria using parameters that can be determined in real time whenever possible If it is found that the control condition is not appropriate, corrective measures shall be taken immediately, so it is desirable for this to be indicated by parameters that can be judged in real time. C) is usually the minimum or maximum value of a critically important parameter related to the control measure and can be used, such as temperature, moisture, time, pH, water activity (AW), available chlorine, contact time, conveyor belt speed, viscosity, conductivity, flow rate, etc, or sensory indicators (color, gloss, odor, taste, viscosity, physical properties, foam, sound, etc.) or observed pump settings, etc. As an alternative to the parameters indicating CL, another indicator, "water temperature of all products; therefore, apart from this indicator, "water temperature of all products; therefore, apart from this indicator, "water temperature of boiling tank, amount of product put in, and heating time" are measured as non-destructive and efficient CLs.	•No change to the guideline
HACCP Step 9 (Principle 4)	Monitoring System	Monitoring procedures shall be established for each CCP.	 <u>What is monitoring2</u> <u>The ansure that CCP is properly controlled and to keep accurate records for later verification, monitoring is the comparison with CL, and, to do the observation, measurement, or test inspection based on a schedule established in the HACCP plan.</u> <u>The the management of CCP, the act of watching to ensure that there are no deviations from CL is called monitoring.</u> <u>Any deviation from the CL requires corrective action.</u> <u>Bionitoring records are also used when verifying the HACCP plan.</u> <u>How to monitor</u> <u>The monitoring</u> <u>The monitoring method shall meet the following conditions:</u> <u>The monitoring</u> <u>The monitoring that the CL is met for every product, from the first one to the last one, or for every batch. When deviations from the CL occur, they shall be done in a manner that minimizes the impact as much as possible and in a way that allows easy corrective actions to be taken.</u> <u>The JEW1H1</u> that defines the monitoring method means the following: (1)Rationale (Why): Is there scientific validity for monitoring the control status of CCP? (2)What (What): Is the CCP within the acceptable range of the CL (does not deviate from the CL)? (3)In which process (Where): Clarify the applicable process (CCP process) (4)How (How): Is it a rapid and accurate physical, chemical, or sensory observation, measurement, or inspection method (5)Frequency (When): Is it continuous? Or, if not, is there a f	HACCP Step 9 (Principle 4)	Monitoring System	The organization shall establish monitoring procedures for each CCP.	 What is monitoring? Ta ensure that CCP is properly controlled and to keep accurate records for later verification, monitoring is the comparison with CL, and, to do the observation, measurement, or test inspection based on a schedule established in the HACCP plan. Ta the management of CCP, the act of watching to ensure that there are no deviations from CL is called monitoring. Any deviation from the CL requires corrective action. Monitoring records are also used when verifying the HACCP plan. How to monitor The monitoring method shall meet the following conditions: To be carried out continuously or with reasonable frequency. The monitor to monitor to be conformed the control measures against hazards for all products. This shall be done continuously or with reasonable frequency to enable monitoring that the CL is met for every product, from the first one to the last one, or for every batch. When deviations from the CL occur, they shall be done in a manner that minimizes the impact as much as possible and in a way that allows easy corrective actions to be taken. The (SW1H] that defines the monitoring method means the following:	•No change to the guideline
HACCP Step 10 (Principle 5)	Corrective	A procedure of corrective actions (correction, and investigation and removal of root cause) shall be established for deviations from a critical limit.	 What is corrective action? Cbrrective action is the immediate action taken when monitoring parameters deviate from the CL. Ifi CCP, which is a process that should be especially strictly controlled to prevent the occurrence of hazards, it is important to determine the methods and procedures for corrective action in advance because any deviation of the monitoring parameters from the CL may result in the occurrence and escalation of food safety risks. (See FSM 24, 25, GMP 9) Ifi the HACCP plan, the actions to restore process control and procedures for restarting the line, as well as the actions to isolate affected product and determine and implement its disposition, shall be defined. Ifi minimize the likelihood that the deviation will recur, the cause analysis shall be performed to identify and correct the cause of the deviation, if possible. The cause analysis shall identify the reason for the deviation or limit the amount of product affected by the deviation. Items to be included in the HACCP plan as corrective actions Items to be included in the HACCP plan as corrective action are as follows: Action to restore the control status of the process Repair, adjust, or replace machinery, etc., to return the process to a normal state of control. Ifieatment for products manufactured during the deviation Identify and withhold products that deviate from the CL and evaluate them. Decide on treatment methods, such as reprocessing or disposal. 	HACCP Step 10 (Principle 5)	Corrective Actions	The organization shall establish a procedure of corrective actions (correction, investigation and elimination removal of root cause) for deviations from a critical limit.	 What is corrective action? Corrective action is the immediate action taken when monitoring parameters deviate from the CL. If CCP, which is a process that should be especially strictly controlled to prevent the occurrence of hazards, it is important to determine the methods and procedures for corrective action in advance because any deviation of the monitoring parameters from the CL may result in the occurrence and escalation of food safety risks. (See FSM 24, 25, GMP 9) If the HACCP plan, the actions to restore process control and procedures for restarting the line, as well as the actions to isolate affected product and determine and implement its disposition, shall be defined. It minimize the likelihood that the deviation will recur, the cause analysis shall be performed to identify and correct the cause of the deviation, if possible. The cause analysis shall identify the reason for the deviation or limit the amount of product affected by the deviation. Items to be included in the HACCP plan as corrective actions Items to be included in the HACCP plan as corrective action are as follows: Action to restore the control status of the process Repair, adjust, or replace machinery, etc., to return the process to a normal state of control. Iteratment for products manufactured during the deviation Identify and withhold products that deviate from the CL and evaluate them. Decide on treatment methods, such as reprocessing or disposal. 	•No change to the guideline

			 3.Person in charge of implementing corrective actions Shall be done by an authorized person in charge who has sufficient knowledge of CCP management, understands the process well, and can make quick decisions. 4.Corrective Action Implementation Records The corrective action implementation record shall include the following items: Details of the deviation, the manufacturing process or location where it occurred, and the date and time of occurrence Name, lot number, quantity, etc. of the product that was the subject of the action Results of investigation into the cause of deviation Details of actions taken to restore the process to its original state Details of treatment to be done to the product manufactured during the deviation Signature of the person in charge who carried out and recorded the above items 				 3.Person in charge of implementing corrective actions Shall be done by an authorized person in charge who has sufficient knowledge of CCP management, understands the process well, and can make quick decisions. 4.Corrective Action Implementation Records The corrective action implementation record shall include the following items: Details of the deviation, the manufacturing process or location where it occurred, and the date and time of occurrence Name, lot number, quantity, etc. of the product that was the subject of the action Results of investigation into the cause of deviation Details of actions taken to restore the process to its original state Details of treatment to be done to the product manufactured during the deviation 6) Signature of the person in charge who carried out and recorded the above items 7) Signature of the person who inspected the corrective action and the date of inspection 	
HACCP Step 11 (Principle 6)	Establish HACCP plan validation and verification procedures	HACCP plan shall be validated prior to implementation. Verification procedures shall be established to confirm whether the defined handling (HACCP Plans) is carried out as specified and to judge whether it is necessary to modify the defined handling. Verification shall be carried out considering the design of equipment, change in processing method and technology development in the manufacturing process.	The following is a procedure showing the requirements of this item in chronological order of actual activities. 1.validation 1) Validation is the assurance that the HACCP plan is capable of controlling the critical hazards and shall be performed before the HACCP plan is implemented. Items for which validation should be performed include the following: ⇒ Identification of hazards, and CCP, CL, control measures, frequency and type of CCP monitoring, corrective actions (improvement measures), frequency, and type of verification and type of information to be recorded, etc. 2) Validation of control measures and CL of CCP shall be conducted during the development of the HACCP plan. 3) Validation involves reviewing the scientific literature, using predictive models, conducting validation studies, and using guidelines developed by authoritative sources (e.g., Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 - 2008)). 4) Evidence should be obtained that demonstrates that control has been consistently achieved, during production under the first implementation period and production conditions of the HACCP plan. 2. <u>Implementation of HACCP Plan</u> Implement activities in accordance with the established HACCP plan. 3. <u>Verification</u> 1) After implementation of the HACCP plan, evaluate its effectiveness and verify that the HACCP system is functioning properly. Verification is basically conducted once a year, or as needed. For verification of the overall food safety management system, please refer to FSM5. 2) Eyr recognizing weaknesses in their own HACCP system from the results of periodic verifications, modify their HACCP plan to make it better. 3) Varification shall be conducted respectively, for HACCP plans for each CCP, and for the entire HACCP system. (1)HACCP plans for each CCP	HACCP Step 11 (Principle 6)	Establish HACCP plan and verification procedures	The organization shall validate HACCP plan prior to implementation. Verification procedures shall be established to confirm whether the defined handling (HACCP Plans) is carried out as specified and to judge whether it is necessary to modify the defined handling. Verification shall be carried out considering the design of equipment, change in processing method and development in the manufacturing process. HACCP system shall be reviewed regularly and updated when there is a significant change that could	 The following is a procedure showing the requirements of this item in chronological order of actual activities. 1.validation 1) Validation is the assurance that the HACCP plan is capable of controlling the critical hazards and shall be performed before the HACCP plan is implemented. Items for which validation should be performed include the following: ⇒ Identification of hazards, and CCP, CL, control measures, frequency and type of CCP monitoring, corrective actions (improvement measures), frequency, and type of verification and type of information to be recorded, etc. 2) Validation for control measures and CL of CCP shall be conducted during the development of the HACCP plan. 3) Validation involves reviewing the scientific literature, using predictive models, conducting validation studies, and using guidelines developed by authoritative sources (e.g., Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 - 2008)). 4) Evidence should be obtained that demonstrates that control has been consistently achieved, during production under the first implementation period and production conditions of the HACCP plan. 2.Implementation of HACCP Plan Implement activities in accordance with the established HACCP plan. 3.Verification 1) After implementation of the HACCP plan, evaluate its effectiveness and verify that the HACCP system is functioning properly. Verification is basically conducted once a year, or as needed. For verification of the overall food safety management system, please refer to FSM5. 2) By recognizing weaknesses in their own HACCP system from the results of periodic verifications, modify their HACCP plan to make it better. 3) Varification shall be conducted respectively, for HACCP plans for each CCP, and for the entire HACCP system. (1)HACCP plans for each CCP 	•No change to the guideline

