Taiwan Quality Food Certification Scheme (TQF Scheme)

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TQF Scheme 2.12.2 Foreword

The <u>"Taiwan Quality Food Certification Scheme"</u> (hereinafter referred to as "TQF Scheme") is a certification standard, which is established upon food safety and food quality management requirements. The TQF scheme is to provide a set of specifications for certifying the packaged products of food suppliers (food factories) for its own benefit and the interest of the food supply chain as a whole. Products produced under the TQF Scheme are expected to gain high recognition on the global food safety certification platforms as well as the distribution channels and markets internationally.

The TQF "Taiwan Quality Food Certification Scheme" 2.12.2 (hereinafter referred to as the "Scheme") aims to connect with the world and harmonize with the global common specifications and standards; In addition to continuing based on the framework of ISO/IEC 17065:2012 for ongoing advances in the TQF Scheme, this revision is also in compliance with the requirements of GFSI Benchmarking Version 7.22020.1, the amendments include the limitations of certification scheme counselling, the compliance with regulations of production and at the place of sale, the rework-related specifications, the specifications for water and steam in food manufacturing, the maintenance-related requirements for machine and equipment, the using order of raw material, the procurement procedures, the retention periods of relevant records, the food safety culture, the internal audit frequency, the requirements of food defence management plan and the internal management methods. food safety policy, the security of document and record storage in food factory, the emergency usage of nonapproved suppliers, the monitoring and calibration requirements of food safety critical measuring instruments, a risk-based environmental monitoring program, and the deletion of claim on level 1 certification showing on an end-product. All For newly applied food factories and production lines that are newly applying, shall use the latest version of scheme since the announcement date; or that for the food factories which have passed the TQF certification, can self-assess the version used for surveillance audit within 6 months of the transition period after the announcement of this version. When the transition period is over, this version will be applied to all surveillance audits. must complete the certification and annual conformity assessment with reference to the specifications and requirements of the Scheme within a transitional period of nine months after the promulgation of the TQF Scheme 2.1.

The Scheme establishes a food safety and quality control system by inheriting the "food Food Good Manufacture Practices" (FGMP), which was established in 1989 by the Industrial Development Bureau (IDB) of the Ministry of Economic Affairs (MOEA), and the "Regulations on Good Hygiene Practices for Food" (GHPs) and the "Regulations on Food Safety Control System" promulgated by the Food and Drug Administration (FDA) of the Ministry of Health and Welfare (MHW). In addition, the Scheme had made reference to the food safety control principles and guidelines regarding "Hazard Analysis and Critical Control Points" (HACCP) in the CODEX Alimentarium of the Codex Alimentarius Commission, and the related contents of the "Food Safety Modernization Act" (FSMA) of the US FDA.

The certification of this Scheme can be divided into two levels. Food Safety certification (Level I) of TQF Scheme is required to comply with the codes stipulated in the Chapter 4 for Food Safety Fundamental Specifications and the Chapter 5 for Food Safety Management Specifications. However,



for a comprehensive of Food Safety and Food Quality certification (Level II) of TQF Scheme, an additional requirement is specified in the Chapter 6, which included the Food Quality Management to establish an Integrated Quality Program (IQP) for validating the conformity with the certification specifications and standards of products.



Chapter 1 Introduction

The <u>"TQF Scheme"</u> was established to strengthen the self-management system of food factories, assure the quality, hygiene, and safety of food processing; protect the common rights and interests of consumers and manufacturers; and promote the overall healthy development of the food industry. The Scheme specifies the preparation and processes for food factories to apply for the TQF certification and provides a guideline for certification bodies to accept applications for TQF certification.

The Scheme is owned by the Taiwan Quality Food Association (hereinafter referred to as "TQF Association") and inherited from the promotion plan, implementation regulations, and amendments of the <u>fF</u>ood Good Manufacturing Practices (FGMP) as established by the IDB of MOEA, Taiwan. The basic principles of the Scheme include:

- The Scheme is offered on a voluntary basis.
- The TQF certification under the Scheme falls into two levels. Level I is the food safety certification and Level II is the food safety and quality certification. The guidance for certification preparations and process requirements are available in Chapter 3 of the Scheme.
- For Level I of TQF certification, the factories are required to carry out the food safety management system within the scope of certification for all products in the same category (Same categorized products) to comply with the requirements specified in Chapter 4 and Chapter 5. The Certification Body will proceed the post-market sampling test of the Same eategorized products. However, Same eategorized products are not allowed to carry the TQF Mark in any possible ways.
- For Level II of TQF certification, the factories must obtain the food safety certification in Level I and then conduct in reference to the conformity with the specifications of TQF food quality certification in Chapter 6, by establish an Integrated Quality Plan (IQP), for the right to use the TQF Mark on the products (Certified Products.) Product-sampling tests will be conducted by the Certification Body on the production line for both Certified Products and Same categorized products. However, the post-market sampling test will only apply to the Certified Products.
- The methods of tests promulgated by the competent authority of the central government and established by the National Standards of the Republic of China (CNS), or internationally accepted or validated methods shall apply for testing the Specifications and Standards for TQF Product Inspection Items.

Table 1-01 Comparison of TQF Scheme Certification Levels

	Level I	Level II*
Level Name	Food sSafety	Food Safety and Quality
Certification Scope Same Categorized Products		Certified Products and Same Categorized Products
The Use of Certification Mark	Not Permitted to Use TQF Certification Mark	Only Certified Products are Allowed to Use TQF Certification mark
Certification Specification	Chapter 4, 5	Chapter 4, 5, 6
Sampling	Post Market Sampling	On-site Sampling + Post Market Sampling

^{*}Note: Level II applicants shall in comply with the certification requirements for Level I.



Chapter 2 System, Scope, Management and Normative Reference of Scheme

1 Scheme System

As the certification program owner, TQF Association takes charge of the planning and management of the whole certification system; maintenance, establishment and amendments, and updates of the specifications and standards to ensure the TQF Scheme is up-to-date; promulgation of the Scheme on the official website (http://www.tqf.org.tw/tw/) and the TQF-ICT platform (https://ict.tqf.org.tw/tqfict/) of the TQF Association to provide a reference for the conformity evaluation of accreditation bodies, certification bodies, and food factories applying for TQF certification. Figure 2-01 shows the framework of technical specification review, maintenance and management of the TQF certification system.

To maintain the professionalism and impartiality of the TQF certification system, a TQF certification body must be accredited by an accreditation body that has been recognized as a member of the Pacific Accreditation Cooperation (PAC) and International Accreditation Forum (IAF), and signed the IAF Multilateral Recognition Agreement (MLA), such as the Taiwan Accreditation Foundation (TAF) or other equivalent accreditation bodies. An accredited certification body must also be recognized, authorized, and registered by the TQF Association before it is qualified to conduct a TQF certification audit and issuing a TQF Scheme certificate.

A periodic review and update of the certification specifications and standards of the Scheme shall be subject to the "Regulations for the Establishment and Amendment of the Taiwan Quality Food Certification Scheme" (TQF-DDM-001) on an annual basis. The Technical Working Committee is responsible for recommending and approving changes to the scheme and should shall hold at least one consultation meeting each year, with the assistance of the Secretariat of TQF Association. Technical Working Committee shall consult with representation of the stakeholder from consumer groups and retailer for updating the content of the Scheme, if necessary. Any changes of the Scheme shall first be announced on the TQF-ICT Platform which includes the implementation measures and schedule. If the contents of the Scheme are not met the current update of law and regulation, it should shall be handled in according to the existing law.

To prevent any potential risks, the TQF Association shall have sound financial capacity or insurance for professional liability. The TQF Secretariat should shall ensure adequate workforce and resources, establish the operating procedures for the management and the maintenance for normal operation of the system. A periodic review and internal audit shall be done on an annual basis and a record shall be kept. Specification reviewers and Board of Directors of TQF Association shall maintain impartiality, which including shall not provide any Scheme-related counselling, and ensure that there is no conflict of interest or anything that will affect impartiality prior to accepting the review assignment.

The TQF Secretariat is also responsible for registration management of auditors, promotion of certification system and the supervision of TQF certified products and member of certified plants.



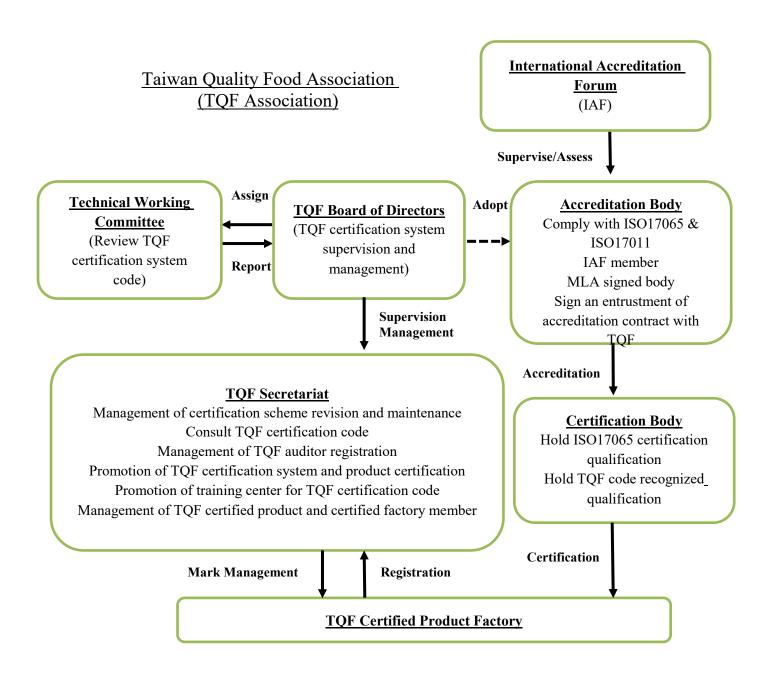


Figure 2-01 Framework of Technical Specification Review and Maintenance and Management of TQF Certification System



2 Scope of Certification

The scope of TQF certification covers the specifications established with food safety fundamentals (Chapter 4), food safety management (Chapter 5), and food quality management (Chapter 6) which is based on the requirements for the manufacturing, processing, and logistic processes of foods for human consumption (including food ingredients and food additives).

Based on product properties, the TQF Scheme has covered the manufacturing of 4 types of processed food: the processing of perishable animal products, the processing of perishable animal and plant products (mixed products), and the processing of products stable at room temperature, that totalling 28 categories of products (as food safety fundamentals specified in Chapter 4). Specific provisions are established for each category product as the technical specifications and the classification is shown at Table 2-01. For more specific details of the 28 categories, please see Addendum 2. Taiwan Quality Food Certification Scheme Food Sector Categories.

Table 2-01 TOF Certification Scheme certified product categories

rable 2 of 1 of Certification Scheme certified product categories				
01. Beverages	02. Baked foods	03. Edible oils	04. Dairy products	05. Powdered infant formula
06. Soy sauce	07. Ice & novelties	08. Noodles	09. Confectionary	10. Ready to eat meals
11. MSG	12. Preserved fruits and vegetables	13. Processed soybean products	14. Processed seafood	15. Frozen foods
16. Canned foods	17. Spices & condiments	18. Processed meat products	19. Chilled prepared foods	20. Dehydrated foods
21. Tea leaf	22. Flour	23. Refined sugar	24. Starch sugar	25. Alcohol & liquor
26. Functional food	27. Food additives	99. Foods in General		

The scope of certification of the Scheme refers to the production field of the above-mentioned categories, which are the products within the range of the main products registered by the food factory. Food factories can apply for Level I food safety certification or Level II food safety and quality certification according to the actual demand.

For Level I of TQF certification, the factories are required to carry out the food safety management system within the scope of certification for all products in the same category (Same categorized products) to comply with the requirements specified in Chapter 4 and Chapter 5. The Certification Body will proceed the post-market sampling test of the Same categorized products during the surveillance audit. However, Same categorized products are not allowed to carry the TQF Certification Mark in any possible way.

For Level II of TQF certification, the factories must obtain the food safety certification in Level I and then conduct in reference to the conformity with the specifications of TQF food quality certification in Chapter 6, by establish an Integrated Quality Plan (IQP), for the right to use the TQF Certification Mark on the products (Certified Products). Product-sampling tests will be conducted by the Certification Body on the production line for both Certified Products and Same categorized products. However, the post-market sampling test will only apply to the Certified Products.

The scope of certification for the Same categorized products shall be determined by the professional judgment of certification body, based on the packaging style or manufacturing methods.



A food factory that manufacturing the TQF certified product shall not outsource the production of its products, unless with contractors that has also passed TQF certification under the same categories. Depending on outsourcing the production of a certified product, wholly or partially, it can be handled in two ways as shown below. In the case of a specific situation that cannot be determined, such case shall report to technical working committee for the judgement.

- 1. Outsource all of the production process: The contract manufacturer shall have passed the same TQF certification level with the contract giver.
- 2. Outsource parts of the production process: The smallest individual pack for selling shall be produced by a certified factory, therefore, the contract giver shall conduct an assessment on contract manufacturer as its supplier management and this shall be checked by certification body when conducting annual surveillance audit.

In addition, if the OEM product does not label the manufacturer's information, it shall not be claimed to be certified by TQF certification system or carry the TQF Mark on the package.



3 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- Act Governing Food Safety and Sanitation and related laws and regulations, Food and Drug Administration, Ministry of Health and Welfare
- Good Hygiene Practice, Food and Drug Administration, Ministry of Health and Welfares
- Regulations on Food Safety Control System, Food and Drug Administration, Ministry of Health and Welfares
- The Establishment Standards of Construction and Equipment of a Food Factory, Food and Drug Administration, Ministry of Health and Welfares
- Regulations of Recall and Destruction for Food and Related Products, Food and Drug Administration, Ministry of Health and Welfares
- Regulations Governing Traceability of Foods and Related Products, Food and Drug Administration, Ministry of Health and Welfares
- Sanitation Standard for General Foods, Food and Drug Administration, Ministry of Health and Welfares
- Regulations Governing the Registration of Food Businesses, Food and Drug Administration, Ministry of Health and Welfares
- Guidelines for Establishing Food Safety Plans of Food Manufacturers, Food and Drug Administration, Ministry of Health and Welfares
- Minimum Inspection Cycle and Related Matters of Food Businesses Requiring Inspection, Food and Drug Administration, Ministry of Health and Welfares
- Regulations on Placement and Management of Food Businesses Employment of Professionals with Vocational or Technical Certification, Food and Drug Administration, Ministry of Health and Welfares
- Regulations Governing the Establishment of the Sanitation Control Personnel of Food Manufacturing Factory, Food and Drug Administration, Ministry of Health and Welfares
- Food Hygiene Inspection Items and Sampling Quantity Table, Food and Drug Administration, Ministry of Health and Welfares
- Chinese National Standard (CNS), Bureau of Standards, Metrology & Inspection, M.O.E.A.
- The Implementation Regulations for Archives on Electronic Storage, National Development Council, Executive Yuan.
- Articles of Incorporation, Taiwan Quality Food Association.
- Committee Organization Rules, Taiwan Quality Food Association.
- ISO/IEC 17065:2012 Conformity assessment Requirements for bodies certifying products, processes and services, Taiwan Accreditation Foundation
- Codex Alimentarius Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003, Annex.: HACCP
- FDA Food Safety Modernization Act (FSMA)
- GFSI Benchmarking Requirements-GFSI Guidance Document Version 2020.17-2
- ISO/IEC 17000 Conformity assessment Vocabulary and general principles
- ISO/IEC 17065:2012 Preview Conformity assessment Requirements for bodies certifying products, processes and services
- IAF MD4:2018 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes



Chapter 3 Certification Preparations and Process Requirements

This Chapter is the procedures for a food factory who applies for the TQF certification and what is the requirements that should shall be complied with. Also it is the guidance for the certification bodies to carry out the certification operations and surveillance audits.

1 Certification Preparation

- 1.1 A food factory may prepare for the TQF certification and evaluate its feasibility, the following options are available:
 - 1.1.1 Participate in the TQF training courses to understand the implementation rules and the requirements of the TQF certification specifications and systems.
 - 1.1.2 Download the latest version of the TQF Certification Scheme and specifications from the TQF-ICT platform to understand the explicit requirements of the technical and management specifications of TQF certification.
- 1.2 Food factories shall satisfy the following criteria before applying for TQF certification:
 - (1) Food factories with a company license or trade name shall have an evidence of registration/establishment or related legal certified documents.
 - (2) Food factories shall have factory registration certificate or factory legal documents which comply with local regulation and have a description of the product item applying for certification.
 - (3) The product shall comply with current relevant food safety sanitation regulations, national standards or relevant international standards (such as CODEX Alimentarius Commission).
 - (4) The product and food production management shall be in accordance with TQF Scheme.
 - (5) Product with re-packaged or changed packaging may apply for TQF certification when the original package product has been certified by the same level or higher level of TQF certification.
 - (6) The product shall be sold publicly.
 - (7) The principle of the product shall be completely packaged.
- 1.3 Figure 3-01 shows the certification preparation flowchart for food factories. The process includes downloading information from the TQF-ICT platform; establish in-house committees for promoting the TQF system; planning for certification implementation; collating food factory procedure documents, records, and forms; and selecting a certification body.
- 1.4 After the feasibility evaluation, a food factory shall apply for certification and audit in accordance with the process requirements specified in the certification specifications as shown in Figure 3-02. Process requirements and process flowchart of TQF certification.



