# Regulations on HACCP Certification for Imported Food

MFDS Notification 2021-58(Established on July 1, 2021)

Article 1 (Purpose) The purpose of this Notice is to prescribe certification requirements, an application for certification, amendment certification, a valid date extension, surveillance audits, etc. for a Hazard Analysis Critical Control Point (HACCP)—certified facility for imported food in accordance with Article 6 (2) of the Special Act on Imported Food Safety Control and Article 3 (2) and Article 3 (4) of the Enforcement Rule of the same Act.

**Article 2 (Definition)** The terms used in this Notice are defined as follows:

1. The term "Hazard Analysis Critical Control Point (HACCP)" means a standard for food safety management certification under the Food Sanitation Act and the Health Functional Foods Act and the term refers to a safety management standard (hereinafter referred to

as "HACCP") designed to prevent harmful substances from being mixed with foods or to prevent foods from being contaminated during all steps including raw material management and the manufacturing, processing, cooking, sorting, handling, packaging, subdivision, storage, distribution, and sales of foods (including health functional foods; hereinafter the same shall apply) by identifying and evaluating hazards for each step;

- 2. The term "Critical Control Point (CCP) means a critical step, process or processing to prevent or control hazards of foods or reduce the hazards to an acceptable level to secure food safety by applying HACCP;
- 3. The term "Pre-requisite Program" means a sanitation management program to apply HACCP in accordance with the Food Sanitation Act and the Health Functional Foods Act;

- 4. The term "HACCP Plan" means an in-house plan describing critical limits for CCPs, monitoring methods, corrective actions and verification methods;
- 5. The term "HACCP-certified facility for imported food" means a foreign food facility certified by the Minister of Food and Drug Safety under the Article 6 (2) of the Special Act on Imported Food Safety Control.

Article 3 (Scope of Application) If a foreign food facility registered according to Article 5 of the Special Act on Imported Food Safety Control (hereinafter referred to as the "Act") intends to be HACCP-certified for imported food under Article 6 (2) of the Act, the facility is subject to this Notice.

Article 4 (Requirements for Certification) Any foreign food facility that intends to be HACCP-certified for imported food pursuant to

Article 6 (2) of the Act, shall establish and operate the following matters set out in the Hazard Analysis and Critical Control Point (HACCP) for Food and Livestock Products:

- 1. Operational Pre-requisite Programs for food manufacturing/processing facilities (The programs refer to facility requirements or sanitation control requirements needed to be established in advance to apply HACCP.);
- 2. HACCP for food manufacturing/processing facilities.

# Article 5 (Application for Certification of HACCP-certified Facility for Imported Food, etc.)

(1) Any foreign food facility that intends to be HACCP-certified for imported food under Article 3 (2) of the Enforcement Rule of the Special Act on Imported Food Safety Control (hereinafter referred to as the "Enforcement Rule") shall submit an Application (including an application in electronic form) for Certification of HACCP Applied Facility in the attached Form 1–3 of the

Enforcement Rule. The application shall be submitted to the President of the Korea Agency of HACCP Accreditation and Services (KAHAS), along with a HACCP plan by food type (including an electronic document).

(2) Where the President of the Korea Agency of HACCP Accreditation and Services (KAHAS) deems that documents submitted pursuant to paragraph (1) are incomplete, the President may request additional information and/or action within a certain period of time (except in special cases, within 30 days).

## Article 6 (Certification of HACCP-certified Facility for Imported Food)

(1) When the President of the Korea Agency of HACCP Accreditation and Services (KAHAS) receives an application for Certification of HACCP Applied Facility pursuant to Article 5 (1) of this Notice, the President of KAHAS shall make an evaluation by means of onsite inspection, document review, or others in accordance with the

attached HACCP Performance Evaluation Table.

- (2) The President of the Korea Agency of HACCP Accreditation and Services (KAHAS) may request additional information and/or action within three months, where such request is deemed necessary as a result of the on-site inspection, document review, or others. Where relevant matters are not supplemented within the deadline for such request, the President may terminate the certification procedure for the HACCP-certified facility for imported food.
- (3) The President of the Korea Agency of HACCP Accreditation and Services (KAHAS) shall recognize a foreign food facility as a HACCP-certified facility for imported food where it is determined to be compliant as a result of the evaluation pursuant to paragraph (1). The President shall issue a Certificate of HACCP applied Facility in attached Form 1–5 of the Enforcement Rule.