follows:	hazards and/or	i.Calibration of measuring devices (instruments) used for monitoring
i.Calibration of measuring devices (instruments) used for monitoring	control measures.	ii. Testing and inspection of raw materials (including containers and packaging
ii.Testing and inspection of raw materials (including containers and packaging		materials), semi-finished products, work-in-process products, reworked
materials), semi-finished products, work-in-process products, reworked		products, and finished products
products, and finished products		iii. Measurement of manufacturing and processing conditions
ii.Measurement of manufacturing and processing conditions		iv. Review CCP monitoring records, corrective action records, and verification
v. Review CCP monitoring records, corrective action records, and verification		records
records		v Confirmation that operators are working in accordance with the HACCP plan
Confirmation that operators are working in accordance with the HACCP plan		vi Observation that control measures are operated according to the HACCP plan
i Observation that operators are working in accordance with the HACCP		vi. Observation that control measures are operated according to the fifecer plan
alan		
2Verification of monitoring also includes verifying that the monitoring is		$\textcircled{2}$ ∇ erification of monitoring also includes verifying that the monitoring is correct
correct by using a different measuring instrument or method. For example,		by using a different measuring instrument or method. For example, for
or temperature, cross-checking with another thermometer or measuring the		temperature, cross-checking with another thermometer or measuring the
center temperature if the steam temperature of the heater is monitored		center temperature if the steam temperature of the heater is monitored instead
nstead of the center temperature, and for verification of the heating process		of the center temperature, and for verification of the heating process
conducting a microbiological test on the sample after the heating process to		conducting a microbiological test on the sample after the heating process to
confirm that no microorganisms remain in the sample		confirm that no microorganisms remain in the sample
(Items that should be stinulated in the HACCP plan as internal verification		(Items that should be stipulated in the HACCP plan as internal verification
work »		work »
WIK.//		WOIK.// @The items to be stipulated in the verification plan are as follows:
		S me items to be supulated in the vernication plan are as follows.
		i. Contents
i. Trequency		II. Trequency
I.Action based on verification results		III. Action based on verification results
v. Method of recording the results of the verification		iv.Method of recording the results of the verification
4) Verification should be performed by someone other than the person		⁽⁴⁾ Verification should be performed by someone other than the person
performing monitoring and corrective action.		performing monitoring and corrective action.
2)Entire HACCP system		(2)Entire HACCP system
$\mathbb{D}V$ erification of the entire HACCP system shall be conducted on a regular		$\textcircled{1}$ \blacksquare erification of the entire HACCP system shall be conducted on a regular basis
pasis using the following procedures as needed:		using the following procedures as needed:
Analysis of consumer complaints or cause for recall		i.Analysis of consumer complaints or cause for recall
i.On-site confirmation that monitoring work is being performed according to		ii.On-site confirmation that monitoring work is being performed according to
established procedures		established procedures
ii.Testing and inspections to verify product safety		iii. Testing and inspections to verify product safety
2 The results of the verification are recorded, inspected, and the HACCP		T The results of the verification are recorded, inspected, and the HACCP system
system is reviewed as necessary.		is reviewed as necessary.
1. <u>Re-validation of the HACCP system</u>		4. <u>Re-validation of the HACCP system</u>
In addition to the validation at the time of HACCP plan development, re-		In addition to the validation at the time of HACCP plan development, re-
alidation shall be performed when any of the following occur:		validation shall be performed when any of the following occur:
1) Change in raw materials		1) Change in raw materials
2) Changes in manufacturing processes or systems (including computers and		2) Changes in manufacturing processes or systems (including computers and
heir software)		their software)
3) Change of packaging		3) Change of packaging
4) Change in final product delivery system		4) Change in final product delivery system
5) Changes in the intended specifications or the intended consumer, of the		5) Changes in the intended specifications or the intended consumer, of the final
inal product		product
5) When verification results indicate deficiencies or potential deficiencies in		6) When verification results indicate deficiencies or potential deficiencies in the
he HACCP plan		HACCP plan
7) When a new hazard is identified in the same food or in the same food		7) When a new hazard is identified in the same food or in the same food group
aroup		8) When new information regarding product safety becomes available
3) When new information regarding product safety becomes available		X. Requirements for testing and inspection methods used for verification are as
*. Requirements for testing and inspection methods used for verification are		follows:
as follows:		1 This includes evaluating and verifying whether CCPs and CLs are properly
1 This includes evaluating and verifying whether CCPs and CLs are properly		established and controlled to ensure product safety
established and controlled to ensure product safety		2 The test and inspection methods for varification shall be validated. For details
The test and increation methods for verification shall be validated. For		2. The test and inspection methods for verification methods for verification shall
e test and inspection methods for vernication shall be validated. FOP		See ו איז איז (אטני נוומג נוופ נפגר מווט וווspection methous for verification Shall

			2. The test and inspection methods for verification shall be validated. For details, see FSM19.1 (Note that the test and inspection methods for verification shall include visual inspection and confirmation by sensory indicators).				see FSM19.1 (Note that the test and inspection methods for verification shall include visual inspection and confirmation by sensory indicators).	
HACCP	Documents	Necessary	What documents and records are required?	HACCP	Documents	The organization	What documents and records are required?	•No change to the guideline
Step 12	and Record	documents shall be	1. Documents and records required by the 12 steps of HACCP include the	Step 12	and Record	shall prepare and	1. Documents and records required by the 12 steps of HACCP include the	
(Principle 7)		prepared and	following:	(Principle 7)		maintain necessary	following:	
		maintained.	1) EACCP Team Member List and Role Assignment			documents.	1) EACCP Team Member List and Role Assignment	
		These documents	2) Product Description			These documents	2) Product Description	
		shall contain	3) Ellow diagram			shall contain	3) Ellow diagram	
		documents related	4) 田azard Analysis			documents related	4) Elazard Analysis	
		to the standard	5) EIACCP Plan			to the standard	5) EIACCP Plan	
		operating	6) Determination of CCP			operating	6) Determination of CCP	
		procedures (SOP)	7) Determination of CL and information providing scientific support for the			procedures (SOP)	7) Determination of CL and information providing scientific support for the CL	
		and the work	CL			and the work	8) Validation of control measures	
		instructions (WI)	8) Validation of control measures			instructions (WI)	9) EACCP plan revision records, etc.	
		necessary and	9) EACCP plan revision records, etc.			necessary and	2.Records of activities according to the HACCP plan include the following:	
		applicable to the	2.Records of activities according to the HACCP plan include the following:			applicable to the	1) Monitoring records	
		scope of	1) Monitoring records			scope of	2) Corrective action records	
		certification of the	2) Corrective action records			certification of the	3) Werification records	
		organization.	3) Verification records			organization.	4) Taining records of the person in charge, etc.	
			4) Taining records of the person in charge, etc.				3.Records of HACCP plan implementation	
			3.Records of HACCP plan implementation				This is important to provide evidence to prove control (scientific literature used	
			This is important to provide evidence to prove control (scientific literature				during validation, minutes of HACCP team meetings, etc.) as well as to address	
			used during validation, minutes of HACCP team meetings, etc.) as well as to				deviations when they occur. Records can be maintained electronically, if	
			address deviations when they occur. Records can be maintained				necessary.	
			electronically, if necessary.				4. The organization shall document standard operating procedures and work	
			4. The organization shall document standard operating procedures and work				instructions covering the scope of certification.	
			5. "Standard Operating procedures (SOPs)" are documented procedures for				5. "Standard Operating procedures (SOPs)" are documented procedures for	
			performing standard tasks.				performing standard tasks.	
			6."Work Instructions (WI)" means documents that instruct employees what				6."Work Instructions (WI)" means documents that instruct employees what	
			work is to be performed.				work is to be performed.	