Learn about TQF certification specification system

Select related general provisions or specified provisions for product sector category

Appoint TQF technical specialist

Implement the TQF certification specifications and requirements

Select a certification body

Figure 3-01 Certification preparation flowchart for food factories



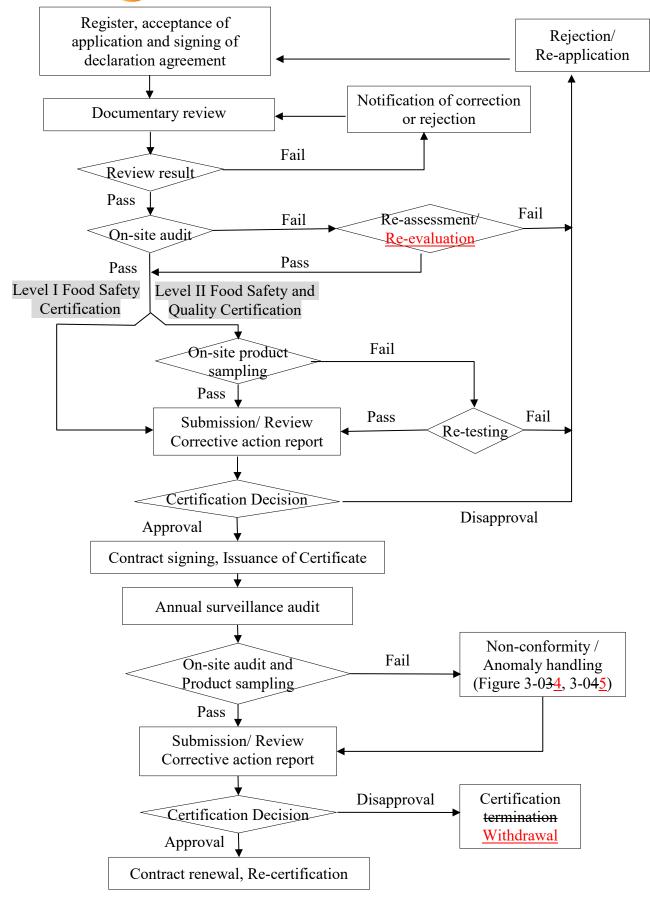


Figure 3-02. Process requirements and process flowchart of TQF certification



2 Certification Application Process

When applying for TQF certifications, a food factory shall register and upload application documents on the TQF-ICT platform. The certification body will precede the documentary review and on-site auditing if the application has been accepted. A food factory shall also sign the TQF Certification Contract with the certification body after certification decision has been made.

The TQF Certification includes level I certification of food safety and level II certification of food safety and food quality. The food factory can apply for either level above in according to the actual demand.

2.1 Registration and Upload

When applying for TQF certification, the food factory shall prepare and upload the relevant documents for the application on TQF-ICT platform and shall register all products within the scope of application for certification on the TQF-ICT platform, and indicated the product items that will be apply as the certified products. For same categorized products, a food factory need to download, fill in and upload the "Same Categorized Products List of Taiwan Quality Food Certification Scheme" (TQF-PCS-000-07) will only need to register product items and specifications for the reference of annual surveillance audit by the certification body. Related data will not be displayed in public on the TQF-ICT platform. A food factory shall continuously make timely updates of the catalogue of products in the latest-scope of certification on the TQF-ICT platform.

2.2 Application acceptance and documentary review

Before a documentary review, a certification body shall examine the qualifications, certification scope of food safety and quality management, and normative documents (such as SOPs and food safety control system documents) of an applicant. The certification body shall assure the applicant has the ability and qualification to proceed the subsequent certification.

- 2.2.1 One copy of the proof of education attainments and the certificate of completion of related training of various professionals and technologists.
- 2.2.2 The following SOPs shall be submitted to the certification body for application. A food factory applying for Level II food safety and quality certification may include the IQP in the HACCP Plan. However, a clear distinction should shall still be made between the Critical control Point (CCP) or Quality controls point (QCP).
 - (1) Management system SOP (for Level I and Level II certification)
 - (2) Sanitation management SOP (for Level I and Level II certification)
 - (3) Quality management SOP (for Level I and Level II certification)
 - (4) Process management SOP (for Level I and Level II certification)
 - (5) Ingredient management SOP (for Level I and Level II certification)
 - (6) Food Safety Control System Plan (for Level I and Level II certification)
 - (7) Integrated Quality Program (for Level II certification)
- 2.2.3 Certification body shall sign the "Statement of Taiwan Quality Food Certification Scheme" (TQF-PCS-000-02Annex 3-02) with the applicant.



3 Documentary Review

- 3.1 Certification body shall complete the documentary review within 20 business days after the date of application is received and notify the applicant of the written review results. A certification body may request a food factory to supplement documents as necessary in accordance with the review results. A food factory shall submit the requested documents within 6 months. If the submission could not be completed within 6 months, a food factory that has justified reasons may apply for extension in writing to the certification body. The certification of application will be considered as a waiver if there are no submissions or extension applied within 6 months. Submission of later than 6 months will be considered as a waiver of an application for certification.
- 3.2 When a food factory passes the documentary review, a certification body shall form an on-site audit team and proceed the certification processes within 3 months. The certification body shall select qualified personnel for the team and may request support from technical experts if necessary. The qualifications of on-site auditors shall conform to the TQF Association's requirements for TQF auditors.

4 On-site Audit

- 4.1 After estimating the minimum man-days of an on-site audit in consideration of the type and scale of a food factory and in accordance with the basic audit time, the number of certified products applied, the number of line workers in production of categorized product, and process complexity, as shown in Table 3-01, a certification body shall notify the applicant of the date and time of the initial on-site audit in writing.
- 4.2 The minimum man-days of audit for the additional production line of the certification shall be determined as zero when the filling style and product hazard factors are identical to other production lines for certification and "none" process complexity is applicable, as shown in Table 3-02.
- 4.3 When a company applies for certification of multi-site categorized production line, i.e. certification of different factories or different sites, the audit man-days and travel expenses shall be calculated and charged separately, because the management system of each factory or site is independent and required individual audits and travels. However, a certification body may calculate the final audit man-days based on the actual situation.
- 4.4 The calculation of man-days based on the number of certified products and the number of workers on the production line of the same categorized products. A certification body may determine the actual audit man-days based on professional judgment.
- 4.5 A certification body may determine the required audit man-days by risk level for the complexity of process patterns that are not defined in the Scheme.



Table 3-01. Guidance of minimum man-days for auditing:

Auditor on-site duration (man-days)					
Dagia time	Product Items		Number of	Complexity	
Basic time for on-site audit	Same categorized products*Note 1	Certified Products	employees on the production line in the scope of certification	of the process*Note 2	
1.0	1.0	1-50=1.0 51-150=1.5 151-250=2.0 251-350=2.5 351-450=3.0 451-550=3.5 551-650=4.0 651-750=4.5 >751=5.0	1-19=0.5 20-49=1.0 50-79=1.5 80-199=2.0 200-499=2.5 500-899=3.0 900-1299=3.5 1300-1699=4.0 1700-2999=4.5 >3000=5.0	N/A=0 Low=0.5 Medium=1.0 High=1.5	

^{*}Note 1: If the column of same categorized product is not applicable for level II, it can be calculated as 0.

Table 3-02. Determination guidance of minimum man-days for auditing by process complexity:

Scope of certification	Complication of process	Risk	Additional man-days
	Same type of filling apparatus in the process and with the same product hazard factors.	None	0
Same production	Different type of filling apparatus in the process but with the same product hazard factors.	Low	man-days
line	Difference in process but with the same product hazard factors.	Medium	
	Both the process and product hazard factors are different.	High	
Different	Different type of filling apparatus in the process but with the same product hazard factors.	Low	0.5
production lines	Difference in process but with the same product hazard factors.	Medium	1.0
mies	Both the process and the product hazard factors are different.	High	0 0.5 1.0 1.5 0.5

^{*}Note 1: If the scope of certification covered two or more different food categories, the additional man-days for auditing shall be added 1 man-day for each different category (as in Table 2-01), process complexity is professionally judged by certification bodies. The determination of Functional Foods in category number 26 is implemented according to Note 2.

^{*}Note 2: Please refer to Table 3-02 for process complexity.

^{*}Note 3: The minimum audit man-days is 2.5.

^{*}Note 2: If the difference of categories involved the Functional Foods in category number 26, the man-days for auditing shall be calculated based on the main production line or functional food production line, which has larger number of audit man-days.



4.6 Implementation of on-site audit

- 4.6.1 The leader of the initial on-site audit team shall notify a food factory of the initial on-site audit duration and obtain the factory's consent in advance. The team leader shall determine the lunch and breaks at work on the audit day based on the actual situation.
- 4.6.2 An on-site audit of TQF certification may implement in accordance with the following operating procedures:

Order	Run-down	Participants	Main Contents	
1	Kick off meeting	Auditing team Representatives of the factory	 Opening address of both parties Introduction of auditing team members Explanation of the preceding schedule and scope of certification 	
2	Introduction of factory	Person-in-charge of the factory	 Business overview Factory profile (including site environment) Organization structure and personnel of the factory 	
3	Briefing on the processing flow chart and building layout	Production and related departments of the factory	 Processing flow chart Building and equipment layout Process and Quality Control Flow Chart (QC Engineering Flow Chart) Introducing of the facility audit route 	
4	On-site audit	Auditing team/ Representatives of the factory	Senior manager from different departments shall accompany the auditing team members to evaluate for the compliance of the TQF certification system in the factory.	
5	Documentary assessment	Auditing team/ Representatives of the factory	Assessment of the factory's documentation regarding to the TQF certification system, such as procedures, standards, production reports, and records.	
6	Internal discussion	Auditing team	The leader of the on-site auditing team shall hold a close room discussion, and factory personnel should temporarily avoided from the meeting room.	
7	Assessment conclusion	Auditing team	 A mutual consent on the number and extent of the nonconformities with factory personnel would need to be achieved, and the assessment team members shall ask the factory representative to sign the "Audit summary report". The leader of the auditing team shall make recommendations based on the results of on-site assessment. 	

- 4.7 Description of on-site audit process
 - 4.7.1 Explain the schedule and scope of certification to the factory's personnel.
 - 4.7.2 The leader of the on-site auditing team shall arrange certification process according



to the schedule.

- 4.7.3 After the "documentary review" and "on-site assessment", the on-site audit team shall ask factory personnel to withdraw from the scene. Then, the team leader shall hold an internal discussion meeting to discuss the audited nonconformities.
- 4.7.4 Every noncompliance audited by the on-site auditing team shall be determined and filed in the "On-site Audit Checklist for TQF Certification System Auditing at XX Factory"(XX is certified product categories of TQF Scheme table 2-01). When there are doubts about nonconformity determination, doubts shall be settled, on principle, by "consensus first and by majority rule next". When no consensus is reached among members, the on-site audit leader may launch an anonymous vote.
- 4.7.5 A certification body shall verify a food factory's ability in the on-site audit to conduct related tests and report the test results.
- 4.7.6 Calculate the number of nonconformities in the On-site Audit Checklist to announce the on-site audit results suggestion. Nonconformities shall be rated by major and minor nonconformities. Please refer to Table 3-05 "TQF Certification Criteria for Determining Production System and Product Anomalies". Production system anomalies refer to the systemic nonconformities caused by the failure of the Prerequisite Program (PRP), the Operational Prerequisite Program (ORP), and Critical Control Point (CCP) of the production system. Such anomalies are determined as the potential causes of food contamination and critical food safety hazards.
- 4.7.7 A major nonconformity refers an un-implemented audit item in the On-site Audit Checklist, and such nonconformity is highly likely to cause immediate hazards and risks on food safety or food quality.
- 4.7.8 A minor nonconformity refers a partly-implemented audit item in the On-site Audit Checklist, and such nonconformity is less likely to cause immediate hazards and risks on food safety or food quality.
- 4.7.9 An opportunity for improvement refers a minor partly-implemented audit item in the On-site Audit Checklist, and such nonconformity does not cause hazards and risks on food safety or food quality. This nonconformity can be considered a recommendation to promote improvement of food factories continuously.
- 4.7.10 Three One "Minor nonconformities" equal is one point; one "Major nonconformity" is three points; and "Opportunity for improvement" will not be rated.
- 4.7.11 When the <u>sum of nonconformities found</u> are less than <u>nine points</u> three "major nonconformities" in accumulation, a food factory shall submit a corrective action report within 20 business days after <u>the on-site audit receiving the notice from a certification body</u>. A certification body may make the certification decision only after verifying the completion of corrective action of nonconformities found.
- 4.7.12 When the sum of nonconformities there are three nine points or more "major nonconformities" in accumulation, a food factory will fail that audit and shall submit the corrective action reports within 6 months. A food factory may apply for a re-evaluation within six months after a certification body verifies the completion



of correction within 20 business days after receiving the report.

- 4.8 A certification body shall make a certification decision and provide audit summary report in writing within 10 business days to the food factory and TQF Association.
- 4.9 After a food factory passes the initial on-site audit, products applying for Level II of food safety and food quality certification shall all be sampled on-site for test, if the TQF Certification Mark is needed for product labelling. A food factory shall classify the other same categorized products within the scope of certification by packaging type, manufacturing method, and risk (Table 3-03) for a certification body to implement on-site product sampling for test.

Table 3-03. Risk classification for samplinge testing

Risk Classification Risk Description		Sampling Ratio within the Scope of Certification
Group I	High water activity and low acidity	≥ 10%
Group II	High water activity and high acidity	≥ 6%
Group III	Low water activity	≥ 3%

Note: High water activity: Aw>0.85; low water activity: Aw≤0.85; high acidity: pH ≤4.6; low acidity: pH>4.6. The product test shall be done in accordance with the "TQF Specifications and Standards for Product Test Items" (TQF-PCS-101~127, 199), and at least three testing items shall be tested on each product.

- 4.10 Products applying for TQF certification of Level II food safety and food quality shall be tested in accordance with the "TQF Specifications and Standards for Product Test Items" (TQF-PCS-101~127, 199). The quality requirements of customers or retailers may be included in the product testing in Level II certification.
- 4.11 <u>In principle, three</u> At least two food safety related testing items shall be arranged for each <u>Level II certified</u> eertification product. These testing items shall include the <u>At least two items of</u> "sanitation standards" in Act Governing Food Safety and Sanitation and the test of "concerned items". At least <u>and</u> one item of "quality specifications" shall be included in the product test. <u>Certification body can test "concerned items" instead of "sanitation standards"</u> where necessary.
- 4.12 If the testing items for the "quality specifications" of certification for food quality in a category are not explicitly defined in the "TQF Specifications and Standards for Product Test Items" (TQF-PCS-101~127, 199), a certification body may perform the sampling test of products in accordance with the specifications of the product testing items in the quality control procedure documents for self-management of a food factory.
- 4.13 After an on-site auditing team completes product sampling for Level II certification, a certification body may send the samples to laboratories that meet the requirement in TQF Scheme Chapter 3, clause 5.2.6.
- 4.14 After passing the on-site audit and product testing and receiving a certification approval decision from a certification body, a food factory shall sign the "TQF Certification Agreement" (TQF-PCS-000-03) with a certification body to issue the TQF certificate. If a



food factory does not pass the product testing, within 105 business days after verifying the test results, a certification body shall notify the food factory in writing to make improvements. Within 20 business days after receiving the written corrective action notice from the certification body, the food factory shall make improvements and submit a corrective action report. After the certification body verifies the completion of improvements based on the corrective action report, the food factory can then apply for a re-testing in a time limits of 6 months. However, the re-testing can only be applied once.

- 4.15 Products approved for TQF Level I certification cannot use the TQF Certification Mark, but products approved for TQF Level II certification of food safety and food quality may use the TQF Certification Mark. The certified products of functional food category can also be labeled in the product packaging with "This product conforms to the TQF OO functional food specifications and standards", however, the food factory should shall offer the sample of the printed packaging of the certified product for verification and upload to the TQF-ICT platform for the certification body to proceed an online review. (Note: OO refers to the specification and standards of a specific functional ingredient food contained in the "TQF Specifications and Standards for Product Test Items" (TQF-PCS-126).
- 4.16 The eertificate code number on the TQF Certification Mark are TQF Certification Mark number, also called mark number, which is made up of eontains nine digits: the first two digits represent the category of product; the third to the fifth digit represent the production line number of products in the same category with the scope of certification for which a food factory applies. The first five digits numbers thus represent the certified production system number, also called production line number, and the first two digits of it represents the category of product. of the food factory. The sixth to the ninth digit represent the product serial number within the scope of certification. These nine digitals together represent the TQF certificate number for the certified product.
- 4.17 After a certification approval decision is made, the production line number would be issued by the certification body. The certification body would verify the number identification identity number on the TQF-ICT platform, and the production line number would be registered on the certificate and be issued to the food factory. is verified in accordingly, a certification body shall register the production system number (five digits) of the certified food factory in the certificate and issue it to that food factory.
- 4.18 The last four digits of certified product mark number are set by the food factory itself. The products with the same identical name, formula and packaging type, but different in net weight, capacity and quantity are allowed to share the same product number. A food factory shall provide a certification body with the last four digits in the Mark that represent the product serial number within the scope of certification before contract signing, for the reference of the nine-digit TQF certificate numbers in the addendum to the TQF Certification Agreement.
- 4.19 For initial application for certification, after passing the documentary review, the food factory may apply in writing for an extension of 6 months, with a justified reason, when it cannot arrange an on-site audit within 6 months. A food factory shall re-apply for a



documentary review if it fails to apply for an extension to the certification body.

- 4.20 A food factory applying for a re-evaluation shall complete and submit a corrective action report within 6 months, after a failed conclusion of an initial on-site audit. A certification body shall verifies the completion of the corrective actions within 20 business days after receiving the correct action report, to enable a food factory to apply for a re-evaluation. Failure to submit the corrective action report in time shall be considered as failure of the certification audit. A food factory unable to arrange a re-evaluation within 6 months after filing an application may apply for an extension of 6 months in writing with a justified reason. A food factory failed to apply for an extension from a certification body is also considered as failure of the certification audit.
- 4.21 The minimum audit man-days of the on-site audit shall apply mutatis mutandis to a reevaluation. A food factory shall apply for only one re-evaluation. The audit team for the reevaluation shall not be the same as that of the preliminary on-site audit. If the re-evaluation is still not approved, the food factory can only restart a new application 3 months after the arrival of the disapproval notice.