Article 7 (Amendments to the Certification of HACCP-certified

#### Facility for Imported Food)

- (1) When a HACCP-certified facility for imported food intends to change Critical Control Points (CCPs) in accordance with Article 3-2(3) of the Enforcement Rule, the facility shall submit to the President of the Korea Agency of HACCP Accreditation and Services (KAHAS), an Application for Certification Amendment of HACCP Applied Facility (including an application in electronic form) in the attached Form 1-4 of the Enforcement Rule along with the following documents (including electronic documents):
- 1. An original or a copy of a certificate of HACCP applied Facility;
- 2. A statement on CCP amendments.
- (2) When the President of the Korea Agency of HACCP Accreditation and Services (KAHAS) receives an Application for Certification Amendment of a HACCP Applied Facility pursuant to paragraph (1), the President shall verify such amendments by means of on-site inspection, document review, etc.

(3) When the President of the Korea Agency of HACCP Accreditation and Services (KAHAS) concludes that such amendments are in compliance with the HACCP certification standards after verifying them pursuant to paragraph (2), the President shall reissue a Certificate of HACCP Applied Facility containing such amendments.

(4) When the President of the Korea Agency of HACCP Accreditation and Services (KAHAS) deems additional information and/or action is required after verifying the amendments pursuant to paragraph (2), the President may request such information and/or action or terminate the amendment procedure by applying Article 6 (2).

# Article 8 (Application for a Certification Extension regarding HACCP-certified Facilities for Imported Food)

(1) Any HACCP-certified facility for imported food that intends to apply for an extension of a valid date of the certification under Article 3-2 (5) of the Enforcement Rule shall submit to the President of the Korea Agency of HACCP Accreditation and

Services (KAHAS) at least 120 days before the validity of the certification expires, an Application (including an application in electronic form) for Extension of HACCP Applied Facility in the attached Form 1–3 of the Enforcement Rule, along with the following documents (including electronic documents):

- 1. A HACCP plan by food type;
- 2. An original or a copy of a Certificate of HACCP Applied F.
- (2) Where the President of the Korea Agency of HACCP Accreditation and Services (KAHAS) deems that documents submitted pursuant to paragraph (1) are incomplete, the President may request additional information and/or action within a certain period of time (except in special cases, within 30 days).
- (3) The President of the Korea Agency of HACCP Accreditation and Services (KAHAS) makes an evaluation by applying Article 6
  (1) after reviewing documents submitted by the applicant and takes measure(s) by applying Article 6 (2) and/or Article 6 (3).

#### Article 9 (Surveillance Audit)

- (1) The President of the Korea Agency of HACCP Accreditation and Services (KAHAS) may conduct surveillance audits to verify the compliance of a foreign food facility which has been HACCP-certified for imported food under Article 3-4 of the Enforcement Rule with HACCP certification standards, by means of on-site inspection, document review, or others in accordance with the attached HACCP Performance Evaluation Table.
- (2) Where some matters are deemed insufficient or need corrective actions as a result of the surveillance audit pursuant to paragraph (1), the President of the Korea Agency of HACCP Accreditation and Services (KAHAS) may order the HACCP-certified facility for imported food to modify, supplement the matters or take corrective actions.
- (3) Where a HACCP-certified facility for imported food is determined to be non-compliant as a result of the surveillance

audit pursuant to paragraph (1), the Minister of Food and Drug Safety may order corrective actions or revoke the certification.

Article 10 (Review Deadline) In accordance with the Regulations on the Issuing and Management of Directives and Rules, the Minister of Food and Drug Safety shall review the appropriateness of this Notice and take follow-up measures such as corrective actions every three years counting from July 1, 2021 (by June 30 of every third year thereafter).

# **ADDENDA**

This Notice shall enter into force from July 1, 2021.