Design, T construction st	he organization hall design, onstruct and	1. The first half of this requirement requires that food manufacturing facilities within the factory buildings and facilities, at the business site that are used to produce food be designed, constructed, and maintained to minimize food	GMP 3	Design, construction	The organization shall design,	1. The first half of this requirement requires that food manufacturing facilities within the factory buildings and facilities, at the business site that are used to produce food be designed, constructed, and maintained to minimize food cafety.	•Alignment with "The GFSI Benchmarking Requirements version 2024"
business m	naintain the	safety risks, and these are primarily hardware measures.		business	maintain the	risks, and these are primarily hardware measures.	2024
site and fa	nd facilities	the premises.		site and work and	and facilities	the premises.	
product flow (s	storage area, raw	On the other hand, the second half of the requirements call for equipment		product	(storage area, raw	On the other hand, the second half of the requirements call for equipment	
lines m	naterial and	layout and lines of flow of people, goods, and operations to be designed to		flow lines	material and	layout and lines of flow of people, goods, and operations to be designed to	
pi ai	roduct nandling rea, preparation	2. The following points shall be considered in the design, construction, and			area, preparation	layout and the flow lines of people, goods, and work shall be designed in	
ai	rea, packaging	layout of factory buildings and facilities:			area, packaging	accordance with the principles of hygienic design outlined in food safety laws	
aı	nd storage area,	Factory buildings and facilities			and storage area,	and regulations of the food manufacturing country, technical information	
et	tc.) of the	1) If is appropriately located on the site and is of appropriate size and construction for the intended use			etc.) of the	magazines on food factory buildings and facilities, know-how provided by food	
01	utside and inside	 2) The structure is easy and feasible to maintain, clean and wash. 			outside and inside	the company, etc. to meet the intended purpose and minimize food safety risks	
th	ne plant to	3) Select durable materials that can handle the weight of work equipment,			the plant to	(refer to FSM 4)	
m	ninimize food	wear, etc.			minimize food	2. The following points shall be considered in the design, construction, and	
50	diety fisks.				Salety HSKS.	Factory buildings and facilities	
						1) ${\rm I\!I}$ is appropriately located on the site and is of appropriate size and	
						construction for the intended use.	
						3) Select durable materials that can handle the weight of work equipment,	
						wear, etc.	
Te	a addition the	E) When decigning manufacturing and proceeding facilities, refer to the			In addition the	4) The material is capable of withstanding cleaning and wasning.	
Ir	n addition, the quipment layout	following and fully identify impacts to manufacturing and processing facilities, refer to the			equipment layout	following and fully identify impacts to manufacturing and processing:	
(i	ncluding drainage	(1)Layout diagram of manufacturing and processing area			(including drainage	(1)Layout diagram of manufacturing and processing area	
S	ystem and	(2)Flow diagram showing manufacturing and processing processes			system and	(2)Flow diagram showing manufacturing and processing processes	
fic	ow lines of	(3)Equipment, personnel, methods of transporting raw materials and products, process capabilities, etc.			flow lines of	(3)Equipment, personnel, methods of transporting raw materials and products, process capabilities, etc.	
p	eople, goods, and	(4)Work classification commensurate with the manufacturing and processing			people, goods, and	(4)Work classification commensurate with the manufacturing and processing	
w	vork shall be	process			work shall be	process	
de ++	esigned to meet ne intended	(c)Install appropriate cleaning facilities for food handling equipment and utensils, etc in the facility.			accordance with	(5)Install appropriate cleaning facilities for food handling equipment and utensils, etc., in the facility.	
pi	urpose and	6) Structures in food facilities shall meet the following specific requirements,			the principles of	6) Structures in food facilities shall meet the following specific requirements, as	
m	ninimize food	as necessary:			hygienic design	necessary:	
Sa	arety risks. he organization	(1) wail, partition, and floor surfaces: use materials that are easy to clean, can be sterilized as needed, and are impervious to water and dirt			outlined in food	(1) waii, partition, and floor surfaces: use materials that are easy to clean, can be sterilized as needed, and are impervious to water and dirt	
s	hall set the	(2)Walls and partitions: to be suitable heights for operation and smooth			regulations to meet	(2)Walls and partitions: to be suitable heights for operation and smooth	
lig	ghting necessary	surfaces.			the intended	surfaces.	
fc	or rood safety to n appropriate	(c) cenings and overnead fixtures (including lighting): constructed to be shatterproof where necessary and finished to minimize dirt and condensation			purpose and minimize food	(3) Centrings and overnead fixtures (including lighting): constructed to be shatterproof where necessary and finished to minimize dirt and condensation	
le	evel of illuminance.	buildup and particle falling.			safety risks.	buildup and particle falling.	
		(4)Windows: installed for ease of cleaning and to minimize dirt buildup, with			The organization	(4)Windows: installed for ease of cleaning and to minimize dirt buildup, with	
		removable and cleanable insect screens installed as needed.			Ishall set the	removable and cleanable insect screens installed as needed.	
		disinfected as needed.			for food safety to	as needed.	
					an appropriate		
A	dditionally, the	7) In particular, the following measures shall be implemented to deal with foods containing allergens. (For details, see FSM 16.)			Additionally, the	7) In particular, the following measures shall be implemented to deal with foods containing allergens. (For details, see FSM 16.)	5
ei	nsure that	(1)For example, if separate production lines are used in the manufacture of			ensure that	(1)For example, if separate production lines are used in the manufacture of	
fa	acilities and	foods that do not contain a particular allergen and foods that do, the			facilities and	foods that do not contain a particular allergen and foods that do, the potential	
e	quipment that	potential for allergen cross-contact from one line to another be prevented or minimized to a level that does not affect food safety			equipment that	for allergen cross-contact from one line to another be prevented or minimized	
w	vith food are	(2)To prevent food from spilling from one line to another, eliminate			with food are	(2)To prevent food from spilling from one line to another, eliminate intersections	5
co	onstructed and	intersections or implement means to contain or defend food.			constructed and	or implement means to contain or defend food.	
lm th	hade of materials	(3)To prevent or minimize cross-contact of allergens by workers, consider the placement of handwashing sinks in appropriate locations and facilities that			made of materials	(3)To prevent or minimize cross-contact of allergens by workers, consider the placement of handwashing sinks in appropriate locations and facilities that allow	,
a	ppropriate	allow workers to change protective clothing, depending on the situation.			appropriate	workers to change protective clothing, depending on the situation.	
m	naintenance,	(4)Equipment, tool containers, and utensils that come in contact with			maintenance,	(4)Equipment, tool containers, and utensils that come in contact with allergen-	
C di	leaning, and isinfection	allergen-containing foods shall be designed and constructed to effectively eliminate allergens			cleaning, and	containing foods shall be designed and constructed to effectively eliminate	
		Lighting				Lighting	
		1) Provide brightness that allows food handlers to work safely and				1) Provide brightness that allows food handlers to work safely and hygienically.	
		hygienically. Illumination and color tones shall not cause misidentification in the work area				Illumination and color tones shall not cause misidentification in the work area.	
		 2) If there is insufficient illumination in the area where work such as visual 				inspection is performed, take measures such as installing supplemental lighting	
		inspection is performed, take measures such as installing supplemental				such as electric stands.	
		lighting such as electric stands. 3) When conducting color tone inspections, etc., Jamp color tone shall be				3) When conducting color tone inspections, etc., lamp color tone shall be considered in addition to illuminance	
		considered in addition to illuminance.				4) Eighting shall be of specifications that facilitate maintenance and cleaning	
		4) Eighting shall be of specifications that facilitate maintenance and cleaning				and minimize deterioration.	
		and minimize deterioration.					
		5) When installing ducts for electrical wiring, etc., the structure shall be such				5) When installing ducts for electrical wiring, etc., the structure shall be such	
		that dust and dead insects do not accumulate on the top, and the ducts shall be installed in a location that is easy to clean. When removing the ducts, they				installed in a location that is easy to clean. When removing the ducts they shall	
		shall be pulled out vertically rather than horizontally to prevent dust from				be pulled out vertically rather than horizontally to prevent dust from falling out.	
		falling out.				6) To prevent physical hazards such as debris from affecting products or	
		6) To prevent physical hazards such as debris from affecting products or manufacturing and processing lines in the quant of demage to lighting				manufacturing and processing lines in the event of damage to lighting fixtures,	
		fixtures, protective covers (dust-proof type) shall be installed or anti-				measures shall be taken with anti-scattering film. etc.	
		scattering measures shall be taken with anti-scattering film, etc.				7) Eor windows used for lighting, select materials that are resistant to	
		7) Ear windows used for lighting, select materials that are resistant to				deterioration and shattering if they are made of resin, and materials that are	
		resistant to dew condensation if they are made of resin, and materials that are				shatterproof measures such as shatterproof film.	
		shatterproof measures such as shatterproof film.				8) Illuminance of the working environment (this item is applicable to the scope	
		8) Illuminance of the working environment (this item is applicable to the scope in Japan)				in Japan)	
		task organization⇔ Illuminance (lux)⇔				task organization↩ Illuminance (lux)↩	
		Precision work← More than 300 lux←				Precision work dealer More than 300 lux dealer dea	
		normal operation More than 150 luxe				normal operation More than 150 lux	
		rough worke More than 70 luxe Paragraph 1 of the				rough worke More than 70 luxe [€] Paragraph 1 of the	
		Office Sanitation Standards Regulations: Enforcement date: December				Office Sanitation Standards Regulations: Enforcement date: December	
		1, 2022)∉				1, 2022)∉	
		Illuminance Standards in Business Establishmentse				Illuminance Standards in Business Establishmentse	
		Work Classification standard				Work Classification standard	
		General office work More than 300 lux				General office work More than 300 lux	
		Incidental clerical work More than 150 lux				Incidental clerical work More than 150 lux	
							1