5 Product Testing

- 5.1 The principle of product sampling quantity is shown in Table 3-04. Any detecting product anomalies in an on-site audit (i.e. the same categorized products are not fully registered), a certification body shall determine the base and items of sampling by their professional judgement. If the above on-site product sampling is not passed, the application for re-testing is limited only once.
 - 5.1.1 In applications for Level I certification, the post market sampling will only be performed on same categorized products that circulating on the market.
 - 5.1.2 In applications for Level II certification, both certified products and same categorized products will be sampled in an on-site audit. All certified product items shall be sampled; the sampled quantity of same categorized product shall be based on the quantity of item registered in TQF-ICT platform and-deducted-the-amount-of-certified-product. The sampling ratio of categorized product shall be based on the risk classification as-of-shown in Table 3-03. Both certified product and categorized product shall be sampled in an annual surveillance audit and will only conduct post market sampling on certified products.
 - 5.1.3 The first on-site audit will be conducted on products covered in the scope of certification when applying. In an annual surveillance audit, the certified products in the addendum to the TQF Certification Agreement will be the base for the sampling. For same categorized products the sampling base shall mainly refer to the registered items in the TQF-ICT platform. The items with the same formula in the category may be sampled as representatives if products share the same formula, however, this situation can be applied only when the food factory provides the statement of the same formula products initiatively.



Table 3-04 Product sampling quantity for TQF Level I and Level II certification

Product sampling	Level I	Level II		
		Certified Product	All items that have registered as certified product will be sampled.	
Initial On-Site Audit Product Sampling	X	Same Categorized product	According to the registration information of the same categorized category product items on the TQF-ICT platform, that item of products (but not including the certificated products) shall be sampled in accordance with the risk classification of sampling shown in table 3-03.	
Annual On-Site		Certified Product	The proportion of certified products sampling is 1/5 of the certified products that are listed on the addendum of certification contract.	
Audit Product Sampling Surveillance Audit (twice per year)	X udit	Same Categorized product	According to the registration information of the same categorized category product items on the TQF-ICT platform, that item of products (but not including the certificated products) shall be sampled. The proportion of sampling is 1/5 in accordance with the risk classification of sampling shown in table 3-03.	
Post market	1/100 of the categorized product	Certified Product	1/10 of the registered certified product based on the certification contract	
sampling (twice per year)	item registered on the TQF-ICT Platform	Same Categorized product	X	

5.2 Product sampling criteria

- 5.2.1 After confirmation, auditors shall sample products in a food factory randomly from both the certification products and same categorized products.
- 5.2.2 When collecting samples for an initial on-site audit and an annual surveillance audit, auditors shall record the name, specifications, lot number, manufacturing/expiry date, certified product mark number, sampling size, and sampling location of products. The purchase receipts for the post market product sampling shall be maintained.
- 5.2.3 The sampled products shall be readily identified (such as using special marks, stickers, seals, or other methods) as samples collected personally by auditors, and sample management shall be implemented.
- 5.2.4 The sampling and testing fees of samples shall be subject to the rates set by a certification body and is paid by the food factory.
- 5.2.5 Sampling size shall be determined based on the net weight of package size of products in their complete packages: 6 samples for products under 200 grams or milliliter; 4 samples for products between 201 grams and 500 grams or milliliter; and 3 samples for products of 500 grams or milliliter and above. A certification body shall collect samples in their basic complete packages with respect to the product testing items to ensure the sampling size is adequate for running all the testing (including adequate quantity for duplication and verification of testing results). If products sampled on-site are in industrial packaging, a certification body



- may re-package such products for sample in accordance with the above principles, provided that the process of re-packing and the sampling methods will not affect the testing results of each inspection items.
- 5.2.6 A product testing laboratory shall conform to the applicable ISO/IEC 17025 requirements or pass the accreditation of food testing facilities by the Taiwan Accreditation Foundation or Food and Drug Administration.
 - 5.2.6.1 Although not all the testing items that listed in the "TQF Specifications and Standards for Product Test Items" have the corresponding accredited laboratory with, if this is the case, the certification body shall provide evidence to prove such case. When a certification body is executing the conformity assessment of laboratory, the competency of employees, calibration of apparatus, the storage and traceability of documents etc. shall be assessed. Accreditation body and TQFA can witness such conformity assessment, where necessary.
- 5.2.7 The testing items of individual product categories shall in comply with the "TQF Specifications and Standards for Product Test Items" (TQF-PCS-101~127, 199).

 Applied for certifying as Level I products, the testing items are three which "quality specification" is optional. Applied for certifying as Level II products, the testing items shall cover at least two "sanitation standards" and one "quality specifications"; certification body can test "concerned items" as replacements of "sanitation standards" where necessary. In addition to "sanitation standards" and "concerned items", the testing items of food safety certification, it shall cover "quality specifications" for products applying for TQF certification of food safety and food quality to conform to the TQF Certification Mark requirements.
- 5.2.8 Product labelling shall conform to its contents. The method of labelling shall conform to the regulatory requirements of the place (country) of production and selling, (country) and those requires set forth in the general and specific TQF food provisions.
- 5.2.9 In the annual surveillance audit, a minimum of three testing items shall be implemented for different types of food industries. These three items may include the compulsory testing items if the food industries comply with the "Minimum Inspection Cycle and Other Related Items of Food Businesses Requiring Establishment of Food Safety Monitoring Plans and Implementation of Inspections" promulgated by the Food and Drug Administration notice.
- 5.3 Principle of product sampling
 - 5.3.1 On-site audit sampling
 - 5.3.1.1 It is not required for Level I certification.
 - 5.3.1.2 Sampling for Level II certification shall be done in annual surveillance audit. If products are not available for sampling when certification body conducting the twice a year unannounced on site audit within the certification period. The food factory shall inform the certification body for sampling when the production operates, the additional cost will be charged. If on-site sampling



cannot be performed due to consumer demands or other special reasons, the food factory shall explain the reason and sign the "Declaration of Certified Products Not Applicable to the Sampling and Testing Requirements for Taiwan's Quality Food Certification Scheme" (TQF-PCS-000-04) and submit it to certification body for approval. The certification body may be determined the sampling and testing mechanism for such product after the permission.

- 5.3.2 Post market sampling: it is required for all TQF certified food factories. For level I certification, same categorised products shall be sampled. For level II certification, certified products shall be sampled.
- 5.3.3 For level II certification, the management of the certified products is applied to all certified products, including certified products without labelling TQF certification mark.
- 5.3.4 When the certification body can only sample Level II certified products with the same batch number during the annual on-site audit sampling and post-market sampling, the testing items could be one "sanitation standards" and one "quality specifications", the third item could be " concerned items" or "quality specifications", however, "concerned items" shall be the priority to consider.
- 5.3.5 The post market sampling is not applicable:
 - 5.3.5.1 For level I certification, if the same categorised products cannot be sampled from the post market, the food factory shall specify such case with reason and the product information in the list of same categorised products on TQF-ICT platform.
 - 5.3.5.2 For level II certification, "Declaration of Certified Products Not Applicable to the Sampling and Testing Requirements for Taiwan's Quality Food Certification Scheme" (TQF-PCS-000-04) shall be signed by a food factory when the certified product is only for exportation, commerce between two businesses, OEM products for unknown target, and special channel products (such as goat's milk) which cannot be reached by general public (including online shopping and e-commerce). The buyer's information of the product shall be specified in the declaration, the certification body may be determined the post market surveillance mechanism for such product after the permission.

6 Certification Decision

- 6.1 A certification body shall assume full responsibility for all decisions made for certification and reserve the right to decision-making.
- 6.2 A certification body shall assign <u>a person or a team</u> at least one staff, who is <u>(are)</u> legally employed by or contracted with the certification body, to make certification decision based on all information and results of on-site audit and annual surveillance audit. <u>and The certification decision maker shall has (have)</u> not involved in that on-site audit or annual surveillance audit to make the certification decisions.
 - 6.2.1 The certification decisions for on-site audit of first time application for Level I



certification are based on on-site audit results and the <u>collective</u> action reports; <u>for Level II that are based on on-site audit results, corrective action reports,</u> products testing report <u>and related information</u> of on-site sampling—shall also be included in decision—making for Level II certification.

- 6.2.2 The certification decisions for annual surveillance audit of Level I certification are based on on-site audit results, the <u>collective corrective</u> action reports,—and—post market product sampling test reports and related information; the Level II certification decision is based on on-site audit results, <u>collective corrective</u> action reports and product test reports (including on-site and post market product sampling.)
- 6.3 Recommendations made for the certification decisions according to the audit review shall be documented; exception is allowed only when the audit review and the certification decision are conducted by the same person.
- 6.4 The certification body shall notify the supplier of a decision not to grant certification, and shall explain the reasons to the food factory.
 - 6.4.1 After the first-time application for certification is rejected by the decision of a certification body, a food factory can only apply for new certification at least 3 months after the rejection decision.
 - 6.4.2 When annual surveillance audit is rejected by the decision of a certification body, the certification qualification of a food factory will be <u>withdrawn</u> terminated, and this food factory shall not apply for new certification within one year. Re-applying for TQF certification, the process of initial application is requested.
- 6.5 Within 20 business days after making a certification decision based on the certification report (on-site audit report, corrective action report, and product test report and related information), a certification body shall publish the decision on the TQF-ICT platform and notify a food factory and TQF association.
- 6.6 After the certification body decided that a food factory fails the application of certification, this food factory may appeal to the TQF Association. If the appeal is involved with nonconformity with the technical specifications and management specifications, a certification body will need to submit related information for making a rejection decision, including the on-site audit reports and product test reports, to TQF Association. The TQF Technical Working Committee will form a task force to assist TQF Secretary Office in judging if the appeal is valid. The convener of the TQF Technical Working Committee will form the special task force with five committee members based on the properties of products in appeal to audit the case. The TQF Technical Working Committee will also hire external technical experts to assist with the audit, where necessary.

7 Contract Execution and Certificate Issuance

7.1 After a food factory applying for certification completes corrective actions for nonconformities, a certification body shall make a certification decision before issuing a



- "TQF Certification Scheme Certificate" (Annex 3-05-TQF-CLM-001-02).
- 7.2 TQF Certification Scheme applies annual contract signing and certificate issuing.

8 Addition, Change and deletion of Products

- 8.1 The food factory that has obtained the product certificates and is applying to add new certified products, shall submit the relevant information to TQF-ICT platform and certification bodies shall do the documentary review within 10 business days. The certification body is responsible for reviewing the required documents online. The submission of an additional product as follow: (1) QC flowchart, (2) package design specimen, (3) finished product specifications of additional products, (4) nutrition claims or nutrition labelling or other supporting data involving regulatory claims, and (5) factory's product self-inspection report.
- 8.2 The self-inspection report on products of a food factory shall compliance with the belonged categories of "TQF Certification Scheme—Specifications and Standards for Product Inspection Items" (TQF-PCS-101~127 \cdot 199) and provide the related test reports as required in accordance with article 5.2.7 of this chapter. and shall cover at least 3 items of "sanitation standards" and "quality specifications". If necessary, the certification body might designate the inspection items.
- 8.3 When adding an item of same categorized products, shall also register the name, specifications and other related information of the additional product on TQF-ICT platform. Food factory shall ensure the list of the same categorized on TQF-ICT platform is up-to-dated.
- 8.4 A food factory shall apply for a change or deletion of certified products on TQF-ICT platform to maintain the directory of certified products. Certification bodies shall review the application within 10 business days.
- 8.5 Name and TQF certification product number of certified products shall be specified in the addendum to the TQF Certification Agreement.
- 8.6 After the addition, deletion (cancellation), or name change of a certified product, the certification body shall update the addendum. A food factory shall destroy the old addendum without returning it to a certification body.
- 8.7 Details of the latest certified products attached on the TQF Certification Agreement are based on the data published on the TQF-ICT platform.
- 8.8 A food factory shall voluntarily verify if the date of update on the TQF-ICT platform is the latest version. A food factory shall assume all responsibility for the untimely change to the registration TQF-certified products.

9 Annual Surveillance Audit

9.1 A certification body shall implement surveillance audit, including the annual on-site audit unannounced (irregularly implemented without prior notice to a food factory) annual surveillance audit and post market sampling of certified products. Level II certification shall include annual on-site product sampling test. The annual surveillance audit would be implemented without announced (irregularly implemented without prior notice to a food



factory).

- 9.2 The production system of a food factory shall accept annual unannounced surveillance audit at least twice a year. The duration of audit shall be subject to the half of the minimum initial on-site audit man-days (see Chapter 3 section 4 for details), and all regulations in the certification scheme shall be audited at least once within the certification period.
 - 9.2.1 Certification bodies shall consider the previous audit results, if there are events of audit records of anomalies or special food safety incident records, the present certification period shall increase at least 1 extra annual on-site surveillance audit.
 - 9.2.2 In the event of a special food safety incident, a certification body shall increase provisional annual on-site audits, provisional on-site audit takes 2 audit man-days as a matter of principle.
- 9.3 The level of anomalies of the production system of a food factory shall be determined based on the "Taiwan Quality Food Certification System XX On-site Audit Checklist" (XX is the food sector categories of Table 2-01, TQF Scheme) established in accordance with the General Provisions and Specified Provisions for TQF Management Technical Specifications from Chapter 4 of TQF Scheme, (please refer to Chapter 4, TQF Scheme) and the anomaly shall be handled in accordance with Figure 3-_04 "TQF Certification Production System Annual On-Site Audit Flowchart".
- 9.4 Certification bodies shall sample the products in the annual surveillance audit, the sampling ratio based on table 3-04, and in accordance with Section 5 of Chapter 3, TQF Scheme.
- 9.5 Table 3-05 "TQF Certification Criteria for Determining Production System and Product Anomalies" shows the criteria for determining the level of production system and product anomaly of the TQF certification system.
- 9.6 Fail to pass the TQF certification in annual on-site audit or product sampling test shall be handled in accordance with Figure 3-04. "TQF Certification Production System Annual On-Site Audit Flowchart," or Figure 3-05." TQF Certification Product Sampling Flowchart."
- 9.7 When anomaly is found in the production system or its certified product; or a "nonconformity" is found in product testing, and the nonconformity persists after re-testing, the food factory shall submit the corrective action report to the certification body within 10 days, and the a certification body shall re-assess such production system or product. During the period of a production system or a product anomaly, a certification body shall request a food factory to temporary suspend the certification qualification. A certification body may withdraw terminate the certification qualification of a food factory failing to complete improvements and notify the food factory to withdraw terminate the agreement. The withdrawal termination of the certification scope is professionally judged by certification bodies based on the exact situation. Details of the procedure please see figure 3-04 and 3-05.
- 9.8 Production within the scope of certification shall comply with the Scheme requirements, including products that do not use the TQF Certification Mark. A certification body may withdrawal terminate the certification qualification of a food factory that does not conform to the Scheme requirements.
- 9.9 In annual surveillance audit, a certification body shall verify if a food factory conforms to the "Guidance for Management of TQF Certification Mark Use" (Annex 3-07TQF-CLM-001). A certification body may withdrawal terminate the certification qualification of a food



factory failing to comply and notify TQF Association.

- 9.10 When a food factory has been reported or discovered to have its certified products manufactured by a factory that is not certified to produce that TQF certified product and this case has been confirmed, a certification body shall withdraw its certification qualification.

 In surveillance audit, a certification body shall verify if a food factory conforms to the "Guidance for Management of TQF Certification Mark Use" (Annex 3-07). A certification body may terminate the certification qualification of a food factory failing to comply and notify TOF Association.
- 9.11 When anomalies of a TQF-certified product production system or the certified product is reported or found by consumers or related units, a certification body shall take actions in accordance with Figure 3-04 "TQF Certification Production System Annual On-Site Audit Flowchart" and Figure 3-05 "TQF Certification Product Sampling Flowchart" after confirming the nonconformity.
- 9.12 When production equipment is changed, the food factory shall notify the certification body and provide relevant documents within 10 business days of the exact change. The certification body shall ensure the equipment complies with TQF Scheme during annual onsite audit.
- 9.13 A food factory planning to shutdown the plant for more than 6 months for the reason such as seasonality procedure or equipment maintenance, shall report to a certification body and TQF Association in advance and shall notify the resumption time to facilitate the annual surveillance audit, and it takes 1/2 of man-days of annual surveillance audit as a matter of principle. A certification body shall conduct an on-site inspection to confirm the halt. Before resuming operations by the notified halt deadline, a food factory shall submit a resumption plan and apply for an inspection to a certification body, and pass the inspection before restarting mass production. If a food factory was discovered for a halt or resuming operations without advance reporting, a certification body shall take actions according to the penalty for violated food factories in the "Taiwan Quality Food Certification Scheme Certification Statement" (Annex 3-02TQF-PCS-00-02).
- 9.14 When a food factory does not resume operations after the notified halt deadline and fails to apply for extension within 20 business days of the halt deadline, a certification body should shall withdraw terminate the certification qualification of the production systems registered in the scope of certification of that food factory. Only one extension is allowed.
- 9.15 When a food factory is halted and unreachable for more than 6 months, a certification body should shall withdraw terminate the certification qualification of the production systems registered in the scope of certification of that food factory.
- 9.16 Non-operating for more than 6 months because of business problems shall be considered as a halt.
- 9.17 When a food factory has only one certified product in Level II of certification and the halt for production is longer than the expiry date of the last lot of that products, the food factory shall apply for an extension of the same categorized products as an additional new certified products to maintain its certification qualification.
- 9.18 A certification body shall inform the result of annual surveillance audit in writing to a food factory and TQF Association and publish the results on the TQF-ICT platform within 20



- business days after certification data (including on-site audit reports, corrective action reports, and-product test reports and related information) are collected.
- 9.19 A certification body may withdraw terminate the certification and cancel the certification agreement and TQF certificate of a food factory which avoids, obstructs, or refuses the annual surveillance audit of a certification body and fails to make corrective actions in writing. Food factory shall provide explanation within 5 business days after receiving the notification, the certification body shall decide whether or not the acceptance of the explanation. If a certification body regards the situation is significant, the certification body shall withdraw terminate the food factory's certification qualification within 5 business days after receiving the explanation. Within 30 business days after receiving the certification withdraw termination notice, a food factory shall return the certification agreement and TQF certificate to the certification body. A certification body may request a food factory to return the certification agreement, cancel its TQF certificate, and register this on the TQF-ICT platform when a food factory fails to do so after the deadline.