[Attached Form] HACCP Performance Evaluation Table

# **HACCP Performance Evaluation**

Evaluation Date	<b>20</b> yy . mm . dd .
Applied Food	
Sales from previous year	

#### Business Receiving Evaluation

	Туре	Name of	Address	Representative	Contact
--	------	---------	---------	----------------	---------

	Business		Phone	Fax/E-mail
Headquarters				
Applied Site				

### **Evaluation Result**

	Result			
Decision (Compliance(Pass)/Non- compliance(Fail))	Pre-requisite	HACCP Standard	Critical Violation*	Training Completed

<sup>\*</sup> Related to the Enforcement Rule of the Special Act on Imported Food Safety Control [Table 1-2]

#### Items to Review

History of Administrative Disposition	History of Foreign Material Detection	History of Non-compliance at Collection Inspection	History of Consignment Production	Remarks
Yes/No	Yes/No	Yes/No	Yes/No	

<sup>\*</sup> This is to check if there is any history of administrative disposition, foreign material detection, and non-compliance issues since the last surveillance audit.

# Information confirmed by

Title	Name	Signature
Executive (Representative)		
HACCP Team Leader (Manager in Charge)		

### Evaluator

Department	Name	Signature

# Executive(Representative) Interview

No.	Question	Answer
1	What is HACCP?	
2	What are the pros and cons of introducing HACCP?	
3	What do you think is important when applying HACCP?	
4	What plans do you have for securing safe raw materials?	
5	What are the future plans for education and training of managers and workers?	
6	What is your follow-up management plan if you get HACCP certification?	

# Interviewees

Department	Title/Position	Name	Signature

# 1. Pre-requisites

# 1-1. Certification Evaluation and Follow-up Management

[Food Manufacturing/Processing Business]

# A. Current Status

	(1)Business Permit (Report)Number					(2)Busine (Report)d		уу	mm dd
	(3)Company Name					(4)Contac	t Number		
	(5) A 11	Headquarters	3						
Applicant	(5)Address	Factory (worksite)							
	(6) Name of Representati						(7)Date	of Birth	
	(8)HACCP-a Food Type	applied					(9)Use of Groundy (Yes/No	vater	
HACCP Team Manager	(10)Title					(11)Name			
	(12)Worksite (Kitchen)	е				(13)Storage			
Surface Area (m²)	(14)Laborate	ory				(15)Other			
	(16)Total								
Types of Worksite (kitchen)	(17) Raw materi Processing Room		turing/ ssing m	(19) Filling Room	(20) Packing Room		y (22) Storage	(23) General/ Clean Area Divided	(24)Other
Evaluation (Yes/No)									
Number of Employees	(25) Manufacturi Managemen Departmen	nt					Mana	spection gement rtment	
Employees	(27)Other Employees						(28)	Total	

#### B. Evaluation

Evaluation (Score)	Results (0-3Point)	Remarks
Work Site Management		
Work Area		
1. Work area should be in independent buildings or separated (It refers to being divided into different rooms or spaces through walls, floors, etc. The same shall apply.) from facilities used for purposes other than food handling. (0~3 point)		
2. Work area (including entrance doors, windows, walls, ceilings, etc.) should have a structure that can be sealed to prevent leakage, ingress of external pollutants, pests, or rodents. (0~3 point)		
3. Work area can be divided into a clean area (A clean area can be further divided into a clean area and a semi-clean area depending on the characteristics of the food product.) and a general area and can be separated, segregated or divided according to product characteristics and processes. (0~3 point)		
Building Floor, Wall, and Ceiling		
4. Floors, walls, ceilings, doors, windows, etc. of a raw material handling room, a food manufacturing/processing room, and an inner packaging room should be constructed of water-proof or heat-resistant materials according to product characteristics. Floors should have no cracks and crevices, and be in a dry condition (except where a moist condition is necessary for certain processing/manufacturing processes). If tiles which have grooves are used for floors, walls, ceilings, etc., they should be kept clean to prevent accumulation of dust, mold, foreign materials, etc., in the grooves. (0~3 point)		
Drainage and Plumbing		
5. Work area should be well-drained, sediment should not accumulate in drains, and plumbing such as drains and drain pipes should be managed to prevent backflow. (0~3 point)		