GMP

1) Drainage routes shall be designed and controlled to minimize the possibility of contamination of products, etc.

2) The floor and drainage basins shall be designed, with a slope to prevent puddles, and to make cleaning easy.

1) Drainage routes shall be designed and controlled to minimize the

Temperature control

GMP

Depending on the characteristics of the food, appropriate facilities for temperature control of the ambient environment in which the food is handled shall be available when necessary.

Air (air conditioning and ventilation) in the manufacturing environment 1) Provide appropriate means of natural or mechanical ventilation, especially for:

• Minimize airborne contamination of food by aerosols and condensation droplets, etc.

•Assistance in controlling ambient temperature

possibility of contamination of products, etc.

Control of odors that can affect food conformity

• Control humidity to ensure food safety and suitability. (e.g., to prevent moisture gain in dried foods that can allow microbial growth and the formation of toxic metabolites)

2) Wentilation systems shall be designed and constructed so that air does not flow from contaminated areas to clean areas. Systems shall be easy to maintain and clean.

2) The floor and drainage basins shall be designed, with a slope to prevent puddles, and to make cleaning easy. Temperature control Depending on the characteristics of the food, appropriate facilities for temperature control of the ambient environment in which the food is handled shall be available when necessary. Air (air conditioning and ventilation) in the manufacturing environment 1) Provide appropriate means of natural or mechanical ventilation, especially for: • Minimize airborne contamination of food by aerosols and condensation droplets, etc. •Assistance in controlling ambient temperature • Control of odors that can affect food conformity •Control humidity to ensure food safety and suitability. (e.g., to prevent moisture gain in dried foods that can allow microbial growth and the formation of toxic metabolites) 2) Wentilation systems shall be designed and constructed so that air does not

flow from contaminated areas to clean areas. Systems shall be easy to maintain and clean. 3.In this standard, "flow lines of people, goods, and operations" refers to the flow of people, goods, and operations taken as a whole, rather than individually, and is described as process design. Efforts to ensure that the flow of people, goods, and operations minimizes food safety risks include the following:

1) Describe manufacturing flow lines, personnel flow lines, etc. on layout drawings of manufacturing and processing areas, and analyze risks to food safety from these flow lines.

2) Ellow lines shall be separated as much as possible so that they do not intersect. Lines of flow include the following. "Goods" and "people" are the most important among them. Control "goods" and "people" as much as possible to avoid cross-contamination.

(1)Goods: Routes from receipt of raw materials to shipment of final products (2)People: Routes for personnel to enter and leave the work area, routes for movement between work areas, and routes for outside workers to enter and leave the work area

(3)Work: Routes between each process to receive and deliver work(4)Waste: Routes for transporting workshop residues and unwanted materials outside

(5)Drainage: Routes of drainage in the work area

(6)Utilities: Routes of utilities such as steam, compressed air, carbon dioxide, nitrogen and other gases, air conditioning and ventilation, lighting, water, etc. used directly or indirectly in manufacturing and processing
3) Areas that implement different levels of sanitation control (e.g., raw material and finished product areas) are separated to minimize cross-contamination by means of physical separation (e.g., walls, partitions) and/or location (e.g., distance), goods or people flow (e.g., unidirectional production flow), air flow, or temporal separation, and are properly cleaned and sterilized between uses.