10 Use of TQF Certificate and TQF Certification Mark

- 10.1 A certification body shall verify if a food factory applying for certification that passes the certification use of TQF certificate and TQF Certification Mark correctly in accordance with "TQF Certification Scheme Certificate" (Annex 3-05 TQF-CLM-001-02) and "Guidance for Management of TQF Certification Mark Use" (Annex 3-07-TQF-CLM-001).
- 10.2 After completing the certification procedures, a certification body shall issue one TQF Certificate proving the scope of certification that the food factory apply for compliance to the Scheme. Contents of a certificate include the name and address of a certification body; the date of issue; the name and address of a food factory; the level of food safety or food quality certification and the scope of certification (refer to section 2 of chapter 2); the certification period; company principal plant manager and other relevant information.
- 10.3 After passing certification, the food factory should shall claim "TQF-certified" only for products within the scope of certification specified in the certificate, in accordance with chapter 3, section 4.15 of the Scheme. The food factory may combined its certified products that belong to different product categories into one certificate, but shall assume the risk of certificate combination. A functional food category certificate may be issued separately or in combination with the original certification category.
- 10.4 The certification body shall verify if the TQF Certification Mark is used on products passing level 2 certification in conformity with related regulations in accordance with the standard format and instructions to production of the TQF Certification Mark, such as the "Guidance for Management of TQF Certification Mark Uses" (Annex 3-07 TQF-CLM-001) and "Agreement on the Use of Taiwan Quality Food Certification Mark" (Annex 3-08 TQF-CLM-001-01).
- 10.5 TQF Association shall control the use of agreement, certificate and certification mark, as well as the ownership, usage and display, or any other ways that demonstrates that the products have been certified.
- 10.6 The abuse, usage, and annual fee of the TQF Certification Mark shall be handled in accordance with the "Guidance for Management of TQF Certification Mark Uses" (Annex



- 3-07 TQF-CLM-001) and "Rates of the Annual Fee of TQF Certification Mark" (Annex 3-09 TQF-CLM-002). TQF Association will notify a certification body to suspend the certification qualification of a food factory failing to pay the annual fee of the TQF Certification Mark within 2 months after notification. A food factory may resume its certification qualification, renew an agreement, or apply for certificate issuance after pay off all fees.
- 10.7 The scope of use for the TQF Certification Mark is limited to TQF-certified products. The TQF Certification Mark shall not be used on same categorized products to prevent confusion and misunderstanding.
 - 10.7.1 Only the food factory who pass the level II certification can apply for the usage of TQF mark for advertisement.
 - 10.7.2 Certified food factories shall provide the documents that include when, how and where the TQF certification mark will be displayed when applying. Citification Certification bodies shall ensure that all the products are included in the scope of certification and the advertisement content shall be checked by TQF association.
 - 10.7.3 The above application and approval procedures shall apply mutatis mutandis to the use of the TQF Certification Mark on tankers intended for transporting TQF-certified low water activity products (e.g. liquid sugar, food oil and fat, and flour).
 - 10.7.4 If the advertisement is only for one specific certified product, its TQF certification mark (include product number) can be used.
 - 10.7.5 When a food factory applies to a certification body for extending the scope of certification to all the production lines of food categories with supporting documents, it may use the Figure 3-03 "TQF Certification Mark without product number"—(as shown in figure 3-03) to advertise, such as signboards, posters, TV, print media, internet advertising, pamphlets, manuals, and product catalogues, TQF-certified products with the consent of a certification body.



Figure 3-03, the TQF certification mark without product number

- 10.8 A Level II certified food factory can only label the TQF Certification Mark on product(s) that has passed TQF certification. Under no circumstances shall a food factory suggest in any form or by any means that the TQF-certified products and other uncertified products in the same category have been directly certified by the TQF Association or the Certification Body.
- 10.9 The TQF Certification Mark shall not be used on uncertified products in the same category. A food factory passing TQF certification shall not use the TQF Certification Mark in excess of the scope of certification and against the use of TQF certification mark.
- 10.10 A TQF Certification Mark shall only be used within the scope of certification and its validity certification period. When a certified product is not carrying a TQF certification mark due to the special request (such as short term sale or design matters), the food factory shall notify



- submit "Notification for not using TQF Certification Mark" (TQF-CLM-001-03) to the certification body and notify TQF association such matter. The notification shall include product name, certification number, package materials, specification of the product, the reason for not using certification mark and the period of not using TQF certification mark.
- 10.11 When a certification body decides to <u>withdraw</u> terminate the certification qualification, <u>the</u> <u>factory shall cease</u> the use of the TQF Certification Mark <u>and the production of the product immediately</u>, <u>which the products produced before the withdrawal date are not limited by this clause</u>. on its certified products shall be ceased immediately.
- 10.12 In acknowledgement of the violation of the above rules and the engagement in acts that may harm the rights and interests of the TQF Certification Mark, a certification body shall inform TQF Association within 48 hours and assist TQF Association in taking any necessary relief measures.
- 10.13 A TQF certified product food factory shall not incorrectly use or use in a misleading manner of the TQF Certification Mark in advertisements and catalogues or engage in any acts that may harm the reputation and reliability of TQF Association with the TQF Certification Mark.
- 10.14 TQF Association reserves the right to amend or supplement the regulations governing the use of the TQF Certification Mark at any time and notifies food factories producing TQF-certified products to make respective changes in the use of the TQF Certification Mark within a transitional period.
- 10.15 When a "nonconformity" is found in the production system or a product, a food factory will be notified to make corrective actions within a specific period. A food factory may continue to distribute products on which the TQF Certification Mark has been labeled and use the use TQF Certificate and TQF Certification Mark., however a certification body shall not accept applications for certification of additional new products or new production lines.
- 10.16 When detecting an "anomaly" within the production system or on the product, the certification body shall conduct a re-assessment audit. During the time period of re-assessment audit to the verification of the corrective action, the food factory shall temporarily suspend the use of TQF mark throughout the production process; and the certification body shall not accept any application for certification of additional new products or new product lines from that food factory. The certification certificate shall also become temporarily invalidated during suspension. The certification body shall change the food factory's status to "suspend" with the reasons and starting date on the TQF-ICT platform within 5 business days after the re-assessment is decided and shall notify the TQF Association and food factory in writing.
- 10.17A certification body shall take appropriate measures to address the incorrect use or misleading application of the certificate and the certification of the mark in a document or other publicity, or any other form in which the product has been validated.
- 10.18 The use of the conformity mark of an accreditation body shall comply with the regulations relating to such marks.
- 10.19 It is prohibited to use or counterfeit certification certificates or TQF certification marks or violate the right of TQF Association with TQF certification mark.
- 10.20 In order to maintain the use of the certification mark, TQF Association shall avoid misuse, abuse, fraudulent use to maintain the validity and trustworthiness of the TQF certification mark, the TQF Association will regularly and irregularly conduct a marketed certification



mark monitoring and increase the consumer's recognition of TQF certification mark at various marketing opportunities.

10.21 When a TQF certified food factory violates the provisions of the Scheme, the TQF Association will notify the food factory to take corrective action and notify the certification body to take such measures as suspending, withdrawing terminating the certification or publishing the violation. If TQF Association thus suffered damage, the food factory should shall be liable for damages; if necessary, TQF Association will take legal action.

11 Changes Affecting Certification (Guidance for the Changes)

- 11.1 The change of a certificate, including the following items:
 - 1. Scope of certification.
 - 2. Name of the food factory.
 - 3. Address of the food factory.
 - 4. The production line system number.
 - 5. Certification Level
 - 6. Company principal
 - 7. Other items registered in a TQF certificate.

11.2 Operating procedures

- 11.2.1 A food factory applying for a change shall make an application over the TQF-ICT platform and upload the relevant supporting details.
- 11.2.2 After receiving an application for change, a certification body <u>or TQF association</u> shall review, approve, and handling the application. A certification body may also conduct an inspection where necessary.
- 11.2.3 After a review, a certification body <u>or TQF association</u> may decide a measure for <u>withdrawal</u> termination, addition or deletion as certification results.
- 11.3 Principles for handling the name, the principal responsible person, or address change of a food factory:
 - 11.3.1 The management systems of a food factory relating to the TQF Certification system shall remain unchanged.
 - 11.3.2 Legal factory documents shall conform to local legal requirements.
 - 11.3.3 The changed items shall be consistent with the items registered in the legal factory documents.
 - 11.3.4 When changing the name, ownership, and address, a food factory shall apply for a change to a <u>TQF association</u> <u>certification body</u> within at least 10 business days after receiving the changed legal documents.

12 Addition, Deletion, Suspension, Withdrawal or Termination of Certification

- 12.1 A certification body shall establish a management mechanism for the addition, deletion, suspension, withdrawal, or termination of certification.
- 12.2 After a change in the scope of certification, a food factory shall apply to a certification body for a change and notify TQF association by proving related documents, such as new specification of the machine, plant layout, monitoring standard etc. within at least 10 business days after the change. A certification body may conduct an on-site visit to verify



the application to decide whether the changes are required, the possibility of a direct approval, for the change or the need for an onsite audit and surveillance audit according to its professional judgment. When there is a change in the scope of certification, an addition or deletion of certification items shall be carried out. When the certification body discovers a change in the scope of certification of the food factory in any situation, it shall require the food factory to apply for an addition or deletion of the scope of certification.

- 12.3 When the addition, deletion, suspension, withdrawal, or termination of certification is in progress, a certification body shall officially notify a food factory of the cause(s) of change and the use of the TQF Certification Mark and disclose such information.
- 12.4 If a food factory is confirmed to have non-compliance with the certification requirements, a certification body shall consider and determine the need for annual surveillance audit to ensure conformity or the deletion of items in the scope of certification to remove product categories nonconforming to the certification requirements, should shall even suspend or withdraw terminate certification qualification before the remediation of a food factory.
- 12.5 TQF certified food factory shall be able to trace the ingredient source and verify product safety. In the event of malicious falsification or violation of laws, such as falsification, adulteration, and fraud, a certification body shall terminate the certification qualification of the food factory.
- 12.6 If a food factory is found having three nine or more opints major of the sum of nonconformities, a certification body shall suspend the operation within the scope of certification until a food factory completes improvements. If more than one anomaly is found and required for a re-assessment, the certification authority shall suspend the operation until the improvement of the food factory is completed. In the event that malicious falsification is found in the anomaly handling process, a certification body shall terminate the certification qualification of a food factory.
- 12.7 In the event of addition, deletion, suspension, withdrawal, and termination, a certification body shall notify the food factory of the cause(s) and the restriction of future use of the TQF Certification Mark; and officially disclose such information on TQF-ICT platform.

13 Requirements for Certification Level Change

- 13.1 A change from certification level II to level I, please see figure 3-06.
 - 13.1.1 Applying on TQF-ICT platform
 - 13.1.1.1 A food factory shall apply for a level change on TQF-ICT platform, update the list of the same categorized products and delete all the certified products.
 - 13.1.1.2 A certification body shall review the application within 20 business days according to the updated list of the same categorized products.
 - 13.1.2 Contract execution and certificate issuance

 The certification body shall sign the new contract with the food factory and issue certification level I certificate.
 - 13.1.3 Annual surveillance audit

 The annual surveillance audit shall follow the certification period that states on the
 new certificate, the post market sampling for the same categorised products shall



be conducted.

13.1.4 Use of TOF certification mark

After changed to certification level I, the TQF certification mark is no longer allowed to be used. The food factory shall provide the amount and sales period of the products that had been produced with TQF certification mark to certification body and TQF association in writing.

- 13.2 A change from certification level I to level II, please see figure 3-06.
 - 13.2.1 Applying on TQF-ICT platform
 - 13.2.1.1 A Food factory shall apply for a level change on TQF-ICT platform and upload new certified product information and IQP.
 - 13.2.1.2 A Certification body shall complete the documentary review within 20 business days, and may request for supplement documents where necessary. The food factory shall submit supplement documents within 3 months.
 - 13.2.2 On-site audit

A Certification body shall conduct the on-site audit and product sampling within 2 months after the documentary review. According to food safety and quality regulation process for level II certification of TQF Scheme, the audit man-day shall be calculated based on 1/2 of the minimum number of man-days of the initial on-site audit for TQF certification level II (the same as the audit man-days of annual on-site audit for certification level II).

13.2.3 Product testing

All the certified products shall be sampled; the sample quantity of the same categorized products shall be based on the quantity of item registered in TQF-ICT platform and the risk classification of sampling testing shown in Table 3-03 deducted the number of certified products (the same as the sampling quantity for an initial on-site audit of certification level II).

13.2.4 Certification decision

Decision is made based on the review of result of on-site audit, corrective action report and product testing report.

13.2.5 Contract execution and certificate issuance

Certification body shall sign the new contract with food factory and issue certification level II certificate.

13.2.6 Annual surveillance audit

The annual surveillance audit shall follow certification period that states on the new certificate. Sampling of certified products and the same categorised products shall be conducted during the annual on-site audit, and the post market sampling for the certified products shall also be conducted.

13.2.7 Use of TQF certification mark

After changed to certification level II, the food factory shall provide a transition plan for using TQF certification mark.

13.3 The certified products which are belonged to the category of functional food shall be sampled during the on-sit audit and from the post-market to ensure the products meets the requirements set in the "Taiwan Quality Food Specification and Standard for Functional Food" (TQF-PCS-126). On-site sampling is not required for certification level I, therefore,



functional food ids only applicable to certification level II.



Table 3-05. TQF Certification Criteria for Determining Production System and Product Anomalies

Ty	Degree of nonconformity	Nonconformity	Anomaly	Malicious Falsehood
	Manufacturing system	The non-compliance caused by the non-conformity occurred in manufacturing system which has food safety concern.		
2.	Results of microbiological testing	Microbiology have exceeded the legal sanitation standard or plant standard for food	Pathogenic bacteria have exceeded the legal sanitation standard for food	
3.	Results of chemical testing		Violation of the legal sanitation standard for food or containing substances with susceptible human hazards	
4.	Purity of the content		The results of content purity testing of TQF-certified products do not meet the legal sanitation standard for food, but is not an intentional conduct of malicious falsehood	In violation of relevant laws and regulations, with an intentional conduct of malicious
5.	Food labelling or nutrition claims	The product labelling or advertisement claims to be in violation of the TQF Scheme, but is not in violation with the Act Governing Food Safety and Sanitation or regulations of food specification, but is not a food safety concern.	Governing Food Safety and	falsehood
6.	Food poisoning		Investigations show that the incident is associated with TQF-certified products	
7.	Use of non-food graded substances as food ingredients		Not an intentional conduct of malicious falsehood had proven by investigations	

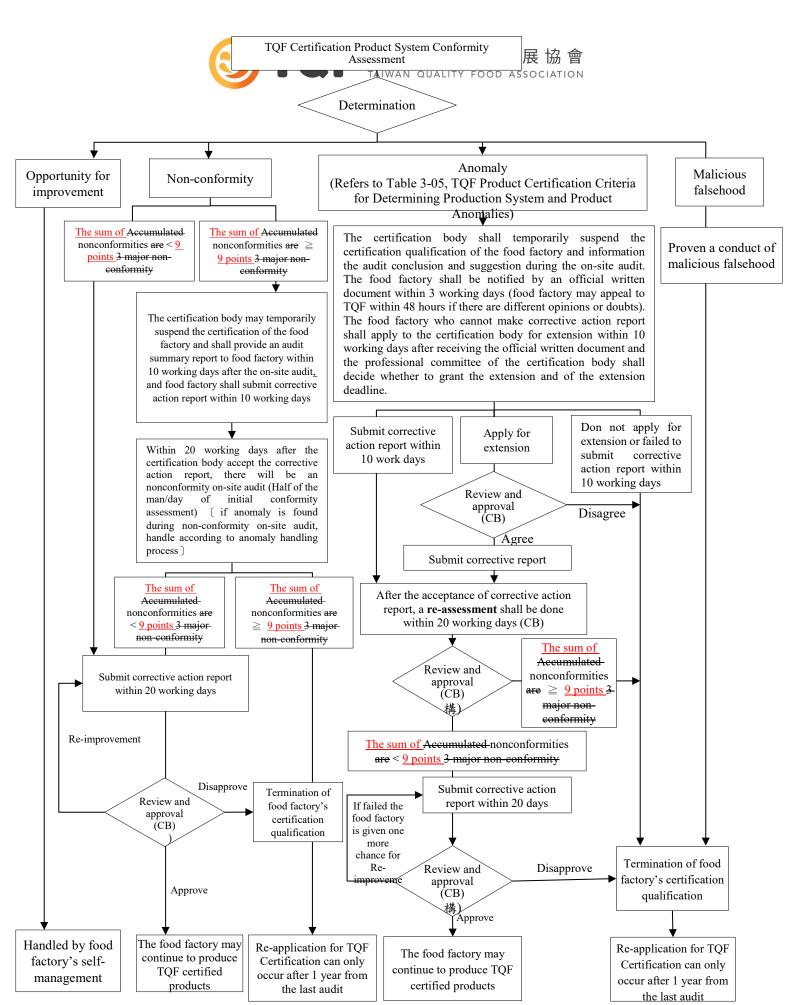


Figure 3-033-04. TQF Product Certification – Production System Annual On-site Audit Flowchart