Entrance	
6. At the entrance of the work area, the instructions for how-to-wear personal protective equipment for each area should be posted and tools for personal hygiene (such as for washing, drying, and sanitizing) should be provided. Workers should remove potential contaminants through cleaning and/or sanitizing before starting work. (0~3 point)	
Passage	
7. The pathways for employee movement should be indicated in the work area, and should not be used for loading or for other purposes. (0 $\sim$ 1 point)	
Window	
8. When the glass of the window is damaged, the glass fragments should not be scattered into the work area nor mixed with raw materials and/or subsidiary materials. (0~1 point)	
Lighting	
9. Brightness should be 220 lux or higher in the work area using natural or artificial lighting to ensure efficient operations. The illuminance of screening and inspection areas should be maintained above 540 lux to assure sufficient lighting for visual confirmation. (0~1 point)	
10. Corrosion-resistant materials should be used for lighting. Protective equipment should be provided to prevent contamination caused by breakage or any fallen-down foreign materials in areas where foods are exposed or inner packaging takes place. (0~1 point)	
Other Facilities	
– Restroom, Locker Room, Etc.	
11. Restroom, locker room, etc. should be equipped with a separate ventilation system that can discharge internal air to the outside. Water-resistant and corrosion-resistant materials should be used for walls, floors, ceilings and the doors in the restroom. Washing, drying and sanitizing equipment should be provided at the entrance of the restroom. (0~2 point)	
12. Locker rooms shall be designed to assure the separated or divided storage of street clothes (including shoes) and sanitary clothes (including shoes), in order to avoid cross-contamination. (0~2 point)	

Sanitation Control	
Management of Working Environment	
- Traffic Flow and Contamination Prevention	
13. Material flows and personnel flows shall be established from receipt of raw materials and/or subsidiary materials to release of products and such flows shall be followed. (0 $\sim$ 2 point)	
14. A prevention management plan against contamination with foreign materials from receipt of raw materials, manufacturing, processing, storing to transportation, should be established and complied with, and if necessary, facilities or equipment for such a purpose should be installed to implement the plan. (0~3 point)	
15. Sanitation programs (including requirements for entry/exit, clothes, washing, and sanitizing) for each area (general area/clean area) should be established and implemented. (0~3 point)	
- Temperature and Humidity Control	
16. A temperature management plan should be established for each process (i.e., manufacturing, processing, packaging, storage). Thermometers should be available to measure temperature of each process and managed properly. A humidity management plan should be established and operated to ensure product safety and suitability if necessary. (0~1 point)	
- Ventilation Control	
17. Ventilation should be installed to remove odors, foul smells, harmful gases, fumes, and steam generated in the work area. (0 $\sim$ 1 point)	
- Pest Control	
18. There should be filter(s) or screen(s) to the intake and exhaust ports that are open to the outside of the work area. (0~2 point)	
19. Work area should be managed to prevent introduction or propagation of pests and rodents and the inflow of pests or rodents should be checked regularly. (0 $\sim$ 2 point)	
20. When performing extermination of pests or rodents, it should take an appropriate protective procedure within a range that does not affect manufacturing processes or food safety in accordance with the established sanitation programs. When the work is completed, any direct or indirect food—contact surfaces should be thoroughly washed or sanitized to remove contaminants. (0~1 point)	

Personal Hygiene	
21. Employees in the work area should always wear work clothes(protective clothing), hair restraints, work shoes, etc. Personal accessories should not be allowed. (0~2 point)	
Waste Management	
22. Waste/wastewater-treatment facilities should be installed and operated in a certain place separated from the work area, and the treatment containers used for waste, etc. should be sealed in a manner that prevents odors and leaking water. Waste, etc should be treated or disposed of according to the management plan and records should be kept. (0~1 point)	
Cleaning and Sanitizing	
23. Facilities should be provided with equipment for sufficiently cleaning and sanitizing machinery, equipment, tools, or containers. (0 $\sim$ 1 point)	
24. Guidelines or instructions for proper hand washing should be posted at a place well visible to employees in cleaning and sanitizing areas. (0~1 point)	
<ul> <li>25. Operators(employer) should set the cleaning and sanitizing standards for each of the following: (0~3 point)</li> <li>Employees;</li> <li>Work clothes, hair restraints, work shoes, etc.;</li> <li>Surroundings of the work area;</li> <li>Inside of each production room;</li> <li>Food manufacturing equipment (including transfer pipes);</li> <li>Refrigeration and freezing facilities;</li> <li>Water tanks (water storage facilities);</li> <li>Storage and transport facilities;</li> <li>Vehicles, tools or containers used for transport;</li> <li>Equipment for monitoring or inspection;</li> <li>Ventilation (including filters and insect-proof screens);</li> <li>Waste disposal containers;</li> <li>Equipment for cleaning and sanitizing;</li> <li>Other requirements.</li> </ul>	
<ul> <li>26. The following should be included in the standards for cleaning and sanitizing: (0~3 point)</li> <li>Cleaning and sanitizing areas for each object;</li> <li>Methods and frequency for cleaning and sanitizing;</li> <li>Person in charge of cleaning and sanitizing;</li> <li>Proper instructions for cleaning and sanitizing equipment;</li> <li>Proper instructions on cleaning agents and sanitizers (general name and common name).</li> </ul>	
27. Equipment or containers used for sanitizing should be stored and managed in designated places. (0~1 point)	