3.In this standard, "flow lines of people, goods, and operations" refers to the flow of people, goods, and operations taken as a whole, rather than individually, and is described as process design. Efforts to ensure that the flow of people, goods, and operations minimizes food safety risks include the following:
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GMP 6.2	Personnel	The organization	2. <u>Personnel workwear</u>	GMP 6.2	Personnel	The organization	2. <u>Personnel workwear</u>	•Supplementary correction of
	workwear	shall evaluate	Food handlers shall maintain a high degree of personal cleanliness and, if		workwear	shall evaluate	Food handlers shall maintain a high degree of personal cleanliness and, if	notation
		product-specific	necessary, change into or out of work clothes, head and beard covers, and			product-specific	necessary, change into or out of work clothes, head and beard covers, and	
		ricks and provide	footwar that are clean and in good condition for the intended nurness			ricks and provide	feetwear that are clean and in good condition for the intended nurness	
		appropriate work	1) Appropriate consideration shall be given to the shape of work clothes and			appropriate work	1) Appropriate consideration shall be given to the shape of work clothes and	
		clothing to	shoes to prevent hair and body hair from falling out and getting mixed in			clothing and	footwear to prevent hair and body hair from falling out and getting mixed in	
		minimize food	with the product. In addition, materials suitable for the working environment			footwear to	with the product. In addition, materials suitable for the working environment	
		cafoty ricks	shall be used			minimizo food	shall be used	
		Salety LISKS.						
			2) Prevent contamination and the introduction of foreign matter by			safety risks.	2) Prevent contamination and the introduction of foreign matter by establishing	
			establishing rules for washing and changing work clothes and footwear so				rules for washing and changing work clothes and footwear so that employees	
			that employees can wear clean and good condition work clothes and				can wear clean and good condition work clothes and footwear for their work as	
			factwar for their work, as needed, and onsure that these rules are followed.				nooded, and ongure that these rules are followed	
			3) Work clothes handling food shall only be worn when working in the				3) Work clothes handling food shall only be worn when working in the facility.	
			facility.				4) Elairnets and masks used by food handlers to ensure food hygiene are also	
			4) Flairnets and masks used by food handlers to ensure food hygiene are				maintained in a sanitary condition that prevents contamination of products.	
			also maintained in a sanitary condition that provents contamination of				5) Do not ontor contaminated areas, including toilets, while wearing capitany	
			also maintained in a sanitary condition that prevents containination of				5) Explose the containing to the second state of the second state	
			products.				work clotnes, nats, masks, or special footwear for the workplace.	
			5) Db not enter contaminated areas, including toilets, while wearing sanitary				6) Eats shall be worn that are designed to completely cover the hair of the	
			work clothes, hats, masks, or special footwear for the workplace.				head (including the sideburns).	
			6) Easts shall be worn that are designed to completely cover the hair of the				7) When using aloves select the material according to the nurnose specify the	
			b and (including the sidebourse)				7) Enter using gioves, select the matchai according to the purpose, specify the	
			nead (including the sideburns).				use and storage method, and handle them in a clean and good condition to	
			7) Then using gloves, select the material according to the purpose, specify				prevent secondary contamination.	
			the use and storage method, and handle them in a clean and good condition				8) When disposable gloves are used, check the material and strength according	
			to prevent secondary contamination				to the work to be performed, establish an appropriate replacement frequency	
							to the work to be performed, establish an appropriate replacement nequency,	
			8) When disposable gloves are used, check the material and strength				and strive to prevent damage. Establish and implement rules for hand washing	
			according to the work to be performed, establish an appropriate replacement				before wearing.	
			frequency and strive to prevent damage. Establish and implement rules for					
GMP 7	Training	The organization	1. This requirement requires that the organization ensure that all employees,	GMP 7	Training	The organization	1. This requirement requires that the organization ensure that all employees,	 Alignment with "The GFSI
	5	shall ensure that all	including newcomers, receive education and training in food safety		5	shall ensure that all	including new personnel and temporary workers, receive education and training	Benchmarking Requirements version
			2 The supering for the last main a superscript in the second second second				in faced asfab.	
		personnei,	2. The organization shall determine, systematically implement, and record			personnei,	in food safety.	2024"
		including new	training programs (contents, implementation timing, methods, frequency			including new	2. The organization shall determine, systematically implement, and record	
		personnel, be	(including retraining), etc.) for employees according to their respective roles.			personnel and	training programs (contents, implementation timing, methods, frequency	
		trained in their	It is important to periodically review the training programs and undate them			temporany	(including retraining) etc.) for employees according to their respective roles. It	
		appropriate	as necessary so that food handlers, maintenance staff, and other personnel			workers, be trained	is important to periodically review the training programs and update them as	
		language on food	involved in food operations continue to be aware of all procedures necessary			in their appropriate	necessary so that food handlers, maintenance staff, and other personnel	
		safety (including	to maintain food safety and suitability (see FSM 2).			language on food	involved in food operations continue to be aware of all procedures necessary to	
		management	3 Ensure that current rules and precedures can be reviewed at any time			safoty (including	maintain food safety and suitability (see ESM 2)	
			S.Ensure that current rules and procedures can be reviewed at any time,			salety (including		
		culture, HACCP,	incorporating the opinions of on-site food handlers.			management,	3.Ensure that current rules and procedures can be reviewed at any time,	
		GMP), and be a	4.As food manufacturing employees are becoming increasingly multilingual,			culture, HACCP,	incorporating the opinions of on-site food handlers.	
		system for each	the organization shall make training and education tools available in the			GMP) and be a	4.As food manufacturing employees are becoming increasingly multilingual, the	
		porconnol to	appropriate language for training and educating employees whenever			system for each	erganization shall make training and education tools available in the appropriate	
			appropriate language for training and educating employees whenever			system for each	la sur se fan heining en der her her sur he	
		deepen their	possible.			personnel to	language for training and educating employees whenever possible.	
		understanding,	5. This education and training is not intended to be a one-time effort, but			deepen their	5. This education and training is not intended to be a one-time effort, but shall	
		implement, and	shall be based on an evaluation of the competence of each employee in his or	-		understanding,	be based on an evaluation of the competence of each employee in his or her	
		maintain food	her role, and shall be a system to improve understanding through repeated			implement and	role, and shall be a system to improve understanding through repeated efforts	
						implement, and	C Laden this system complexes shall develop an understanding of the	
		salety in their	enorts.			maintain 1000	b. Onder this system, employees shall develop an understanding of the	
		respective work.	6.Under this system, employees shall develop an understanding of the			safety in their	procedures pertaining to food safety in their respective jobs until they are able	
			procedures pertaining to food safety in their respective jobs until they are			respective work,	to implement them as prescribed.	
			able to implement them as prescribed			commensurate	7 The important idea is not to remove employees who lack the skills from their	
			7 The important idea is not to remove employees who lack the skills from			with their activity	work, but to adveste and train them within this system so that they can acquire	
						with their activity.	work, but to educate and train them within this system so that they can acquire	
			their work, but to educate and train them within this system so that they can				the skills they need.	
			acquire the skills they need.					
		The organization	8.In addition, education and training not only contributes to food defense			The organization	8.In addition, education and training not only contributes to food defense (FSM	
		shall keep records	(FSM 7), but can also be used for the individual evaluation of each employee.			shall keep records	7), but can also be used for the individual evaluation of each employee. This is	
		of the	This is important for building a food safety culture in an organization because			of the	important for building a food safety culture in an organization because it also	
		implementation of	it also relates to communication with employees and performance evaluation			implementation of	relates to communication with employees and performance evaluation of feed	
			it also relates to communication with employees and performance evaluation				relates to communication with employees and performance evaluation of food	
		education and	of food safety activities, which are part of the elements of food safety culture			education and	safety activities, which are part of the elements of food safety culture (FSM 2).	
		training.	(FSM 2).			training.	9.Specific actions that the organization will take in its educational program	
		Additionally, the	9. Specific actions that the organization will take in its educational program			Additionally, the	include the following:	
		system for	include the following:			system for	1) Polate each employee's work procedures to feed safety policies and goals	
							1) Relate each employee's work procedures to food safety policies and goals	
		retraining as	1) Relate each employee's work procedures to food safety policies and goals			retraining as	(FSM 6).	
		necessary shall be	(FSM 6).			necessary shall be	2) Demonstrate that adherence to operational procedures contributes to	
		documented and	2) Demonstrate that adherence to operational procedures contributes to			documented and	ensuring food safety.	
		implemented	ensuring food safety	1		implemented	3) This not that "deviation" or "nonconformity" is a had thing that occurs in the	1
				1			a short that deviation of noncontorning is a bad utiling that occurs in the	1
	1	I his education and	з) шis not that "deviation" or "nonconformity" is a bad thing that occurs in			I his education and	course of dusiness, but it indicates "what kind of thing" or "what kind of state"	
	1	training shall	the course of business, but it indicates "what kind of thing" or "what kind of			training shall	is a deviation or nonconformity, and how to take measures and actions	
	1	enable employees	state" is a deviation or nonconformity, and how to take measures and actions	;		enable employees	(reporting, communication, and consultation) after the occurrence of a	
	1	to recognize their	(reporting communication and consultation) after the occurrence of a			to recognize their	deviation or nonconformity	
	1						A) White each isk	
		role in food safety	deviation or nonconformity.	1		role in food safety	4) within each job, procedures pertaining to food safety shall be provided and	1
	1	and the	4) Within each job, procedures pertaining to food safety shall be provided			and the	trained until they can be implemented.	
	1	significance of their	and trained until they can be implemented.			significance of their	5) At a minimum, train HACCP team members to a level that they can build the	
		efforts	5) At a minimum train HACCP team members to a loval that they can build	1		efforts	organization's HACCP plan	1
	1		the experimentary date the CO stars				() Then have a when we are then CODE should be achieved a should be the should be shou	
	1						b) Employees who monitor CCPs shall be educated and trained to a level where	
	1		6) Employees who monitor CCPs shall be educated and trained to a level				they understand and can implement correction and corrective actions to be	
	1		where they understand and can implement correction and corrective actions				taken in the event of a deviation from the CL.	
			to be taken in the event of a deviation from the Cl					1
	1	T		•	1	1	1	1