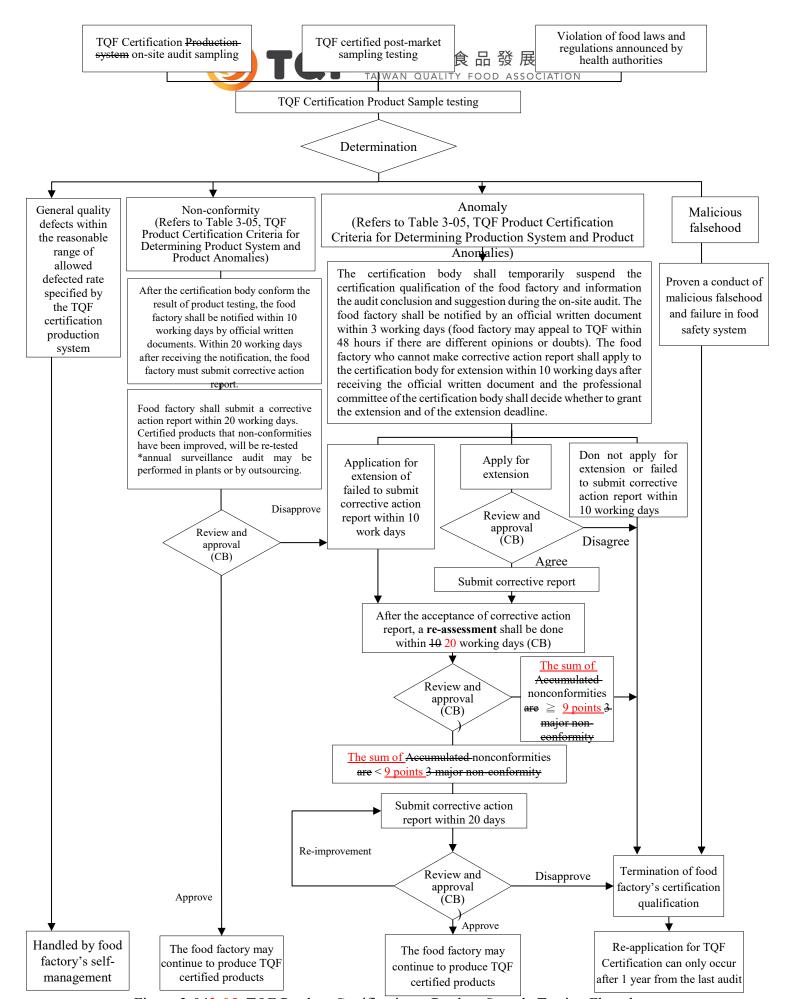


Figure 3-043-05. TQF Product Certification – Product Sample Testing Flowchart

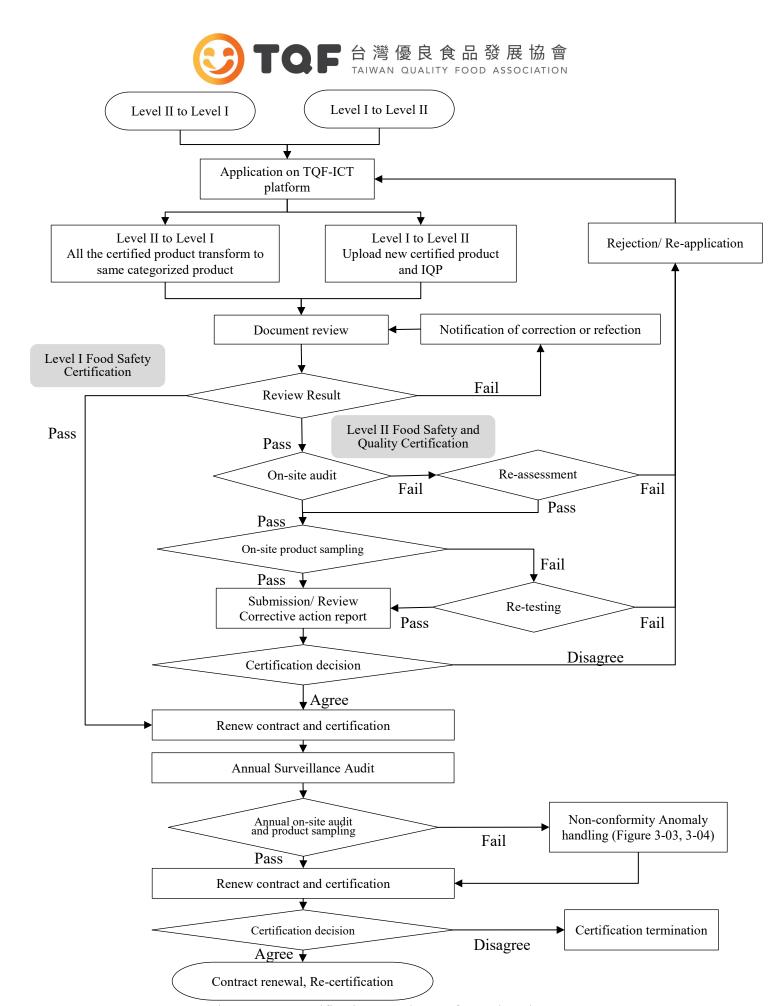


Figure 3-06. Certification Level Transform Flowchart



Chapter 4 Food Safety Fundamental Specifications

When a food factory applies to a TQF certification body for TQF certification, the certification body shall review a food factory in accordance to the specifications and standards of the testing items specified in the TQF Product Specification Scheme and the General Provisions for TQF Technical Specifications and Specified Provisions for TQF Technical Specifications. Auditors of a certification body shall record the audit trail based on the actual scenario in the on-site audit as the reference of certification decision-making.

This chapter is based on the Taiwan Quality Food General Technical Specifications (99 Other Food Products). Certification of different category is based on the characteristic of product and processing, selecting the most suitable technical specifications (TQF-PCS-001~027) and "TQF Certification Scheme—Specifications and Standards for Product Inspection Items" (TQF-PCS-101~127, 199).

- TQF-PCS-001 Taiwan Quality Food Beverage Technical Specifications
- TQF-PCS-002 Taiwan Quality Food Baked Foods Technical Specifications
- TQF-PCS-003-Taiwan Quality Food Edible Oil Technical Specifications
- TQF-PCS-004 Taiwan Quality Food Dairy Products Technical Specifications
- TQF-PCS-005 Taiwan Quality Food Powdered Infant Formula Technical Specifications
- TQF-PCS-006 Taiwan Quality Food Soy Sauce Technical Specifications
- TQF-PCS-007 Taiwan Quality Food Ice and Novelties Technical Specifications
- TQF-PCS-008 Taiwan Quality Food Noodles Technical Specifications
- TQF-PCS-009 Taiwan Quality Food Confectionary Technical Specifications
- TQF-PCS-010 Taiwan Quality Food Ready to Eat Meal Technical Specifications
- TQF-PCS-011 Taiwan Quality Food MSG Technical Specifications
- TQF-PCS-012 Taiwan Quality Food Preserved Fruits and Vegetables Technical Specifications
- TQF-PCS-013 Taiwan Quality Food Soya Bean Products Technical Specifications
- TQF-PCS-014 Taiwan Quality Food Processed Seafood Technical Specifications
- TQF-PCS-015 Taiwan Quality Food Frozen Foods Technical Specifications
- TQF-PCS-016 Taiwan Quality Food Canned Foods Technical Specifications
- TQF-PCS-017 Taiwan Quality Food Spices and Condiments Technical Specifications
- TQF-PCS-018 Taiwan Quality Food Meat Processed Products Technical Specifications
- TQF-PCS-019 Taiwan Quality Food Chilled Prepared Foods Technical Specifications
- TQF-PCS-020 Taiwan Quality Food Dehydrated Foods Technical Specifications
- TQF-PCS-021 Taiwan Quality Food Tea Leaf Technical Specifications
- TQF-PCS-022 Taiwan Quality Food Flour Technical Specifications
- TQF-PCS-023 Taiwan Quality Food Refined Sugar Technical Specifications
- TQF-PCS-024 Taiwan Quality Food Starch Sugar Technical Specifications
- TQF-PCS-025 Taiwan Quality Food Alcohol and Liquor Technical Specifications
- TQF-PCS-026 Taiwan Quality Food Functional Foods Technical Specifications



- TQF-PCS-027 Taiwan Quality Food Food Additives Technical Specifications
- TQF-PCS-101TQF Specifications and Standards for Product Test Items (01 Beverages)
- TQF-PCS-102TQF Specifications and Standards for Product Test Items (02 Baked Foods)
- TQF-PCS-103 TQF Specifications and Standards for Product Test Items (03 Edible Oil)
- TQF-PCS-104TQF Specifications and Standards for Product Test Items (04 Dairy Products)
- TQF-PCS-105TQF Specifications and Standards for Product Test Items (05 Powdered Infant Formula)
- TQF-PCS-106TQF Specifications and Standards for Product Test Items (06 Soy Sauce)
- TQF-PCS-107TQF Specifications and Standards for Product Test Items (07 Ice and Novelties)
- TQF-PCS-108TQF Specifications and Standards for Product Test Items (08 Noodles)
- TQF-PCS-109TQF Specifications and Standards for Product Test Items (09 Confectionary)
- TQF-PCS-110TQF Specifications and Standards for Product Test Items (10 Ready to Eat Meal)
- TQF-PCS-111TQF Specifications and Standards for Product Test Items (11 MSG)
- TQF-PCS-112TQF Specifications and Standards for Product Test Items (12 Preserved Fruits and Vegetables)
- TQF-PCS-113TQF Specifications and Standards for Product Test Items (13 Soya Bean Products)
- TQF-PCS-114TQF Specifications and Standards for Product Test Items (14 Processed Seafood)
- TQF-PCS-115TQF Specifications and Standards for Product Test Items (15 Frozen Foods)
- TQF-PCS-116TQF Specifications and Standards for Product Test Items (16 Canned Foods)
- TQF-PCS-117TQF Specifications and Standards for Product Test Items (17 Spices and Condiments)
- TQF-PCS-118TQF Specifications and Standards for Product Test Items (18 Meat Processed Products)
- TQF-PCS-119TQF Specifications and Standards for Product Test Items (19 Chilled Prepared Foods)
- TQF-PCS-120TQF Specifications and Standards for Product Test Items (20 Dehydrated Foods)
- TOF-PCS-121TOF Specifications and Standards for Product Test Items (21 Tea Leaf)
- TQF-PCS-122TQF Specifications and Standards for Product Test Items (22 Flour)
- TQF-PCS-123TQF Specifications and Standards for Product Test Items (23 Refined Sugar)
- TQF-PCS-124TQF Specifications and Standards for Product Test Items (24 Starch Sugar)
- TQF-PCS-125TQF Specifications and Standards for Product Test Items (25 Alcohol and Liquor)
- TQF-PCS-126TQF Specifications and Standards for Product Test Items (26 Functional Foods)
- TQF-PCS-127TQF Specifications and Standards for Product Test Items (27 Food Additives)
- TQF-PCS-199TQF Specifications and Standards for Product Test Items (99 Other Food Products)



Taiwan Quality Food General Technical Specifications

1 Purpose

This specification provides special guidance for food factories to ensure that during food processing, packaging and transportation, the personnel, premises, facilities, equipment, and sanitary, processing, and quality management are in conformity with good manufacturing practices benchmark and that through the principle of hazard analysis and critical control points (HACCP) will prevent operating under unsanitary conditions, and in environments that may cause food contamination or quality deterioration. It also aims to reduce operation errors and to establish a sound quality assurance system to ensure food safety and product quality stability.

2 Scope of application

- 2.1 The scope of this specification is applicable to food factories which supply properly packaged foods for human consumption.
- 2.2 The General Technical Specifications provides the basic requirements for the establishment of special technical specifications of good manufacturing practices for different category of food factories.

3 Definition of special terms

- 3.1 Food: Refers to the products and their raw materials for human consumption, either for eating, drinking or chewing.
- 3.2 Food factory: Refers to the registered factories and manufacturers of properly packaged food, which main products are included in the product categories of product certification application.
- 3.3 Materials: Refers to raw materials and packaging materials.
 - 3.3.1 Raw materials

Refers to the constituents in edible parts of finished product, including primary raw materials, secondary raw materials, and food additives.

- 3.3.1.1 Primary raw materials
 - Refers to the major materials used for manufacturing finished products.
- 3.3.1.2 Secondary raw materials
 - Refers to the raw materials used for manufacturing finished products excluding primary materials and food additives.
- 3.3.1.3 Food additives

Refers to the <u>food unit or compound</u> material which is added to or brought into contact with food in the course of manufacturing, processing, mixing, packing, transport and storage of food, with the purpose of colouring, seasoning, preserving, bleaching, emulsifying, flavouring, stabilizing the quality, fermentation, increasing viscosity, strengthen nutrition, preventing oxidation or



other necessary purposes and added to or come in contact with food unit or compound.

3.3.2 Packaging material

Refers to the material used as the inner and outer packaging.

3.3.2.1 Inner packaging material:

Refers to the container which is brought into direct contact with food, such as bottle, tin can, carton, pouch etc. and to the packaging material which wraps and covers directly the food, such as foil, film, paper, waxed paper etc. All those materials shall be in compliance with food sanitation and hygiene laws and regulations.

3.3.2.2 Outer packaging material:

Refers to the packaging material which is not brought into direct contact with food, such as label, carton, wrapping materials etc.

3.4 Product

Refers to semi-finished product, bulk product materials to be reworked and finished product.

3.4.1 Semi-finished product

Refers to the partly processed product which must undergo further processing before it becomes a finished product.

3.4.2 Bulk product Materials to be reworked

Refers to the material, semi-finished product or the finished product which leaves the normal production line and requires to take measures to be sold and suitable for re-use during the manufacturing process. Refers to the product which had undergone complete processing, but not packaged or labelled.

3.4.3 Finished product

Refers to the product which has undergone all levels of manufacturing with packaging and labelling.

3.4.4 Perishable ready-to-eat product

Refers to the finished product which is directly supplied for human consumption not subject to any further processing or that only needs to go through simple heating, that are stored at room temperature or refrigerated for a short period of time, such as ready-to-eat meals, liquid dairy products, high water activity pulses processed foods, high water activity baked food, high water activity noodles, cold drinks, high water activity confectionery, high water activity aquatic processed food, high water activity meat processed food, chilled prepared food.

3.5 Premises

Refers to the entire or partial plant construction or facilities which are used in food processing, packaging, storage etc. or their relevant operation.

3.5.1 Food processing and operation areas

Refers to the areas for handling raw material, manufacturing, processing and preparation, and packaging and storage.



3.5.1.1 Raw material handling areas

Refers to the areas that are provided for raw material to undergoing preparation, thawing, sorting, cleaning, trimming, cutting, peeling, hulling, and entrails removal, blanching or salting operation.

3.5.1.2 Processing and preparation areas

Refers to the areas that are provided for materials processing operations to undergoing cutting, grinding, mixing, blending, moulding, shaping, cooking, extracting and improving food characteristic or preservation (such as oil extraction, starch separation, bean paste manufacturing, emulsification, coagulation, fermentation, sterilization, freezing or drying, etc.).

3.5.1.3 Packaging room

Refers to the place for packaging of finished product, which includes the rooms for inner and outer packaging.

3.5.1.3.1 Inner packaging room

Refers to the place for inner packaging operation in which the packaging material is in direct contact with the product content.

3.5.1.3.2 Outer packaging room

Refers to the place for outer packaging operation in which the packaging material is not in direct contact with the product content.

3.5.1.3.3 Inner packaging material preparation room

Refers to the place where the inner packaging materials that can be used directly without requiring any further cleaning and disinfection procedures go through pre-forming or have their outer packaging removed.

3.5.1.3.4 Buffer room

Refers to the area that is set up at the entrance of the controlled operation area to avoid its direct connection with the exterior, when raw materials or semi-finished products are not going through normal manufacturing process and have directly accessed to the operation areas.

3.5.1.3.5 Weighing room

Refers to the area for weighing operation of raw materials, secondary raw materials, food additives, ingredients etc..

3.5.2 Controlled operation areas

Refers to the areas where higher degree of cleanliness are required, including clean operation areas and semi-clean operation areas. The entrance for both people and raw materials and the prevention of pests and vectors invasion in those areas shall be strictly controlled.

3.5.2.1 Clean operation areas

Refers to the area such as the inner packaging room among others where it are required highest degree of cleanliness.

3.5.2.2 Semi-clean operation areas



Refers to the processing, preparation areas among others where the required degree of cleanliness are below the clean operation areas.

3.5.3 General operation areas

Refers to the storage of raw materials, storage of ingredients and outer packaging room among others where the required degree of cleanliness are below the controlled operation areas.

3.5.4 Non-food handling areas

Refers to the quality control (laboratory) room, office, rest room and toilet where there are not direct involvement with food preparation or processing.