r		· · · · · · · · · · · · · · · · · · ·
28.	The effectiveness of cleaning and sanitizing should be verified, and cleaning and sanitizing should be conducted in accordance with the established plan. $(0 \sim 3 \text{ point})$	
Ma	nagement of Manufacturing/Processing Facility and Equipment	
Ma	nagement of Manufacturing, Processing Equipment or other Machir	nery
29.	Manufacturing, processing, sorting, and treatment equipment /facilities should be properly arranged according to the process flow to avoid cross contamination between processes or between handling facilities/equipment. A risk management plan should be prepared to prevent contamination caused by hazardous factors in the case of the use of compressed air or lubricants that may directly or indirectly affect the product by keeping the compressed air or lubricants clean. (0~3 point)	
30.	Food-contact facilities/equipment should be made of water- and corrosion-resistant materials that are not harmful to human and should be able to be adequately cleaned/sanitized with hot water, steam or sanitizing agents. Equipment and containers should be used and stored for intended use. $(0 \sim 3 \text{ point})$	
31.	Temperature control facilities should be equipped with a device that measures and records temperature changes, or temperatures should be manually measured on a regular basis. The records should be kept and the temperatures should be maintained according to the management plan. $(0 \sim 2 \text{ point})$	
32.	Food-handling equipment/facilities should be inspected regularly and kept in repair and the results should be recorded and maintained. $(0\sim1~\text{point})$	
Ref	rigerator and Freezer Maintenance	
33.	Refrigeration facilities should have an internal temperature of $10^\circ\text{C}$ or less. Freezer facilities should be kept at $-18^\circ\text{C}$ or below, and temperature changes should be able to be indicated from the outside and the temperature sensor should be located where highest temperatures are detected. $(0^\circ2$ point)	
Wa	ter Management	
34.	Water used for food manufacturing/processing or cleaning equipment, containers, and personal cleanliness of employees that may come into contact with food should be tap water or should be groundwater that meets relevant drinking water quality standards specified in the exporting government's regulations. When groundwater is used, the water source should be managed in a manner that protects against contamination generated from toilets, waste/waste water treatment facilities, animal farms, etc., and if necessary, disinfection or sanitizing equipment should be provided. $(0 \sim 3 \text{ point})$	

<ul> <li>35. Water used for food manufacturing/processing or cleaning equipment, containers, and personal cleanliness of employees that may come into contact with food should be tested according to the following sub-paragraphs:</li> <li>a. Groundwater should be tested thoroughly based on relevant drinking water quality standards at least once a year when applicable. (Yet, groundwater used for direct consumption such as beverages should be tested at least once every half-year.);</li> <li>b. Microbiological tests specified in the relevant drinking water quality standards should be conducted at least once a month. (This may only apply to where groundwater or city supply water is used for cleaning raw materials for non-thermal food or used as mixing water for food production.) The tests may be conducted internally using simple test kits. (0~3 point)</li> </ul>	
36. Water storage tanks, pipes and others should be made of materials	
that are not harmful to the human body, and locks should be installed to prevent the inflow of contaminants from the outside. Leaks and contamination should be checked regularly. $(0 \sim 1 \text{ point})$	
37. Water tanks should be cleaned and sanitized at least once per semi-annual period, or it should be carried out by a water-tank cleanup agency. The cleaning records should be kept and maintained. (0~3 point)	
38. Pipes for non-potable water should be identifiable in order to be distinguished from and to avoid being crossed or joined with pipes for potable water. (0~1 point)	
Storage and Transport	
Purchasing and Receiving	
39. Only raw materials and/or subsidiary materials that meet in-house receiving standards/specifications or that are verified through a certificate of analysis should be purchased. (0 $\sim$ 2 point)	
Management of Contractors	
40. Operators should check sanitation controls of contractors such as suppliers of raw/subsidiary materials, and document the results. $(0 \sim 1 \text{ point})$	
Transport	
41. Food products and livestock products should be separated from non-food/livestock products during transport to prevent cross contamination and should be treated in a way to prevent contamination from delivery vehicles (including folk lift). $(0 \sim 1 \text{ point})$	