		In addition, there shall be a system to improve comprehension by repeating the training as necessary after evaluating competence.	 7) If addition to the above, the educational program shall include, at a minimum, the following items: Product reliability, including food fraud Product Characteristics Food Defense Food-related legal requirements Product/process changes Feedback from previously documented training/instructional programs 8) Establish and implement training programs for all personnel, including newcomers, to obtain the necessary knowledge and skills according to their role in handling food products. 9) Ensure that the current rules and procedures for each job can be reviewed at any time, with input from employees. (See FSM 27) 10) Records created in education and training can be used for individual evaluation and other purposes. (See FSM 2) 11) Ebsed on an evaluation of the employee's competence, education and training shall be repeated as necessary. This retraining system shall be established and implemented in writing. 			In addition, there shall be a system to improve comprehension by repeating the training as necessary after evaluating competence. Scope of the above education and training shall include relevant subcontractors, and their management shall be carried out in accordance with FSM 13.3.	 7) In addition to the above, the educational program shall include, at a minimum, the following items: Product reliability, including food fraud Product Characteristics Food Defense Food-related legal requirements Product/process changes Feedback from previously documented training/instructional programs 8) Establish and implement training programs for all personnel, including new personnel, to obtain the necessary knowledge and skills according to their role in handling food products. 9) Ehsure that the current rules and procedures for each job can be reviewed at any time, with input from employees. (See FSM 27) 10) Records created in education and training can be used for individual evaluation and other purposes. (See FSM 2) 11) Ebsed on an evaluation of the employee's competence, education and training shall be repeated as necessary. This retraining system shall be established and implemented in writing. 12) Stope of the above education and training shall include relevant subcontractors who perform processes that can affect food safety (such as contract manufacturers, labor suppliers, and service providers), and their management shall be carried out in accordance with FSM 13.3. 	
GMP 8	Housekeepi ng, cleaning, sterilization, and disinfection	The organization shall identify product-specific risks based on a hazard analysis throughout all processes and stages and establish, implement, and maintain documented organization, cleaning, sterilization, and disinfection procedures.	 <u>I.Establish procedures based on hazard analysis</u> <u>I.I.Establish procedures shall station and disinfection procedures shall take into account product-specific risks throughout all processes and stages, and effective procedures shall be developed and documented. Since cleaning shall remove food residues (including allergens), this procedure shall include the target facility, equipment, areas of the facility, cleaning tools, detergents, procedures, disassembly, monitoring, and actions for food in case of deviation from the procedure, as required by the scope of the food operation. The procedure shall be reviewed periodically to reflect changing conditions, and revised as necessary.</u> <u>III is important that cleaning equipment, cleaning agents, and disinfectants themselves be risk-assessed and selected before use to ensure that they do not pose hazards. In addition, they shall be clearly identified and stored in areas separated from food manufacturing, packaging, and storage areas. However, if sufficient separation is possible, zoning (such as separate rooms) is not required.</u> <u>III</u> establishing procedures, the required frequency of tidying, cleaning, sterilizing and disinfecting shall be included according to the manufacturing environment and product characteristics. <u>Cleaning shall remove food residues and contaminants that could be a source of contamination, including allergens. Containers and other items that have been exposed to allergens shall be cleaned as soon as they are emptied. Cleaning methods and materials required depend on the nature of the food business, the type of food, and the surfaces to be cleaned. Some surfaces, especially those in contact with food, can require disinfection after cleaning.</u> 	GMP 8	Housekeepi ng, cleaning, sterilization, and disinfection	The organization shall identify product-specific risks based on a hazard analysis throughout all processes and stages and establish, implement, and maintain documented organization, cleaning, sterilization, and disinfection procedures.	 <u>Establish procedures based on hazard analysis</u> <u>I</u>dying, cleaning, sterilization and disinfection procedures shall take into account product-specific risks throughout all processes and stages, and effective procedures shall be developed and documented. Since cleaning shall remove food residues (including allergens), this procedure shall include the target facility, equipment, areas of the facility, cleaning tools, detergents, procedures, disassembly, monitoring, and actions for food in case of deviation from the procedure, as required by the scope of the food operation. The procedure shall be reviewed periodically to reflect changing conditions, and revised as necessary. <u>I</u> is important that cleaning equipment, cleaning agents, and disinfectants themselves be risk-assessed and selected before use to ensure that they do not pose hazards. In addition, they shall be clearly identified and stored in areas separated from food manufacturing, packaging, and storage areas. However, if sufficient separation is possible, zoning (such as separate rooms) is not required. <u>I</u> establishing procedures, the required frequency of tidying, cleaning, sterilizing and disinfecting shall be included according to the manufacturing environment and product characteristics. <u>O</u> Cleaning shall remove food residues and contaminants that could be a source of contamination, including allergens. Containers and other items that have been exposed to allergens shall be cleaned as soon as they are emptied. Cleaning methods and materials required depend on the nature of the food business, the type of food, and the surfaces to be cleaned. Some surfaces, especially those in contact with food, can require disinfection after cleaning. 	•Alignment with "The GFSI Benchmarking Requirements version 2024"
		In these procedures, the organization shall include steps to verify that product- specific risks have been minimized. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended purpose, clearly identified and stored in areas separated from areas where food is manufactured, packaged, and stored.	 5) Attention should be paid to sanitation during cleaning and maintenance operations so that food safety and appropriateness are not compromised. In food preparation and storage areas, use cleaning agent materials appropriate for food contact surfaces. 6) Chemicals used for cleaning and disinfection shall be handled with care and used according to the manufacturer's instructions. For example, they shall be used at the appropriate dilution and contact time and, if necessary, stored away from food in clearly identified containers to avoid food contamination. 7) Care should be taken to ensure that cleaning procedures do not lead to food contamination. For example, it could happen that spray from high-pressure washing could spread contamination from dirty areas such as floors and drains over a large area. It could also contaminate food contact surfaces or bare food. 8) In some operations and/or food processing areas where water increases the potential for microbial contamination, such as when handling low-moisture foods and manufacturing products under dry conditions, controlling the amount of water used in cleaning (e.g., implementing dry cleaning to remove and collect residues and debris) can reduce microbial risks. 2.Education and Implementation 1) Educate food handlers on standardized methods. It is also effective to educate them by showing them the actual cleaning process, or by posting pictures or illustrations of the procedures. Trained personnel shall perform cleaning, washing, and sanitizing. Educate those who handle cleaning approximation for handling them. 			In these procedures, the organization shall include steps to verify that product- specific risks have been minimized. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended purpose, clearly identified and stored in areas separated from areas where food is manufactured, packaged, and stored.	 5) Attention should be paid to sanitation during cleaning and maintenance operations so that food safety and appropriateness are not compromised. In food preparation and storage areas, use cleaning agent materials appropriate for food contact surfaces. 6) Chemicals used for cleaning and disinfection shall be handled with care and used according to the manufacturer's instructions. For example, they shall be used at the appropriate dilution and contact time and, if necessary, stored away from food in clearly identified containers to avoid food contamination. 7) Care should be taken to ensure that cleaning procedures do not lead to food contamination. For example, it could happen that spray from high-pressure washing could spread contamination from dirty areas such as floors and drains over a large area. It could also contaminate food contact surfaces or bare food. 8) In some operations and/or food processing areas where water increases the potential for microbial contamination, such as when handling low-moisture foods and manufacturing products under dry conditions, controlling the amount of water used in cleaning (e.g., implementing dry cleaning to remove and collect residues and debris) can reduce microbial risks. 2.Education and Implementation Educate food handlers on standardized methods. It is also effective to educate them by showing them the actual cleaning process, or by posting pictures or illustrations of the procedures. Trained personnel shall perform cleaning, washing, and sanitizing. Educate those who handle cleaning agents and other potentially risky chemicals, including methods for handling them. 	
		Food safety information on potentially harmful chemicals shall be obtained and confirmed.	 Whether cleaning and disinfection shall be implemented according to the rules is monitored by visual inspection, and its effectiveness shall be verified by using hygiene tests such as product testing and wipe testing. Monitoring methods can depend on the nature of the procedure, but can include pH, water temperature, conductivity, detergent concentration, disinfectant concentration, and other parameters important to ensure that the cleaning and disinfection program is being carried out as planned and to verify its effectiveness. Education shall be provided based on the results of basic education and hygiene inspections. To cleaning and washing shall be implemented planned accordingly, a plan and procedures shall be created as follows: Plan sheet for cleaning and washing facilities Education such as the backs and bottoms of equipment, facilities, and fixtures. Describe the frequency of the work, the date it is performed, who performs it, and how it is recorded. Written procedures for cleaning and vashing facilities Describe the person responsible for the work, the target, the method, the frequency, the monitoring and verification procedures, the work tools to be used, the inspection procedures after the work is completed, and the inspection procedures before production begins, etc. Selection and maintenance of chemicals used for cleaning and sterilization and disinfection, not only shall the chemicals be suitable for the intended use, but also their effects on the product and safety for employees shall be evaluated, and their contents confirmed before making a decision on their use. The following items shall be implemented for the handling of detergents and chemicals used for cleaning, sterilization, and disinfection: Appointment of a person in charge of management Appointment of chemical			Food safety information on potentially harmful chemicals shall be obtained and confirmed.	 Whether cleaning and disinfection shall be implemented according to the rules is monitored by visual inspection, and its effectiveness shall be verified by using hygiene tests such as product testing and wipe testing. Monitoring methods can depend on the nature of the procedure, but can include pH, water temperature, conductivity, detergent concentration, disinfectant concentration, and other parameters important to ensure that the cleaning and disinfection program is being carried out as planned and to verify its effectiveness. Education shall be provided based on the results of basic education and hygiene inspections. I to cleaning and washing shall be implemented planned accordingly, a plan and procedures shall be created as follows: I plan sheet for cleaning and washing facilities O Edude in the plan consideration of areas that are easily overlooked for contamination, such as the backs and bottoms of equipment, facilities, and fixtures. O Ebscribe the frequency of the work, the date it is performed, who performs it, and how it is recorded. Written procedures for cleaning and washing facilities O Ebscribe the person responsible for the work, the target, the method, the frequency, the monitoring and verification procedures, the work tools to be used, the inspection procedures after the work is completed, and the inspection procedures before production begins, etc. Selection and maintenance of chemicals used for cleaning and sterilization 1) In selecting chemicals to be used for the intended use, but also their effects on the product and safety for employees shall be evaluated, and if necessary, safety data sheets (SDS) shall be obtained and their contents confirmed before making a decision on their use. The following items shall be implemented for the handling of detergents and chemicals used for cleaning, sterilization : (1)Appointment of a person in charge of management (2)Invent	

(4)Maintenance of procedures for formulating detergents and chemicals from undiluted solutions

(5)Education for food handlers regarding handling of chemicals, etc.(including proper dilution, contact time, etc.)(6)Preventing detergents and chemicals from being mixed into food (e.g., labeling containers with the names of their contents)

4.<u>Management of cleaning tools, washing equipment, etc.</u> 1) <u>Selection, inspection and maintenance</u>

(1)If foreign matter or microorganisms adhere to equipment, facilities, or utensils used for cleaning, washing, sterilization, or disinfection, it can lead to contamination of products with foreign matter or microorganisms. Separate cleaning machinery, equipment, and utensils designed for different sanitation zones (areas), such as for food-contact surfaces and non-contact surfaces, shall be used for different purposes. Contaminated cleaning tools and washing equipment can also spread contamination.