- 3.6 Cleaning: Refers to the operation of removing dust, scrap, stain, dirt or other possible impurities that may contaminate the food.
- 3.7 Disinfection: Refers to appropriate operations to effectively kill and remove pathogenic micro-organisms without affecting food quality or safety, by using chemical reagent and (or) physical method in compliance with food hygiene.
- 3.8 Food-grade detergent: Refers to the substances employed in cleaning the equipment, utensils, containers and packaging materials and shall not bring any risk for the food safety and hygiene.
- 3.9 Foreign matters: Refers to any contaminant or undesirable substances which are mixed or adhered in the raw materials, semi-finished products, <u>materials to be reworked</u>, finished-products or inner packaging materials during processing (excluding raw materials), making the food to be unsafe and unhygienic.
- 3.10 Pest: Refers to small animals or insects which direct or indirectly contaminate the food or disseminate diseases, such as rats, cockroaches, flies and vermin.
- 3.11 Pathogenic micro-organism: Refers to the microorganism capable of causing food quality deterioration and having public health significance.
- 3.12 Prevention of vector-borne infestation: Refers to appropriate and tangible isolation means to prevent vector invasion, such as traps, fence with appropriate aperture, gauze, etc.
- 3.13 Sanitation management personnel: Refers to the staff responsible for the sanitation of the interior and exterior environment of a plant, the premises and facilities and the health and hygiene of personnel.
- 3.14 Food appliances and utensils: Refers to the devices, tools or utensils in direct contact with food or food additives.
- 3.15 Food contact surface: Refers to the food direct or indirect contact surfaces, including utensils and equipment contact surface with the food. The food indirect contact surface: Refers to the contact surface between food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs under normal processing condition.
- 3.16 Appropriate: Refers to the measures taken for intending to complete the expected target or result under good sanitary operation condition.
- 3.17 Shall: Refers to a requirement that is mandatory.
- 3.18 Should: Refers to a guideline or recommendation.
- 3.19 Safe moisture level: Refers to a reference level of moisture which can prevent the survival



of pathogenic microorganisms, under pre-established processing, storing and distributing conditions. Basically, a maximum safe moisture level for food is indicated by water activity (Aw). The water activity is considered to be safe to the food if there is sufficient data to show that it does not contribute to the growth of pathogenic microorganisms under a certain water activity.

- 3.20 Water activity: Refers to the indicator of free water in foods, and is the quotient of the water vapor pressure of the food divided by the vapor pressure of pure water under the same temperature.
- 3.21 High water activity finished product: Refers to finished products' water activity that are above 0.85 (inclusive).
- 3.22 Low water activity finished product: Refers to finished products' water activity that are below 0.85.
- 3.23 Lot number: Refers to the specific letters, numbers or symbols for tracing back its processing history of each batch, while "lot" alone refers to the specific quantity of product produced during a specific period of time or location.
- 3.24 Labelling: Refers to the text, pictures or, symbols, or additional instructions affixed on food, food additive or, container of food-grade detergent, food utensil, food container, and or packaging for indicating its name or a descriptive information.
- 3.25 Isolation: Refers to the partition of sites and facilities by physical means.
- 3.26 Separation: Separation has a broader meaning than isolation, including, physical and non-physical means of partition. Separation of operation areas may be accomplished by one or more of the following ways, such as separation in terms of space, time, and control of air flow, use of closed system or other effective methods.
- 3.27 Food Safety Management System: A systematic approach to the identification, evaluation and control of food safety hazards, invoke the principle of hazard analysis and critical control points (HACCP), and manage food safety hazards throughout the reception of raw materials and ingredients, the manufacture, packaging, storage and distribution.
- 3.28 Critical Control Points (CCP): Refers to a point, step, or procedure of food manufacturing at which control can be applied and prevent, eliminate or reduce a food safety hazard to an acceptable level.
- 3.29 Control limits: Refers to a maximum and/or minimum value to which a physical, biological or chemical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.
- 3.30 Deviation: Failure to meet a critical control limit.
- 3.31 Hazard Analysis and Critical Control Points (HACCP) Plan: The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.
- 3.32 Hazard: A biological, chemical, or physical agent that is most likely to cause illness or injury on consumers in the absence of its control.
- 3.33 Hazard Analysis: The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.



- 3.34 Monitoring: To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
- 3.35 Control Measure: Any action or activity that can be used to prevent, eliminate or reduce a significant biological, chemical, or physical hazard.
- 3.36 Validation: That element of confirmation focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.
- 3.37 Verification: Activities other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan, to confirm its effectiveness.
- 3.38 Rework: The steps for taking appropriate measures on the material, semi-finished product or the finished product which leaves the normal production line and letting it be sold or suitable for re-use during the processing process.

4 Factory Environment

- 4.1 The food factory shall not be located in areas which are liable to contamination, except otherwise, there is an effective measure to prevent contamination.
- 4.2 The surroundings of the plant shall always be easy to clean. The ground shall be free from puddle of water, mud, dirt, etc. that can cause food contamination, also to prevent it from being source of pollution. The open ground of the plant site shall be paved with cement, asphalt or grasses may be planted to prevent dust and beautify the environment.
- 4.3 The roads in the vicinity or within the plant shall be paved with cement to prevent contamination from dust.
- 4.4 The processing plant shall be free from any facility which is able to cause odors, harmful (toxic) gases, smoke, or other unsanitary conditions.
- 4.5 Raising poultry, livestock or pets shall be prohibited inside the plant, with exception of guard dogs, but they shall be properly constrained to avoid contaminating food.
- 4.6 A proper drainage system shall be installed inside the plant, the drainage channels shall be at a proper degree of inclination and the drainage system shall be cleaned regularly and kept unblocked. Drainage shall be free from bad odor, water puddle, seeping, silt, dirt, breakage or propagation of vector that could cause food contamination.
- 4.7 The surrounding of the production site shall be constructed and designed to adequately protect against the entrance of external contamination. If fences are installed, at least 30 cm from the ground shall be constructed with insulated materials.
- 4.8 Premises built with staff dormitory and cafeterias, staff lounges, offices or laboratory, shall be isolated and separated from the manufacturing, preparation, processing, and food or food additives storage areas, and have good lighting and ventilation; must be equipped with devices to prevent vector intrusion or microbial contamination, cleaned regularly and assigned a specialist in charge.

5 Premises and Facilities



5.1 Lay-out and Space:

- 5.1.1 The premises shall be designed to meet food process flow, sanitation and hygienic requirement, providing good order and tidy conditions, and to prevent cross-contamination.
- 5.1.2 The premises shall provide sufficient space for required facilities, including sanitation facilities, storage areas, staff amenities, etc. Adequate working space shall be provided to ensure food safety and sanitation. Food utensils and devises shall have a clean place for storage. Operational areas for strict vegetarian food production shall not share the same production line for the production of non-vegetarian food, and their utensils and devises shall not be shared. Ovo-vegetarian, Lactovegetarian, Ovo-lactovegetarian and Vegan production site shall have their production line, utensils and devises effectively separated from the non-vegetarian and strict vegetarian foods.
- 5.1.3 The food processing equipment in a food plant shall be provided with proper working space or aisles with enough distance in between the equipment or between the equipment and the walls. It shall provide with sufficient width to permit employees to carry out their operations (including cleaning and sanitizing) without contaminating the food, food-contact surfaces, or packaging materials with their clothing or physical contact.
- 5.1.4 Laboratory in a food plant shall be provided with enough space for the installation of experimental table and instruments to perform physical, chemical, sensorial and (or) microbiological test. Microbiological testing laboratory shall be properly separated from the other testing areas, especial isolation shall be made when the laboratory is equipped with pathogenic microbial testing facility.

5.2 Premises separation

- 5.2.1 Different purposes premises (e.g. warehouse for raw material, packaging material, and raw material handling area) shall be built separately or be effectively separated.
- 5.2.2 Premises shall be effectively separated or isolated from one another according to the cleanliness level classification (Table 4-01).

5.3 Premises structure

The Plant buildings shall be durable, easy to maintain, be kept clean and shall be able to prevent food, food-contact surfaces and inner packaging materials from being contaminated (such as vector intrusion, habitat, breeding, etc.)



Table 4-01: Cleanliness level classification of the different operation areas of a food manufacturing plant (1)

	Plant facility	Classification of cleanliness level		
	(arranged by processing order)			
•	Raw materials storage			
•	Packaging materials storage	General operation area		
•	Raw materials handling areas			
•	Inner packaging washing areas (2)			
•	Empty bottles (cans) arrangement area			
•	Sterilization treatment areas (for closed system equipment and pipeline)			
•	Processing and preparation areas		Controlled operation area	
•	Sterilization treatment areas (in case of open system equipment)			
•	Inner packaging materials preparation room	Semi-clean operation area		
•	Buffer rooms			
•	Packing area for non-perishable ready-to-eat finished products			
•	Cooling and storage area of final semi-finished product of a perishable ready-to-eat product before packaging Packing room of perishable ready-to-eat finished products	Clean operation area		
•	Outer packing area			
•	Finished product storage	General operation area		
•	Quality control (testing) area	Non-food handling area		
•	Office (3)			
•	Change room and hand washing and sanitizing area			
•	Toilet			
•	other			
Mad		<u> </u>		

Notes:

- (1) The classification of cleanliness level of the different operation area can be improved according to actual conditions, and if there is a specific provision for it, comply with the specific provision.
- (2) The exit of the inner packaging container washing area shall be located within the controlled operation area.
- (3) The office shall not be located in the controlled operation area (except for the production management and quality control area, but appropriate control measures area required).



5.4 Safety facilities

- 5.4.1 The electricity system installed inside the plant shall be waterproof.
- 5.4.2 Power supply shall be grounded and with circuit breaker.
- 5.4.3 The electrical outlet and power switch in workplaces with high humidity shall should be waterproof.
- 5.4.4 The electrical outlet used for different voltage shall be clearly marked and labeled.
- 5.4.5 Fire alarm system shall be set in all buildings and working areas, in accordance with the Fire Services Act.
- 5.4.6 Fire extinguisher devises and equipment shall be installed in appropriate places with strict control to prevent food contamination.

5.5 Floor and Drainage

- 5.5.1 Floor shall be smooth, non-slippery, and kept clean; it shall also be free from corrosion, cracks and accumulation of water and other circumstances. Floors of the controlled operation area shall be constructed with non-absorbent and water impermeable materials.
- 5.5.2 Proper slope (no less than 1/100) and adequate floor drainage system shall be provided in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- 5.5.3 Wastewater or effluent disposal shall be made into an adequate sewerage treatment system or disposed of through other adequate means.
- 5.5.4 Drainage system shall be equipped with screen that allow water to flow and trap to prevent solid wastes from flowing, and free of filthy odor.
- 5.5.5 No other pipelines shall be arranged inside the drainage system and it shall remain unobstructed. The joint between the side and the bottom of the ditch shall have a proper arc (the radius of the curvature shall be 3cm or above).
- 5.5.6 Drainage outlet shall be equipped with devices to prevent vectors from entering the facility.
- 5.5.7 The flow direction of indoor drainage should shall be from the area with higher requirement of cleanliness to the area with lower requirement of cleanliness, and should shall be designed to prevent the backflow of wastewater.

5.6 Roof and Ceiling

- 5.6.1 The roofs inside the processing, packaging and storage rooms shall be easy to clean to prevent dust accumulation, water condensation, mold growth and it shall not shed particle matters. The V-type supported roof in the controlled operation areas or food exposure areas (except for raw material handling areas) which are easy to harbor contaminant, shall be provided with smooth ceiling easy to be clean. When the construction is made of reinforced concrete, the roof shall be smooth and free from cracks and open joints.
- 5.6.2 The surface of flat-type roof or ceiling shall be constructed with white or light-colored water proof materials. Where paint spray is required, the paint shall be anti-mold, not easy to flake off and easy to clean.



- 5.6.3 Pipes and cables of steam, water or electricity shall not be located directly above the exposed food, otherwise devices shall be installed to prevent dust and water condensation from falling, and their exterior shall be kept clean and cleaned regularly. Air ducts should be located above the ceiling.
- 5.6.4 Stairways or over-pass across production lines shall be constructed and designed so as to avoid food and food contact surfaces in the vicinity from being contaminated and equipped with safety devices.

5.7 Walls and Windows

- 5.7.1 The walls inside controlled processing area shall be constructed with non-absorbent, smooth, easy to clean, water-impermeable and light-colored materials (except from closed-type fermentation tank, and outdoor operations). The corner and column feet of the wall shall have an appropriate arc (with a radius of curvature of 3 cm or above, as shown in Figure 4-01) to facilitate cleaning and avoid dust and filth accumulation, except from dryer operation area.
- 5.7.2 Windows that are opened frequently during operation shall be equipped with easy-to-dismantle, easy to clean and rust resistant gauze to protect against food contamination and to prevent vectors from entering the facility. Windows shall be kept clean and shall not be opened during operation in the clean operation area. If the depth of the windowsill in the controlled production area is more than 2 cm, the windowsill in the controlled production area shall be sloped 45 degree or more (as shown in Figure 4-02). If the depth is less than 2 cm, the windowsill corner shall be filled with impervious material.
- 5.7.3 Windows, doors, and opening entrances in the controlled processing area shall be provided with automatic closing screened door (or air curtain), and (or) provided with shoe cleaning and sanitizing equipment (operation area that needs to be kept dry shall set up shoe changing facilities). Doors shall be made of smooth, easy to clean and impermeable strong material, and be kept closed.

5.8 Lighting

- 5.8.1 Facilities shall be provided with adequate daylight and (or) lighting in all areas of the building, and lighting installation shall be kept clean to prevent food contamination. In principle, the lighting facilities shall not be suspended over exposed food in any step of the production line, or otherwise, lighting facilities shall be equipped to prevent food contamination in case of breakage or fall.
- 5.8.2 Lighting shall be provided so that there shall be no less than 110 lux for working tables in the general operation area, 220 lux or above for working tables in the controlled operation area and 540 lux or above for inspection tables. The source of artificial light shall not alter the original food color.

5.9 Ventilation

5.9.1 The processing, packaging and storing areas shall be well ventilated, and the ventilation system shall be kept clean. When necessary effective ventilation system should shall be installed to prevent the temperature from being too high, the air steam condensation or odor formation, and to keep indoor air fresh. Clean operation area of perishable ready-



- to-eat products and finished products that require transportation at low temperature shall be equipped with air-conditioning equipment
- 5.9.2 In the presence of filthy odors and gases (including vapor and toxic gases) or dusts that may contaminate food, appropriate means of exclusion, collection or control shall be provided.
- 5.9.3 The exhaust vent of the controlled operation area shall be equipped with devices to prevent vectors from entering the facility, and the intake vent shall be equipped with air purification devices. Both equipment should shall be easily disassembled for cleaning or replacement.
- 5.9.4 Airflow direction from low-cleanliness areas to high-cleanliness areas should shall be avoided, when air conditioning, air intake and exhaust systems, or fans are used in the plant to prevent food, food contact surfaces and inner packaging materials contamination.

5.10 Water Supply

- 5.10.1 Water supply shall be capable of providing sufficient water, with adequate water pressure and quality to all the food plants. If necessary, there shall be water storage facilities and appropriate temperature of hot water available.
- 5.10.2 The reservoirs (towers and tanks) shall be made of non-toxic materials that do not contaminate the water, they shall be cleaned regularly at least once a year, kept clean and recorded. Measures shall be taken to prevent water contamination.
- 5.10.3 Water used for food manufacturing (including water that come in contact with food surface, water for cleaning equipment and utensils and water for making ice cubes and steam), shall meet "potable water quality standards" that is enacted by Environmental Protection Administration. When potable water is not used, there shall be a water purification and disinfection equipment, and pH and chlorine residual shall be tested, and recorded on a daily basis.
- 5.10.4 Pipeline of non-potable water (such as cooling water, sewage or waste water) that shall not be in contact with foodstuffs and the pipeline of water for food manufacturing shall be clearly distinguished by color and transported in completely separate piping system, there shall be no backflow or cross-connection.
- 5.10.5 Groundwater sources should shall be located at a distance of more than 15 meters from sources of potential pollution or contamination (septic tanks, waste dumps, etc.), and water storage facilities should shall be kept at a distance of more than 3 meters away from sources of pollution or contamination (septic tanks, waste dumps, etc.).

5.11 Hand-washing facilities

- 5.11.1 A sufficient number of hand-washing and hand-dryer facilities shall be provided at suitable and convenient locations (e.g., at the entrance to the controlled operation area, toilet and processing area). If necessary, warm or hot and cold water should shall be provided, and faucets with adjustable hot and cold water should shall be installed.
- 5.11.2 Liquid soap shall be provided near the hand-washing facilities, and if necessary, hand sanitizers dispensers shall also be provided when needed (e.g., when there is a concern that hands are at the risk of contaminating food, if they are not disinfected).



- 5.11.3 The hand washing sink shall be made of impervious material such as stainless steel and ceramic, and designed so that it can be easily cleaned and disinfected.
- 5.11.4 Hand dryer or paper towels shall be used for hand drying. When paper towels are used, they should shall be thrown into an easy to clean receptacles (preferably use foot pedal hands free bins). When using hand dryer, it shall be cleaned and disinfected regularly to prevent contamination.
- 5.11.5 Faucets shall be foot pedal operated, elbow operated or electric eye sensor operated, to prevent re-contamination after cleaning or disinfecting hands.
- 5.11.6 Drainage of hand washing facilities shall be fitted with devises to prevent backflow, vector entry and filthy odor.
- 5.11.7 A concise and easy understanding hand-washing instruction shall be posted in the vicinity of the hand-washing facilities.

5.12 Hands-sanitizing room

- 5.12.1 Separated hands-sanitizing room should be provided in the entrance and exit of the controlled operation area. (It is a must for the perishable ready-to-eat food production plant).
- 5.12.2 In addition to the elements in 5.11, the room should shall be equipped with working shoes or boots sanitizing facilities, but shoes changing areas should shall be provided in working areas that need to be kept dry. When shoe-dipping ponds are used, the solution should shall be kept clean and be able to cover the shoes upper part. The free residual chlorine concentration should shall be maintained at 200ppm or more when chlorine solutions are used.