42.	Refrigerated delivery vehicles should maintain their compartment temperature at $10^\circ\!$	
Sto	rage	
43.	Receiving and releasing of raw materials or finished products should be monitored and documented based on the First In, First Out (FIFO) principle. (0 $\sim$ 1 point)	
44.	Raw materials, subsidiary materials, semi-finished products and finished products should be stored separately, and should be stored off the floor or wall. (0 $\sim$ 1 point)	
45.	Non-conforming raw materials, subsidiary materials, semifinished or finished products should be stored in separate designated area(s) and marked clearly to identify for return or disposal. The results should be recorded and maintained. (0 $\sim$ 1 point)	
46.	Toxic substances, inflammables and/or non-edible chemicals should be stored and handled separately in a well-ventilated designated area isolated from the food handling area. (0 $\sim$ 1 point)	
Tes	sting / Inspection	·
Pro	duct Test	
47.	Product test should be conducted in accordance with the test plan in its own laboratory (i.e., in-house laboratory) or in accordance with an agreement with an external testing agency approved by an exporting government. (0 $\sim$ 2 point)	
48.	Test results should contain the following information (0~2 point): Sample name; Production date or expiration date (best-before date); Test date (YY/MM/DD); Test items, criteria and results; Evaluation results and date (YY/MM/DD); Signature/seal of personnel who conducted the test or evaluation; Other requirements.	
Insı	pection of Facility, Equipment, Etc.	4
49.	Temperature measuring devices for refrigeration, freezing or heat—treatment facilities should be calibrated at least once a year. Tools or equipment for test/inspection should be calibrated regularly. The results should be recorded and maintained when the operators conduct calibration internally. The results should be kept when calibration is conducted by an accredited national	

				r	
calibration	agency. (0 $\sim$	2 point)			
managed ac cleanliness the cleanlir due to one process, sp	0. Bacteria falling in the air or others should be measured and managed according to the established plan to maintain cleanliness of the work area. However, this may not apply when the cleanliness of work area is unlikely to affect food products due to one of the following: automation of the manufacturing process, special nature of facility/product, non-exposed food, food that is handled while packaged, or others. (0~3 point)				
Recall Program					
the steps products sh	to be taker nould be estal	ing procedures or methods that describe a against non-conforming or returned blished and operated. (0~2 point)			
production identify no the non-c be establis	52. It is necessary to record and maintain information such as production place, date, and manufacturing line by product to identify non-conforming products or determine the cause(s) of the non-conformance. Appropriate verification methods should be established such as code display or lot management for product tracking. (0~2 point)				
Final Bank	Total Score	<b>How to Determine Final Result&gt;</b> Evaluation for Certification: If the total score greater than or equal to 85; Compliant (Pass or equal to 70; Corrective Action Required, of (Fail). However, if there are non—applicable evaluation, the total score will be calculated applicable item(s) and be put into a percental place). In this case, the final result will be defenses)" if the percentage is 85% or higher, "less than 85% and greater than or equal to 7% if less than 70%. However, evaluation items they are scored zero, the final result is determined.	or less than 85 a for less than 70; Note item(s) exclude after excluding the getermined to be corrective Action (1), or "Non-como. 34 and 39 and mined to be non-como.	nd greater than Non-compliant ed from the he non-one decimal "Compliant on Required" if ompliant (fail)" re critical. If —compliant.	
Final Result	Percentage (%)	[ [ ompliant (page) at the total ecore is X5% or higher or Non-com		is 85 or be determined plicable calculated after age (rounded to mined to be	
		<pre><deduction> Periodical Surveillance Audit: Failure to take against non-conforming item(s) from the pr result in double deduction points for the non-</deduction></pre>	evious year's ev	aluation will	