(2)Check operation and deterioration, etc. before and after use, and immediately repair or replace any defects.

(3)Since dirt remains on the undersides and bottoms, etc. of equipment, facilities, and utensils, disassemble them and check them. Cleaning equipment shall be kept clean, maintained, and replaced regularly so as not to become a source of cross-contamination of contact surfaces or food.
(4)Separate facilities shall be provided for cleaning fixtures of highly contaminated areas such as restrooms, wastewater treatment and waste areas. As needed,

Separate facilities for washing food and washing cooking utensils.Separate sinks for hand washing and washing food.

(4)Maintenance of procedures for formulating detergents and chemicals from undiluted solutions

(5)Education for food handlers regarding handling of chemicals, etc. (including proper dilution, contact time, etc.)

(6)Preventing detergents and chemicals from being mixed into food (e.g., labeling containers with the names of their contents)

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(4)Separate facilities shall be provided for cleaning fixtures of highly contaminated areas such as restrooms, wastewater treatment and waste areas. As needed,

Separate facilities for washing food and washing cooking utensils.Separate sinks for hand washing and washing food.

			 <u>Storage</u> (1)When selecting a storage location, select an appropriate location that does not pose a risk of contamination to products or the manufacturing environment. (2)Cleaning tools shall be stored properly to prevent contamination of the tools themselves, for example by hanging them so that they do not touch the floor, etc. (3)Designate a storage location and keep it clean so that it is readily available to food handlers. (4)Posting of indicating the storage location. <u>Identification</u>				 2) <u>Storage</u> (1)When selecting a storage location, select an appropriate location that does not pose a risk of contamination to products or the manufacturing environment (2)Cleaning tools shall be stored properly to prevent contamination of the tools themselves, for example by hanging them so that they do not touch the floor, etc. (3)Designate a storage location and keep it clean so that it is readily available to food handlers. (4)Posting of indicating the storage location. 3) <u>Identification</u> (1)Measures shall be taken to prevent the misuse of cleaning and washing equipment used in contaminated areas in clean areas. It is important to color-code equipment according to its use, such as "red" for floors and "blue" for cooking utensils, or to store them in separate locations. (2)Allergen-specific cleaning utensils (sponges, cloths, cleaning solutions, etc.) shall be designated and used for allergens only. *FSM19.3 requires the establishment, implementation, maintenance and verification of effectiveness of the cleaning and disinfection program, while GMP8 requires specific implementation details for housekeeping, cleaning, sterilization, and disinfection. 	
GMP 12	Waste Managemen t	The organization shall establish adequate systems for segregation, collection and disposal of waste (including wastewater). The flow lines of waste shall be established so as not to cause cross- contamination of food.	1.Waste, etc. (including by-products not suitable for food use) generated as a result of food production and processing shall be properly managed because they can become a breeding ground for microorganisms, rodents, insects, and other harmful organisms, which may lead to contamination of the production and processing environment. For example, the purpose is to prevent contamination of the surrounding environment and attraction of pests due to overflowing waste (including by-products not suitable for food use) in waste containers in factories and outdoor waste storage areas, as well as outbreaks of sanitary pests and microorganisms due to long-term storage, etc. 2.Avoid contact between waste and raw materials, ingredients, food, or manufacturing/processing facilities. Keep disposal facilities away from food production facilities. 3.Designate a person in charge of consistent management (identification, accumulation, segregation, storage, removal, and disposal) of waste, etc., prepare a written procedure for such management work, and provide training. The status of waste management shall be periodically checked to ensure that the procedures are being followed, etc. Records of disposal shall be maintained. 4.For example, check that the following flow is being processed promptly: Waste, etc. generated in manufacturing/processing lines \rightarrow Containers of waste, etc. \rightarrow Temporary storage area \rightarrow Indoor/outdoor waste storage area \rightarrow Pickup by designated contractors \rightarrow issue and storage of manifest slips (according to laws and regulations)	GMP 12	Waste Managemer t	The organization shall establish, implement and maintain adequate systems for segregation, collection and disposal of waste (including wastewater) to ensure they do not pose any food safety hazards. The flow lines of waste shall be established so as not to cause cross- contamination of food.	1.Waste, etc. (including by-products not suitable for food use) generated as a result of food production and processing shall be properly managed because they can become a breeding ground for microorganisms, rodents, insects, and other harmful organisms, which may lead to contamination of the production and processing environment. For example, the purpose is to prevent contamination of the surrounding environment and attraction of pests due to overflowing waste (including by-products not suitable for food use) in waste containers in factories and outdoor waste storage areas, as well as outbreaks o sanitary pests and microorganisms due to long-term storage, etc. 2.Avoid contact between waste and raw materials, ingredients, food, or manufacturing/processing facilities. Keep disposal facilities away from food production facilities. 3.Designate a person in charge of consistent management (identification, accumulation, segregation, storage, removal, and disposal) of waste, etc., prepare a written procedure for such management work, and provide training. The status of waste management shall be periodically checked to ensure that the procedures are being followed, etc. Records of disposal shall be maintained 4.For example, check that the following flow is being processed promptly: Waste, etc. \rightarrow Temporary storage area \rightarrow Indoor/outdoor waste storage area \rightarrow Pickup by designated contractors \rightarrow issue and storage of manifest slips (according to laws and regulations)	• No change to the guideline
		Locations and containers for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro- organisms. Containers for storing waste materials (including by-products not suitable for food use) shall be clearly distinguished from other containers.	 5.Waste, etc. shall be managed and stored so as not to affect products, raw materials, and materials and equipment that come in contact with the products. 6.In order to prevent cross-contamination between wastes, etc. and products, in principle, wastes, etc. should not be stored in areas where food is handled or stored. (Excluding temporary storage during production, and similar activities. However, even in this case, care shall be taken to prevent cross-contamination with products.) 7.Containers (trash cans, containers, etc.) for storing waste shall be clearly distinguishable from other containers and made of a material suitable for the waste application. They should be impermeable if necessary. Containers used to hold hazardous substances prior to disposal shall be stored in specific containers and locked as necessary to prevent intentional or accidental contamination of food. In addition, tools used to store and handle allergencontaining wastes shall be garbage cans, transport tools, or containers, with a lid that are handled in a manner that prevents or minimizes the potential for allergen cross-contact. 8.Design and construct effluent and wastewater systems so that they do not interfere with food safety. 1) Effluent: All water discharged from food establishments 2) Wastewater: Water discharged from manufacturing processes that needs to be treated, including organic matter, cleaning agents, chemicals, etc. 3) E&r piping used, measures shall be taken to prevent backflow of effluent and wastewater (including backflow of gases generated in sewers, etc.) and cross-connections. 4) Ehsure that effluent does not flow from highly contaminated areas (e.g., restrooms and production areas) to areas where finished food is placed. 			Locations and containers for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro- organisms. Containers for storing waste materials (including by-products not suitable for food use) shall be clearly distinguished from other containers.	 5.Waste, etc. shall be managed and stored so as not to affect products, raw materials, and materials and equipment that come in contact with the products 6.In order to prevent cross-contamination between wastes, etc. and products, in principle, wastes, etc. should not be stored in areas where food is handled or stored. (Excluding temporary storage during production, and similar activities. However, even in this case, care shall be taken to prevent cross-contamination with products.) 7.Containers (trash cans, containers, etc.) for storing waste shall be clearly distinguishable from other containers and made of a material suitable for the waste application. They should be impermeable if necessary. Containers used to hold hazardous substances prior to disposal shall be stored in specific container and locked as necessary to prevent intentional or accidental contamination of food. In addition, tools used to store and handle allergen-containing wastes shall be garbage cans, transport tools, or containers, with a lid that are handled in a manner that prevents or minimizes the potential for allergen cross-contact. 8.Design and construct effluent and wastewater systems so that they do not interfere with food safety. 1) Effluent: All water discharged from food establishments 2) Wastewater: Water discharged from manufacturing processes that needs to be treated, including organic matter, cleaning agents, chemicals, etc. 3) E&r piping used, measures shall be taken to prevent backflow of effluent and wastewater (including backflow of gases generated in sewers, etc.) and cross-connections. 4) Ehsure that effluent does not flow from highly contaminated areas (e.g., restrooms and production areas) to areas where finished food is placed. 	
GMP 15	Transport	The organization shall establish a system to ensure that containers and transportation vehicles, including contracted vehicles, used for the transportation of raw materials and ingredients (including packaging materials), partially processed products, works in progress, recycled products, reworks, and finished products (including packed fresh products in final packaging) are	The organization is required to ensure that products (including intermediate stages) are delivered to the customer or proceed to the next process without any abnormalities. 1. When transporting semi-finished products, work-in-process, recycled products, reworked products, and finished products 1) When delivering to the destination, check the product specifications and consider the necessary conditions for a trouble-free delivery. Examples: temperature and humidity settings, stacking and loading methods, pallet-related items used, delivery containers, and other special conditions. 2) Confirm that the delivery vehicle can handle the set conditions without problems and that the environment is such that the product can be delivered without damage or contamination. (1)Can the required temperature and humidity be set? Also, can the required temperature and humidity recorded at the required frequency? Also, is it possible to check that there are no abnormalities with the thermometer and hygrometer as appropriate? (3)If containers and pallets are not the company's own, check the frequency of cleaning, disinfecting, and replacement. (4)Is the interior of the vehicle kept in proper clean condition?	GMP 15	Transport	The organization shall ensure that all containers and transport vehicles used to transport raw materials (including packaging materials), semi- finished products, work-in-progress, recycled products, and finished products (including final packaged and packed perishable foods) that can affect food safety, are designed, constructed, monitored, and maintained to minimize risks.	The organization is required to ensure that products (including intermediate stages) are delivered to the customer or proceed to the next process without any abnormalities. 1. When transporting semi-finished products, work-in-process, recycled products, reworked products, and finished products 1) When delivering to the destination, check the product specifications and consider the necessary conditions for a trouble-free delivery. Examples: temperature and humidity settings, stacking and loading methods, pallet-related items used, delivery containers, and other special conditions. 2) Confirm that the delivery vehicle can handle the set conditions without problems and that the environment is such that the product can be delivered without damage or contamination. (1)Can the required temperature and humidity be set? Also, can the required temperature and humidity recorded at the required frequency? Also, is it possible to check that there are no abnormalities with the thermometer and hygrometer as appropriate? (3)If containers that come into direct contact with products, lorry tanks (including associated hoses, air pipes, air intake filters, truck pumps, etc.), pallets, etc. are not the company's own, check the frequency of cleaning, disinfecting, and replacement. (1)It is desirable to be able to verify that a validated cleaning program is being implemented for lorry tanks, including their associated parts (this includes the lorry tank body and associated parts). (4)Is the interior of the vehicle kept in proper clean condition?	 Alignment with "The GFSI Benchmarking Requirements version 2024"
		suitable for the intended use, maintained in good repair and clean, protected from contamination, and transported within its intended temperature range.	 (5)Confirmation of whether mixed loading with non-products is allowed, and if so, the loading capacity, items that can be loaded, etc. (6)Confirmation that no outsiders other than the person in charge of delivery are involved. 2.On the organization, too, if necessary, check and make efforts to maintain the delivery environment. If any abnormalities are found, it shall be necessary to request appropriate improvements. 3.The following are points to be considered in transportation equipment: 1) <u>Transport vehicles</u> (1)Vehicles and containers used to transport products shall be clean and constructed to prevent external contamination 			These containers and transport vehicles, including contracted vehicles, are suitable for the intended use, maintained in good repair and clean, protected from contamination, and	 (5)Confirmation of whether mixed loading with non-products is allowed, and if so, the loading capacity, items that can be loaded, etc. (6)Prevention of fraud through the use of sealing or other agreed upon devices or systems to ensure that no outsiders other than the person in charge of delivery are involved. 2.On the organization, too, if necessary, check and make efforts to maintain the delivery environment. If any abnormalities are found, it shall be necessary to request appropriate improvements. 3.The following are points to be considered in transportation equipment: 1) <u>Transport vehicles</u> (1) Vehicles and containers used to transport products shall be clean and 	2