5.13 Change room

- 5.13.1 Change room shall be located in an appropriate and convenient location near the controlled operation area, and separated dressing rooms shall be provided for men and women. Adequate lighting and ventilation shall also be provided. The change rooms of a perishable ready-to-eat factory shall be located near the hand washing and sanitizing areas.
- 5.13.2 There shall be enough space for staff to change clothes, and facilities such as mirror, dust removing devices and sufficient number of personnel cabinets or lockers and shoes racks shall be provided in these rooms.

5.14 Storage areas

- 5.14.1 Storage areas for raw materials, packaging materials, <u>and materials to be reworked</u>, semi-finished and finished products shall be stored separately and have sufficient space for transport. Chilled or frozen storage shall be provided when needed.
- 5.14.2 Raw materials and finished products storage shall be separated or isolated from the other areas, and different types of items in the same storage should shall also be properly separated.
- 5.14.3 The storage area shall be constructed so as to minimize the quality deterioration of the raw materials, <u>materials to be reworked</u>, semi-finished products and finished products and to prevent contamination. The storage area shall also be constructed with strong



- materials, provide sufficient working space and should shall be well organized and easy to keep clean. These areas should shall also be equipped with devices to protect against the entry of vectors.
- 5.14.4 Storage areas shall be laid out to permit effective and orderly segregation of the various categories of materials stored. Materials shall be stored on pallets, shelves, or other effective method, and keep tidy, clean, and be at a distance of at least 5cm from the floor and walls.
- 5.14.5 Chilled (frozen) storage for food products that are more prompt to microbial growth shall be equipped with accurate temperature sensor, temperature indicator or automatic temperature recorder, and also automatic controller or temperature alarm system shall be installed to alert of abnormal temperature variation.
- 5.14.6 Chilled (frozen) storage shall be equipped with an alarm switch that connects to the monitoring department in case a working personnel is locked inside accidentally or due to any failure and needs to contact and gets assistance from the exterior.
- 5.14.7 Temperature shall be recorded in the storage area, and also record humidity when necessary.

5.15 Toilet facilities

- 5.15.1 Toilets shall be located in appropriate and convenient places of the plant to prevent contaminating water source and in sufficient number for the staff to use.
- 5.15.2 Flush toilets shall be installed using materials that are impermeable, easy to clean and sanitize.
- 5.15.3 Hand washing facilities within the toilet shall be in compliance with element 5.11, and shall should be installed near the exit.
- 5.15.4 Toilet doors shall remain close and shall not face directly toward the controlled operation area, unless a buffer facility with air curtain control system to prevent contamination is provided.
- 5.15.5 Toilets shall be equipped with adequate illumination and well ventilated to prevent odors. Windows and doors in the toilets shall be equipped with rustproof screens.
- 5.15.6 The words "Wash hands after using the toilet" should shall be clearly marked.

6 Machine and Equipment

6.1 Design

- 6.1.1 Food processing equipment shall be designed and constructed in a way that does not pose a threat to food hygiene. It shall easily be cleaned, disinfected (and easy to disassemble as possible) and inspected. Lubricants, metal fragments, contaminated water or other substances shall not represent a food safety hazard when using these equipment.
- 6.1.2 The food contact surfaces shall be smooth, free of cracks or recesses as to reduce the accumulation of food debris, dirt and organic matter and thus minimize the potential microbiological growth.
- 6.1.3 Design shall be simple, easy to drain and easy to dry.



- 6.1.4 The design and construction of all equipment for storage, transportation and processing shall be kept in a sanitary condition.
- 6.1.5 Equipment and appliances used in the food processing or handling area that does not come into contact with food shall also be kept in a sanitary condition.
- 6.1.6 Finished coating (e.g. plating, painting, etc.) surfaces of equipment, utensils and piping shall ensure that it does not represent any risk to food and food contact surfaces contamination.

6.2 Material

- 6.2.1 Equipment and utensils in direct contact with food used in the food handling area shall be made of nonabsorbent materials that do not transmit toxic substances, odors, and corrosion resistant, capable of withstanding repeated cleaning and sanitation. At the same time, materials that could cause corrosion shall be avoided.
- 6.2.2 Wood shall not be used as food contact surfaces material unless it is proved that it will not become a source of contamination.

6.3 Food processing equipment

- 6.3.1 The food processing equipment in a food plant shall be properly laid out to meet process flow with sufficient space to avoid cross-contamination. The production capacity of each equipment should shall be compatible with each other.
- 6.3.2 Instruments or recorders used for measuring, controlling or recording shall be in good condition and be of suitable accuracy for the intended use, and periodically calibrated.
- 6.3.3 Compressed air or other gases which are introduced into food or used to clean food contact surfaces or equipment shall be adequately pretreated to prevent indirect contamination.
- 6.3.4 A maintenance plan shall be in place and regular inspections shall be carried out for equipment to reduce food safety risks and the potential for breakdowns.
- 6.3.5 The maintenance standard for production equipment shall be established and detail the maintenance instructions and procedures for all equipment.

6.4 Quality control equipment

The food factory shall have adequate testing equipment for the routine QC testing and inspection to determinate the quality of raw materials, semi-finished and finished products. When necessary, testing and inspection shall be performed by an approved researching or testing institutes when suppliers do not possess the equipment on site.

7 Organization and Personnel

7.1 Organization and duties

7.1.1 The food factory shall have and disclose the organizational structure and its responsibilities related to food safety activities publicly available, including the specialist in charge for food safety and quality and their authority to supervise and carry out the tasks. Personnel in charge of the management of the production, quality assurance, sanitation, food safety and other departments shall be assigned as a specialist to supervise, monitor or perform their respective functions and activities.



- 7.1.2 Production specialist are in charge of raw material handling, processing and packaging operations. Quality assurance supervisor are responsible for the establishment of quality standards and sampling requirements, testing and annual traceability management of raw materials, intermediate and finished products. Sanitation and hygiene supervisor are responsible for the sanitary aspects of the internal and external environment, premises and facilities, personnel hygiene, production and cleaning operation and personnel hygiene training. The food safety control specialist is responsible for the implementation and maintenance of the food safety management control program based on the HACCP principles and the TQF specifications and product certification scope; While the specialist is responsible for labor safety management and in charge of the food plant safety and defense.
- 7.1.3 A committee to promote the TQF system shall be established. The committee should shall consist of at least three person from senior executives and department specialists, in which the senior executives or their designees are necessary members and are responsible of identifying the food safety management system and verifying the HACCP plan of TQF product certification, and to formulate, implement and manage relevant records; in the meantime, the committee is also responsible for planning, reviewing, supervising and assessing the quality management of the matters concerning the food plant's quality management. The senior executives shall supervise the implementation and maintenance of food safety and provide sufficient manpower and resources to achieve the goal of food safety management and to ensure that effective and sustainable resources are continuously provided to meet the operation, maintenance and corrective action of the food safety management system. The Quality Assurance Department shall be independent from the other departments and shall have full authority to manage quality assurance tasks. The person in charge shall have the authority to stop production or product release.
- 7.1.4 The Quality Assurance Department shall designate a food testing and inspection personnel to analyze and test the general and sanitary-hygienic quality of the products.
- 7.1.5 A working group for sanitation and hygiene management (which can be incorporated into the relevant committees that implement the TQF system) shall be established, comprising of the specialist of sanitation management and personnel of other departments. The group shall be responsible for planning, evaluating, instructing and monitoring, and auditing sanitation and hygiene matters of the whole plant. The name of the person should be clearly marked based on the appropriate workplace.
- 7.1.6 The person in charge of the production and the person in charge of the quality control shall not be the same. However, personnel of other departments are allowed to share interdepartmental responsibilities.

7.2 Personnel and qualification

- 7.2.1 The person in charge of production, quality control, sanitation management and safety management shall be a college graduate from related fields, or have a high school or vocational education diploma, or a higher degree with at least four years experiences in food manufacturing.
- 7.2.2 Food testing personnel should shall have passed the government-certified examination



for food testing technicians or be graduated from related fields at university degree. If the personnel is graduated from high school, vocational education or unrelated university degree, the personnel shall have gone through government-approved professional training (i.e., food testing training course), and hold a certificate of completion.

- 7.2.3 The person in charge of a department and the technical assistants shall receive, within three years of employment, professional pre-employment or on-the-job training by attending the training courses organized by government entities, research institutions or private training organizations and hold a certificate of completion.
- 7.2.4 All categories of specialized technical personnel shall comply with the relevant laws and regulations stipulated by the central competent authority.
- 7.2.5 At least one member of the related committee implementing TQF Technical Specification shall be a certified food technologist or being graduated from a food related department with a university degree, and have attended and passed the training courses in Good Hygiene Practice (GHP) and Hazard Analysis and Critical Control Points (HACCP) organized by training agencies approved by the central competent authority.

7.3 Education and training

- 7.3.1 New employees should shall receive appropriate education and training so that their capacity of execution are in line with the production, sanitation, hygiene and quality management requirements. Employees should shall set annual training plans to be carry out and documented. The annual training program should shall include on-site and off-site training courses, and the effectivity in enhancing the management and implementation capacity of the TQF certification shall be considered during its planning.
- 7.3.2 Relevant internal or external training Training on GHP and HACCP shall be conducted periodically (even inside the factory) for employees engaged in food manufacturing and related operations.
- 7.3.3 Personnel of the Quality Assurance Committee responsible for the food safety management system shall, at least once every three years, be subjected to HACCP related professional training, seminars, workshops, meetings or other courses approved by the central competent authority, with a cumulative training duration of more than 12 hours.
- 7.3.4 All departmental managers shall be committed to their responsibilities, lead by example, and supervise and educate their staff to follow the established operating procedures or rules.
- 7.3.5 Employees are required to obtain a certificate of participation in a hygiene seminar or training course conducted by the competent health authority or approved related institution.



8 Sanitation and Hygiene Management

- 8.1 Establishment and implementation of the "Standard Operation Program for Sanitation Management".
 - 8.1.1 The food plant shall establish standards for sanitation management as the basis for sanitation and hygienic management and assessment, which shall include the provisions of this chapter, even when amendments are made.
 - 8.1.2 A sanitation inspection plan shall be established with specification of schedules, items and frequency to be checked, and a sanitation management personnel shall be designated to carry out the sanitation inspection in according to the plan to confirm the sanitation condition of the specific day and that it was actually carried out and recorded.
 - 8.1.3 Pests and vector control measures should shall be developed, implemented and documented.
 - 8.1.4 Establishment of environmental monitoring program
 - 8.1.4.1 A Food factory shall consider about the characteristic of product and establish monitoring program for each operational field (such as controlled operation area), equipment etc. base on food safety risk.
 - 8.1.4.2 Environmental monitoring program shall include monitoring frequency, sampling method (e.g. swabbing), sampling number, sampling location (including food connected surface and non-connected surface), and the database of the monitoring bacteria and their limitation, and shall ensure the effectively performance of the program and shall be well documented.
 - 8.1.4.3 If the testing result cannot meet the required standard, then shall provide corrective actions and preventive measures to improve this matter.
- 8.2 Environmental sanitation management
 - 8.2.1 Roads adjacent to the factory, along with passages ways and garden inside the factory shall always be kept clean. The open ground inside the plant shall be kept in good state of repair without damage, accumulation of water and no dust.
 - 8.2.2 Vegetation inside the plant shall be trimmed periodically, and accumulation and storage of unnecessary equipment and articles are prohibited to prevent <u>vextor</u> <u>vector</u> breeding.
 - 8.2.3 Premises and plant facilities shall be kept in good sanitary condition and properly maintained to protect against the contamination of food.
 - 8.2.4 Gutters shall be kept unobstructed, with no accumulation of sludge, and waste water shall be properly addressed and treated.
- 8.3 Plant facilities sanitation management
 - 8.3.1 Facilities inside the plant shall be kept clean and in a good state of maintenance at all times. When the roof, ceiling and walls of the factory are damaged, they shall be repaired immediately, and the ground and drainage facilities shall not be damaged or stagnant.
 - 8.3.2 Raw material handling areas, processing and preparation areas, and toilets shall be cleaned daily (including floors, drains, and walls) before production and disinfected when necessary.



- 8.3.3 Steam generated during the operation shall not be allowed to remain inside the factory for a long period of time and shall be vented out through effective facilities.
- 8.3.4 The outer surfaces of the lighting and piping shall be kept clean, and cleaned periodically.
- 8.3.5 Chilled (Frozen) storage shall always be kept organized, defrost regularly, kept clean, and shall avoid water accumulation on the ground, moldy walls and other conditions that may affect food storage sanitation condition.
- 8.3.6 Production and storage areas shall take effective measures to prevent or eliminate pests and vectors, such as screens, air curtain, fences or insect traps.
- 8.3.7 No traces of pest or vector shall be found inside the plant. However, when present the source shall be eliminated using methods that do not cause contamination of food, food contact surfaces and inner packaging material (pesticides are better to be avoided).
- 8.3.8 Raw materials, inner packaging materials or other unnecessary articles that are not being immediately used shall not be kept in the controlled operation area.
- 8.3.9 Equipment and tools for cleaning and sanitizing shall be stored at specific designated location.
- 8.3.10 Do not place or store any substance in the processing area that pose a risk to food safety.
- 8.3.11 Periodical cleaning and daily inspection of chlorination treatment (prior to production), and regular monitoring to avoid contamination of processing water quality are recommended if reservoirs (tower or pool) are used. When using non-potable water, a personnel shall be designated in charge of checking the residual chlorine and pH value every day, and at least once a year a government recognized inspection agency shall be sent to ensure that water meets drinking water quality standards (with exception of boiler water, cooling water for refrigeration compressor or evaporator, or floor cleaning water etc.).
- 8.4 Machinery and equipment sanitation management
 - 8.4.1 Equipment and appliances for manufacturing, packaging and storage, and transportation shall be cleaned and sanitized periodically.
 - 8.4.2 When water needs to be disposed from the equipment, it shall be design to properly collect the water and direct it to the drainage system to avoid any contamination.
 - 8.4.3 Cleaning agents or disinfectants used in the cleaning operation shall not contaminate food, food contact surfaces and inner packaging materials.
 - 8.4.4 All food contact surfaces, including the surfaces of equipment and appliances in direct contact with food, shall be disinfected regularly and thoroughly cleaned after disinfection to prevent food from disinfectants contamination.
 - 8.4.5 Used equipment and appliances shall be fully cleaned after finishing production. If disinfected, they should shall also be cleaned again before starting the next production (except for those that are exposed to dry food surface).
 - 8.4.6 The water <u>and steam</u> used to clean the equipment and tools in direct contact with food shall meet drinking water quality standards.



8.4.7 Equipment or facilities used in food manufacturing shall not be used for other non-food production purposes.

8.5 Personnel hygiene management

- 8.5.1 Hands should shall be kept clean and washed with cleaning detergent before starting work. Staffs who come into direct contact with food shall keep their fingernails short, and may not wear nail polish, jewellery and other accessories.
- 8.5.2 If hands are used to handle foods that will no longer be heat-treated, staff shall wear impermeable gloves that shall be maintained in a clean and sanitary condition. Hands shall still be cleaned before wearing gloves.
- 8.5.3 Operators must wear a clean work clothes and hair nets to prevent hair, dandruff and foreign materials from falling into and contaminating the food, food contact surface or inner packaging materials. Shall wear mask when necessary.
- 8.5.4 No smoking, chewing gum or betel nut, eating, drinking and other behaviour that may cause food contamination is allowed in the production area. Do not allow sweat, saliva or topical medicines and cosmetics to contaminate food, food contact surfaces or inner packaging.
- 8.5.5 New employees shall have a health examination in a health or medical institution prior to employment. During the course of their employment, employer shall take the initiative to establish routine health examinations which shall include relevant examinations in compliance with the "Good Hygiene Practice (GHP)" provision.
- 8.5.6 Employees infected with hepatitis A, hand skin diseases, rash, abscess, wounds, tuberculosis, typhoid or other infectious diseases even in its incubation period, that may contaminate food shall take the initiative to inform the person in charge on site and shall not be working in direct contact with food.
- 8.5.7 Hand washing or (and) disinfection shall be properly done according to the hand washing procedures and instructions.
- 8.5.8 Personal clothing should shall be stored in the change room and should shall not brought into food handling areas or equipment, appliances and utensils cleaning areas.
- 8.5.9 Before entering food factory (including in between the work shifts), or after using the toilet (the sign indicating washing hands after use should shall be posted in the toilet), and when hands are contaminated by spiting or wiping snot, hands shall be washed and even disinfect when necessary.
- 8.5.10 The access of visitors or off-site staffs shall be properly controlled. Hygienic requirements for them should shall comply with those for on-site operation personnel.
- 8.6 Management of chemicals and supplies such as detergents and disinfectant
 - 8.6.1 Detergents and sanitation agents should shall have been proven that it is safe and applicable for the purpose being used.
 - 8.6.2 Inside the food operation area, with the exception of those agents necessary for environmental protection and sanitation purposes, other agents are not allowed in the food operation area.
 - 8.6.3 Sanitizing agents, sanitizers, and dangerous reagents shall comply with relevant



specifications, and shall be clearly identified and labelled with indication of its toxicity, instruction of how to use, and emergency handling and stored and kept locked in a specific designated location to avoid food from being contaminated. A specialist in charge should be assigned of their storage and record the amount of usage.

8.6.4 Environmental agents using for vector prevention shall comply with Environmental Agent Management Act and related regulations. Strict preventive measures and limitations shall be taken regarding the use of pesticides and sanitizing agents, to protect against contamination of food, food-contact surfaces, or food-packaging materials. They shall be used by or under the supervision of a sanitation personnel who understands their potential harm to the human body (including in the event of food contamination).