# 2. HACCP Management

# **2–1. Certification Evaluation** (Food Manufacturing/Processing Business)

Items	Evaluation (Score)	$\frac{\text{Results}}{(0 \sim 10}$ $\frac{\text{Point})}{}$	Remarks
1. HACCP Team	<ol> <li>A HACCP team was established and the responsibility, authority, and takeover method for each team member have been assigned. (0~5)</li> <li>Team members have adequate knowledge of HACCP for its concept, principles, procedures, and their roles.(0~5)</li> <li>A team leader actively participates in the HACCP team and each team member is involved actively. (0~5)</li> </ol>		
	Subtotal (0~15)		
2. Product Description and Process Flow Chart	<ol> <li>There is a detailed product description. (0~5)</li> <li>Process flow chart is available. (0~5)</li> <li>Process flow chart is consistent with the site. (0~5)</li> </ol>		
	Subtotal (0~15)		
3. Hazard Analysis	<ol> <li>Hazards are identified and the cause of risk occurrence is described in detail. (0~10)</li> <li>Risk assessment criteria (severity, likelihood, etc.) of the identified hazards and the principles of the use of the evaluation results are presented. (0~10)</li> <li>Risk assessment for individual hazards is conducted properly. (0~5)</li> <li>Realistic preventive measures and management plans are established to control identified hazards. (0~10)</li> <li>Scientific evidence for hazard analysis is presented. (0~5)</li> <li>The concepts and procedures for hazard analysis are well understood. (0~5)</li> </ol>		
	Subtotal (0~45)		

Items	Evaluation (Score)	$\frac{\text{Results}}{(0 \sim 10}$ $\frac{\text{Point})}{}$	Remarks
4. Determination of Critical Control Point and Establishment of Critical Limit	<ol> <li>Each CCP is properly determined according to a CCP decision tree. (0~10)</li> <li>Team members have good understanding of the established CCP decision tree. (0~5)</li> <li>The management items of critical limits and criteria are set in detail. The established critical limits are sufficient to control the identified hazards. (0~10)</li> <li>Person(s) in charge of CCP monitoring have sufficient knowledge of the established critical limits. (0~10)</li> <li>Evaluation results for effectiveness used to set the critical limits should consider the characteristics of the site. (0~10)</li> </ol>		
	Subtotal (0~45)		
5. CCP Monitoring and Corrective Action	<ol> <li>A monitoring method is set in order to manage critical limits sufficiently. (0~10)</li> <li>A monitoring manager is at designated location(s) and conducts monitoring according to the monitoring procedure. (0~10)</li> <li>A monitoring manager has good understanding of his/her role and responsibility after training. (0~5)</li> <li>Equipment used for monitoring is properly calibrated and managed. (0~5)</li> <li>Plans and procedures for corrective action are in place and team members understand their roles and responsibilities. (0~5)</li> <li>Corrective actions are taken in detail and promptly and the results are documented properly. (0~10)</li> </ol>		
	Subtotal (0~45)		

Items	Evaluation (Score)	Results (0~10 Point)	Remarks
6. HACCP System Verification	<ol> <li>A verification work process and a verification plan are properly established. (0~10)</li> <li>Initial verification is properly conducted after a HACCP plan is established based on the verification plan. (0~5)</li> <li>Follow-up management, such as corrective action against non-compliance resulting from the verification result, is carried out. (0~5)</li> </ol>		
	Subtotal (0~20)		
7. Education and Training	<ol> <li>Education and training procedures and plans are established for efficient HACCP system.         (0~10)</li> <li>Education and training are conducted in accordance with the education/training policy and procedure. Records are maintained. (0~5)</li> </ol>		
	Subtotal (0~15)		
	Total Evaluation Score (0~200)		

#### **¾**How to Determine Final Result

① Scores for each item are given according to the table below.

#### <Evaluation Score Table>

	Point	
	0~5	0~10
	0	0
	1	2
Coore	2	4
Score	3	6
	4	8
	5	10

② The final result will be determined to be "Compliant (pass)" if the score is 170 or higher out of 200, "Corrective Action Required" if less than 170 and greater than or equal to 140, or "Non-compliant (fail)" if less than 140. However, evaluation items 4-1, 4-3, 5-2, and 5-6 are critical. The final result will be determined as "Non-compliant(fail)" if those items receive insufficient scores.