constructed to prevent external contamination.	contamination, and	(1)Vehicles and containers used to transport products shall be clean and
Carry carts, etc. used on site are not considered vehicles under this item, and	transported within	constructed to prevent external contamination.
their management shall be conducted in accordance with GMP 18.	its intended	Carry carts, etc. used on site are not considered vehicles under this item, and
(2)Controlled by temperature and humidity according to the characteristics of	temperature range.	their management shall be conducted in accordance with GMP 18.
the products to be transported, and equipped with refrigeration/freezing and		(2)Controlled by temperature and humidity according to the characteristics of
dehumidification functions when necessary.		the products to be transported, and equipped with refrigeration/freezing and
(3)If products are transported refrigerated or frozen, be sure to regularly		dehumidification functions when necessary.
inspect and record the instrumentation of the thermometer in the vehicle.		(3)If products are transported refrigerated or frozen, be sure to regularly
(4)Use vehicles with sufficient capacity for the items and quantities of food		inspect and record the instrumentation of the thermometer in the vehicle.
handled, and that can be effectively separated in the vehicle.		(4)Use vehicles with sufficient capacity for the items and quantities of food
(5)Cross-check thermometers (e.g., install two different types of		handled, and that can be effectively separated in the vehicle.
thermometers and confirm that there is no difference between them) as		(5)Cross-check thermometers (e.g., install two different types of thermometers
appropriate to ensure that accurate temperatures are maintained.		and confirm that there is no difference between them) as appropriate to ensure
(6)Do not allow unauthorized persons to enter the loading area, and do not		that accurate temperatures are maintained.
place unnecessary items, etc. in the loading area.		(6)Do not allow unauthorized persons to enter the loading area, and do not
		place unnecessary items, etc. in the loading area.
(7)For pallets used for transportation and storage, avoid using wooden		(7)For pallets used for transportation and storage, avoid using wooden pallets
pallets from the viewpoint of pest generation/contamination, and damage.		from the viewpoint of pest generation/contamination, and damage.
(8)When transportation is outsourced, manage it with reference to FSM 13.3		(8)When transportation is outsourced, manage it with reference to FSM 13.3
(Outsourcing Management).		(Outsourcing Management).
2) <u>Containers for transportation</u>		1For lorry tanks, it is advisable to enter into a contract that includes
(1)Containers used to transport food are designated and labeled for food and		documentation of cleaning frequency and methods, cleaning records, and
used only for that purpose.		maintenance schedules.
(2)To maintain cleanliness, the materials shall be washable, and they shall be		2) <u>Containers for transportation</u>
washed and disinfected regularly. If stains or unusual odors are observed,		(1)Containers used to transport food are designated and labeled for food and
clean immediately.		used only for that purpose.
(3)If the container serves as both a shipping container and a storage		(2)To maintain cleanliness, the materials shall be washable, and they shall be
container, check for damage during transportation, and take action if any		washed and disinfected regularly. If stains or unusual odors are observed, clean
leaks, etc. are found.		immediately.
		(3)If the container serves as both a shipping container and a storage container,
		check for damage during transportation, and take action if any leaks, etc. are
		found.

GMP 16	Storage	The organization	Design, construct and operate appropriate storage facilities for the safe and	GMP 16	Storage	The organization	Design, construct and operate appropriate storage facilities for the safe and	 Additional corrections to the
		shall hold or store	hygienic storage of food products (raw materials, semi-finished products,			shall hold or store	hygienic storage of food products (raw materials, semi-finished products, work-	notation
		foods (raw	work-in-process products, reworked products and finished products).			foods (raw	in-process products, recycled products, reworked products and finished	
		materials, semi-	1.Food storage facilities shall be designed and constructed with the following			materials, semi-	products).	
		finished products,	in mind			finished products,	1.Food storage facilities shall be designed and constructed with the following in	
		work in progress,	1) Prevent pests from entering and living in the area.			work in progress,	mind	
		reworked products,	2) Specifications shall effectively protect food and prevent contamination.			recycled products,	1) Prevent pests from entering and living in the area.	
		and final products)	(Contamination includes cross-contact of allergens.)			reworked products,	2) Specifications shall effectively protect food and prevent contamination.	
		at designated	3) The environment shall minimize deterioration of food due to temperature			and final products)	(Contamination includes cross-contact of allergens.)	
		locations, and	and humidity.			at designated	3) The environment shall minimize deterioration of food due to temperature	
		manage them	4) Non-food chemicals (including cleaning agents, lubricants, fuels, etc.)			locations, and	and humidity.	
		under appropriate	should be stored in a secure storage facility separate from food.			manage them	4) In the second	
		conditions to	2.Food storage facilities shall be operated with the following in mind:			under appropriate	be stored in a secure storage facility separate from food.	
		minimize food	1) Control the product in consideration of pre-sterilization, post-sterilization,			conditions to	2.Food storage facilities shall be operated with the following in mind:	
		safety risks.	distribution temperature (ambient, chilled, frozen), expiration date, and best-			minimize food	1) Control the product in consideration of pre-sterilization, post-sterilization,	
			before date.			safety risks.	distribution temperature (ambient, chilled, frozen), expiration date, and best-	
			2) Establish procedures to avoid mixing the test product with the genuine				before date.	
			products.				2) Establish procedures to avoid mixing the test product with the genuine	
			3) Distinguish between raw and cooked foods.				products.	
			4) Distinguish between foods that contain allergens and those that do not.				3) Distinguish between raw and cooked foods.	
							4) Distinguish between foods that contain allergens and those that do not.	