# **2-2. Surveillance Audit for Follow-up Management** (Businesses for Food Manufacturing/Processing)

Items	Evaluation (Score)	Results (0~10 Point)	Remarks
1. HACCP team	<ol> <li>Team members have adequate knowledge of HACCP for its concept, principles, procedures, and their roles. (0~5)</li> <li>A team leader participates in the HACCP team and each team member is involved actively. (0~5)</li> <li>A take-over process is established and well observed in case of changes in team member(s). (0~5)</li> </ol>		
	Subtotal (0~15)		
2. Product Description and Process Flow Chart	<ol> <li>A product description and process flow chart are reflected in the standard. (0~10)</li> <li>A process flow chart and floor plan are consistent with the site. (0~5)</li> </ol>		
	Subtotal (0~15)		
3. Hazard Analysis	<ol> <li>Information on hazard analysis is constantly collected or updated. (0~5)</li> <li>Hazard analysis is conducted for identified hazards in the case of change(s) in potential hazards. (0~5)</li> <li>Scientific evidence for hazard analysis is available. (0~5)</li> <li>The concepts and procedures of hazard analysis are well understood. (0~5)</li> </ol>		
	Subtotal (0~20)		

Items	Evaluation (Score)	Results (0~10 Point)	Remarks
4. Determination of Critical Control Point and Establishment of Critical Limit	<ol> <li>Each CCP is properly determined according to a CCP decision tree. (0~5)</li> <li>The established critical limits are sufficient to control the identified hazards. (0~10)</li> <li>Evaluation results for effectiveness used to set critical limits should consider the characteristics of the site. (0~5)</li> </ol>		
	Subtotal (0~20)		
5. CCP Maritaing and Corrective Action	<ol> <li>A monitoring method is established to manage critical limits sufficiently. (0~10)</li> <li>A monitoring manager is at designated location(s) and conducts monitoring according to the procedure and keeps the record accordingly. (0~10)</li> <li>A monitoring manager and has good understanding of his/her role and responsibility after training. (0~5)</li> <li>Equipment used for monitoring is properly calibrated and managed. (0~10)</li> <li>Plans and procedures for corrective actions are in place and team members understand their roles and responsibilities. (0~5)</li> <li>Corrective actions are taken and the results are documented and maintained properly. (0~10)</li> </ol>		
	Subtotal (0~50)		
6. HACCP System Verification	<ol> <li>A verification plan, method, and frequency are established based on each target. (0~10)</li> <li>A person in charge of verification has good understanding of verification procedures, methods, and his/her roles. (0~10)</li> <li>Verification is conducted according to the verification plan and procedure. (0~10)</li> <li>Follow-up management, such as corrective action against non-compliance resulting from the verification result, is carried out. (0~10)</li> <li>Verification results are periodically reviewed and analyzed and such results are factored in the operation of the HACCP system. (0~10)</li> </ol>		
	Subtotal (0~50)		

Items	Evaluation (Score)	Results (0~10Point)	Remarks
7. Education and Training	<ol> <li>Education and training procedures and plans are established for efficient HACCP system. (0~10)</li> <li>Education and training are conducted in accordance with the education/training policy and procedure. Such records are maintained. (0~10)</li> <li>HACCP team members periodically review and analyze the results of the education and training and factor in the results when operating the HACCP system. (0~10)</li> </ol>		
	Subtotal (0~30)		
	Total Evaluation Score (0~200)		

#### < How to Determine Final Result >

① Scores for each item are given according to the table below.

#### <Evaluation Score Table>

	Points			
	0~5	0~10		
	0	0		
	1	2		
C	2	4		
Score	3	6		
	4	8		
	5	10		

② The final result will be "Compliant(pass)," if the total score is 170 or higher out of 200 points.

"Non-compliant(fail)," if the total score is less than 170 points.

#### <Deduction>

**Regular Surveillance Audit:** If there is failure to take corrective action(s) required in response to the surveillance audit from the previous year and the failure continues, there will be double deduction points for applicable evaluation item(s).