8.7 Waste material

- 8.7.1 Handling of waste material shall comply with waste material cleaning law and related regulations of the provisions of removing and handling, and shall be collected, classified and properly disposed according to their characteristics. Perishable waste shall be removed at least once a day, the container shall be cleaned and disinfected after emptied.
- 8.7.2 Waste disposal areas shall not present bad odours or harmful (toxics) gases. It is necessary to prevent the harbouring of pests and the food, food contact surface, water source and ground from being polluted.
- 8.7.3 Waste material and receptacles shall not be allowed to accumulate inside the food operation area or outside the building to prevent the breeding of pests and vectors.
- 8.7.4 Raw materials handling, processing, packaging, storage and other areas, shall have waste receptacles that are easy to clean and disinfect (with exception of the ones that are discarded after usage), can be closed (or sealed), and regularly (at least once a day) removed from the plant. Reusable containers should shall be cleaned and disinfected immediately after discarding the content. If a large number of waste is generated, it shall be transported outside the facility, as soon as possible, and also away from the plant, in order to prevent pests breeding, and the contamination of water sources, ground, ground water etc.. The machines and equipment used for waste handling shall be cleaned and disinfected immediately upon finishing operation.
- 8.7.5 When there is waste exposure that may put human health and food safety in direct danger such as chemicals, radioactive materials, pathogenic microorganisms and food spoilage, etc. special storage facilities shall be set up.
- 8.7.6 Harmful (toxic) gases, waste water, litter, noise pollution, etc. shall be avoided or handled in accordance with relevant laws and regulations in order to prevent environmental pollutions.



9 Food Production Management

- 9.1 Establishment, and implementation and maintenance of the "Standard Operation Procedure for Food Manufacturing".
 - 9.1.1 The Production Department is responsible for the establishment and revision of the "Standard Operation Procedure for Food Manufacturing", when a new product is developed or the process of a product has been changed, and it shall be approved by the quality assurance and related departments to ensure the safety and quality of the product.
 - 9.1.2 The "Standard Operation Procedure for Food Manufacturing" shall specify the recipe, standard operation procedure, <u>rework standard procedure</u>, process control standard (including at least the manufacturing process, control object, control item, control standard value and precautions, etc.) and machinery and equipment operation and maintenance standards.
 - 9.1.3 The employees shall be educated and trained to carry out their work in accordance with the "Standard Operation Procedure for Food Manufacturing" so as to be in compliance with the production, sanitation, hygiene and quality control requirements.

9.2 Raw material handling

- 9.2.1 The food factory shall establish raw material inspection standard procedure for its reception, and shall not use primary or secondary raw materials from which microorganisms and toxic substances (e.g., cyanide in the cassava) cannot be removed or reduced to an acceptable level during normal processing. When semi-finished products or finished products from both interior and exterior products using for the raw materials, manufacturing environment, manufacturing process and quality control shall meet the hygiene requirements of the Good Manufacturing Practices'" (The Regulations on Good Hygiene Practice for Food" (GHP) of food factories.
- 9.2.2 Raw materials shall be sensory tested before use, and sorted to remove foreign materials and those that are substandard, where necessary. The food factory shall establish raw material inspection standard procedure for its reception, and shall not use primary or secondary raw materials from which microorganisms and toxic substances (e.g., eyanide in the cassava) cannot be removed or reduced to an acceptable level during normal processing. When semi-finished products or finished products from both interior and exterior products using for the raw materials, manufacturing environment, manufacturing process and quality control shall meet the hygiene requirements of the "The regulations on Good Practice Hygiene Practices for Food" (GHP).
- 9.2.3 Fresh raw materials, should shall be cleaned when necessary, and the water should shall meet drinking water quality standards. If water is recycled, it shall be properly disinfected, and filtered, when necessary, so as to avoid raw materials from secondary contamination.
- 9.2.4 Ready-to-eat finished products that are no longer going through heat treatment shall be strictly guard against microbiological re-contamination.
- 9.2.5 Approved raw materials and substandard raw materials shall be stored separately, and clearly identified.



- 9.2.6 Raw materials shall be stored in such a way that they can be protected from contamination and damages, and minimize quality deterioration. When temperature and humidity control are needed, control limits shall be established. Frozen raw materials should shall be kept below -18°C, and refrigerated raw materials below 7°.C and above the freezing point of water.
- 9.2.7 Raw material usage shall be in order of the manufacturing date and following in accordance with the principle of the priority use for the raw material that less shelf life remains, first in and first out, and used within the expiration date. Thawing of frozen raw materials shall be carefully controlled to prevent quality deterioration.

9.3 Manufacturing operation

- 9.3.1 All food manufacturing operation procedures, including packaging and storage, shall be in accordance with the principles of food safety and sanitation. Food shall be quickly processed under controlled condition to minimize microbial growth and food contamination as possible.
- 9.3.2 When the control of temperature, humidity, pH value, water activity, pressure, flow rate and time are needed during operation procedures, a related control methods and control limits shall be established and recorded, to ensure that food is not spoiled or being contaminated by mechanical failure, time delays, temperature changes and other factors.
- 9.3.3 Food subject to the growth of pathogenic microorganisms, especially those that may cause food borne diseases, shall be stored under conditions sufficient to prevent its deterioration. To achieve the above-mentioned requirement, effective measures are listed as follows:
 - 9.3.3.1 Core temperature of the refrigerated food shall be kept below 7°C and above freezing point.
 - 9.3.3.2 Frozen food shall be kept at suitable frozen state and product core temperature shall be kept below -18°C.
 - 9.3.3.3 Hot-storage food shall be kept above 60°C.
 - 9.3.3.4 Proper heating to kill mesophilic bacteria should shall be applied to those acid or acidified foods in hermetically sealed containers, stored at ambient temperature.
- 9.3.4 In the course of operation, appropriate methods shall be used to prevent pathogenic microorganism growth, and to prevent food degradation during manufacturing, storage and transportation, such as sterilization, irradiation, pasteurization, freezing, refrigeration, and pH or water activity control.
- 9.3.5 Effective measures should shall be adopted to prevent raw materials, semi-finished products, materials to be reworked and finished products from being contaminated during processing or storage.
- 9.3.6 The operation, utilization and maintenance of equipment, containers and utensils which are in contact with the raw materials, semi-finished products, materials to be reworked and finished products shall not contaminate food during processing and storage. Equipment, containers and utensils in contact with raw materials or contaminants shall not be used for handling finished food products unless thoroughly cleaned and disinfected. Food containers that contain semi-finished food shall not be directly put on



the ground to avoid splashing water contamination or cross-contamination from the bottom of the container. When entering from the general operation area into the controlled operation area, appropriate cleaning and disinfection measures shall be established to prevent food contamination.

- 9.3.7 Water for making ice cubes <u>or steam</u> which directly come into contact with food during processing shall meet the standard of potable water, and the ice cubes shall be made under sanitary conditions.
- 9.3.8 Effective measures should shall be taken to avoid food from being contaminated with metal or other foreign matter. This requirement may be achieved by using screen, trap, magnet, electronic metal detector or other effective means.
- 9.3.9 During blanching, temperature (especially temperature of the inlet and outlet) and time shall be strictly controlled, quickly cool down and moved to the next operation procedure. Equipment shall be routinely cleaned to prevent thermo-resistant bacteria growth and contamination, and to minimize its contamination. If the blanched food is cooled before filling, the cooling medium should shall conform to the principle of safety, hygiene and sanitation.
- 9.3.10 Food such as instant soup powder, nut, semi-dry food and dehydrated food that rely on water activity control to prevent the growth of pathogenic micro-organisms shall be processed and kept at safe moisture reference level. This requirement can be achieved through the following effective means:
 - 9.3.10.1 Adjustment of water activity.
 - 9.3.10.2 Controlling the ratio of soluble solids and water in the finished product.
 - 9.3.10.3 Using waterproof packages or other methods to prevent water absorption of the finished product so that water activity does not increase to unsafe levels.
- 9.3.11 Foods that rely on pH control to prevent pathogenic micro-organism growth, such as acidic or acidified foods, shall be regulated and keep the pH below 4.6. This requirement should shall be achieved by one or more of the following effective methods:
 - 9.3.11.1 Adjustment of pH values of raw material, semi-finished product and finished product.
 - 9.3.11.2 Controlling the amount of acidic or acidified food added to the low acid food.
- 9.3.12 When selecting inner packaging materials, it must protect food during normal storage and transportation, and to avoid migration of harmful substances into food and meet sanitation and hygiene standard. Inner packaging materials shall not be reused with the exception of glass bottles, stainless steel containers and barrels (e.g. used as water or invert syrup container), but they shall be properly cleaned before using. If necessary, they shall be effectively sterilized.
- 9.3.13 The use of food additives shall be in compliance with the "Standard for Specification, Scope, Application and Limitation of Food Additives" promulgated by the Food and Drug Administration. Weighing and batch feeding procedures shall have a double check system for process verification established, truly implemented and recorded.
- 9.3.14 When the total polar compounds of frying oil are above 25%, they shall not be used,



and shall be replaced with new oil.

9.4 Rework

A food factory shall establish, implement and maintain the "Standard Operation Procedure for Rework", which shall include the procedure for rework and the requirements for the materials, products, and packaging, to minimise the food safety risk, and all the rework information shall be recorded.

- 9.4.1 The raw material for rework shall be reprocessed within the expiration date and shall be free from contaminations and potential hazards.
- 9.4.2 The process for rework shall comply with the "Food Safety Plans" of the food factory, and consider all the possibility of allergen cross-contaminations.
- 9.4.3 The safety and quality of reworked products shall be confirmed before shipping.
- 9.4.4 The reworked products shall be clearly identified and traceable.

10 Quality Control

- 10.1 Establishment and implementation of the "Standard Operation Procedure for Quality Control"
 - 10.1.1 The Quality Assurance Department is responsible for the establishment of the "Standard Operation Procedure for Quality Control", and it shall be approved by the Production Department and effectively implemented to ensure that food produced are suitable for human consumption. The content of the manual shall include the provisions from section 10.2 to 10.6, as a basis for quality control ensuring product quality. It is also applicable when amended.
 - 10.1.2 "Process and Quality Control Engineering Flow Chart" that is based on critical control factors shall be established for every product. Its contents shall include the scope, control points, control limits, sampling frequency and testing methods etc., and shall be implemented and recorded.
 - 10.1.3 Testing methods shall be based on promulgated normative. When a modified testing method is adopted, it shall be checked regularly against the promulgated normative and recorded. When there is no national normative or regulations, the manufactures shall provide clear product specification, testing items and internationally recognized testing methods as supporting documents.
 - 10.1.4 A control system shall be established to avoid possible biological and chemical contamination during testing, and effectively implemented.
 - 10.1.5 Drugs or chemicals using in quality control tests shall be used under effective conditions and controlled.
 - 10.1.6 Food factory shall identify and monitor all measuring instrument (e.g., thermometers, pressure gauges, weighing scale, etc.) that have been used in productions, and shall have an annual calibration program for measuring those instruments. The measuring instruments that are considered as critical control point to food safety (such as CCP) may be calibrated by entrust credible authority at least once a year. The calibration standard object shall be able to trace back to domestic or international standard, and shall be implemented and recorded.



- 10.1.7 Food factory shall be able to confirm the effectiveness of monitoring equipment that is important for food safety (such as CCP), and shall keep the traceable records.
- 10.1.8 Appropriate statistical methods shall be used for analyze the quality control data recorded.
- 10.1.9 All food factories shall be up-to-date with all current relevant regulations or normative information.

10.2 Contract management

The food factory shall establish and maintain written procedures for contract review and for its operational coordination.

10.2.1 Contract review

Upon acceptance of each order placed by customers, it is necessary to review that the requirements have been clearly written and ensure that the customer requests and requirements can be properly met.

10.2.2 Contract amendment

Amendment of contract or purchase order shall be documented and communicated accurately to relevant departments and executed in accordance with the revised content.

10.3 Quality control of raw materials

- 10.3.1 For the quality control of raw materials, it is necessary to specify the quality specifications of raw materials, <u>materials to be reworked</u> and packaging materials (including source information and control points for risks and hazards), testing items, inspection criteria, sampling plans (sample containers should shall be properly identified) and testing methods, and effectively implemented.
- 10.3.2 Purchasing and suppliers Suppliers evaluation procedure shall be established, implemented and maintained, which the purchasing procedure shall include all input materials and services to comply with the specific food safety requirements or regulations. The suppliers evaluation procedure shall include the method applied and frequency and record the result. be effectively implemented and recorded. When possible, on-site assessment of suppliers shall be conducted. Food factory shall use the ingredients from approved suppliers. Besides, non-approved suppliers shall be accepted in an emergency situation when assessment has been conducted and the products meet the specification. If the food factory need to accept the raw material from non-approved suppliers, it shall be followed by this assessment.
- 10.3.3 Each batch of raw materials (additives) shall be inspected and approved by quality assurance personnel before released for use. Traceability and source control measures of raw material shall be established (including supplier's raw material quality certificate and certificate of origin, raw material provenience details and testing reports). Establishment of a TQF certificated products quality history or curriculum (including product name, lot number, manufacturing plant, expiration date, ingredients of raw material and its origin, raw materials testing report, finished product testing report information). Raw materials that are not approved during inspection shall be clearly identified, and appropriately managed.



- 10.3.4 Prior to release for use, it is necessary to verify that those raw materials with potential contamination of pesticides, heavy metal or toxins are safe and the amount of residues permitted are in compliance with regulatory requirements.
- 10.3.5 The acceptance of packaging materials should shall include the source, the application of materials and their use and storage, etc., in order to avoid contamination of the product. Inner packaging materials shall meet hygienic and sanitation normative standards, and suppliers of those packaging materials should shall provide periodic test reports to verify the compliance with food safety, sanitation and hygiene requirements. The testing reports shall be provided again by the supplier upon changing suppliers or specification.
- 10.3.6 Special designated storage for food additives shall be set up and be managed and controlled by authorized personnel who is responsible for issuing the materials and controlling the expiration date. Log sheets with list of food additives type, registration number under central authority, material check-in and check-out etc. shall be documented.
- 10.3.7 Raw materials which are provided by the consignor for contract manufacturing shall be properly stored and controlled, and any missing, damaged, or out of specs materials shall be recorded and reported to the contract supplier. When contract manufacturing products apply for certification, the food factory shall be able to trace back the source of the raw materials and confirm the composition, purity, etc. of the product, providing supporting documents to ensure the quality of the products. Qualification for the TQF product certification will be withdrawn from the supplier for providing false information.

10.4 Quality control during processing

- 10.4.1 Hazard Analysis and Critical Control Points shall be performed, and testing items, criteria and methods for sampling and testing shall be established, effectively implemented and documented.
- 10.4.2 Corrective actions and preventive measures shall be established when deviation from control limits occur during processing, and immediate investigation and corrective action shall be taken and documented.

10.5 Quality control of finished products

- 10.5.1 Quality specifications, testing items, testing standards, sampling and testing methods shall be established, <u>implemented</u>, and <u>maintained to ensure the finished products</u> comply with the food safety legislations in the county of manufacture and sale.
- 10.5.2 Sampling retention plan shall be established for finished products, and each lot of sampling shall be retained until expiration day of the product. Perishable ready-to-eat finished products shall be kept for 1 to 2 days after the expiration date. Shelf life test of finished products shall be carried out when necessary.
- 10.5.3 Every lot of finished products shall be subject to quality testing. Non-conforming products shall be appropriately managed.
- 10.5.4 Finished products shall not contain foreign matters and toxic or pathogenic substances that have adverse effects on humans health, and shall be in compliance with product



hygiene and sanitation normative standards in the country of manufacture and sale.

10.5.5 Product packaging process shall be properly handled, classified, graded and packaged to avoid contamination.

10.6 Testing condition

Raw materials, semi-finished products, final semi-finished material to be reworked products and finished products shall be properly identified, handled and controlled. When the regulation of "Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatorily Conduct Tests and Meet the Minimum Testing Cycle and Other Relevant Matters" enacted by the Ministry of Health and Welfare is applicable to the raw materials, semi-finished products, materials to be reworked or finished product being produced, it shall comply with the requirements of that regulation.

10.7 Non-conforming product handling

- 10.7.1 The factory shall establish a non-conforming product control plan, and effectively implemented and recorded.
- 10.7.2 Non-conforming products shall be effectively separated and make sure that they are not placed on the market; those introduced into the market shall be recalled and appropriately managed.
- 10.7.3 The quality control of the third-party: food manufactories shall establish and maintain the documented procedure of any service that is related to food safety matters (such as equipment maintenance, instrument calibration, disinfection, and vector control, logistics, etc.). Each document shall be stored properly, easy to access when necessary and reviewing periodically.

11 Storage and Transport Control

- 11.1 Storage and transport operations and sanitation control
 - 11.1.1 A storage and transport control procedure shall be established, it shall include storage area separation, storage conditions, inventory control, storage management, etc., and be effectively implemented and recorded.
 - 11.1.2 Storage and transport methods and the surroundings shall avoid direct exposure of sunlight, rain, wide fluctuation of temperature or humidity and any direct impact or collisions and water accumulation to prevent <u>deforming</u>, <u>damaging of the package and</u> the food ingredients, composition, quality and concentration from being affected by undesirable external factors, and maintaining food degradation at a minimum level.
 - 11.1.3 Storage shall be always kept clean and organized, swept and cleaned, and storage items shall not be placed directly on the ground. Cold chain storage and transportation equipment shall be available when necessary, to ensure products are maintained in insulated (temperature control) condition.
 - 11.1.4 Temperature (and humidity, if necessary) in the storage shall be recorded, and the storage items shall be regularly checked, when abnormalities are detected, corrective action shall be immediately performed. When possible risks of quality deterioration are presented due to damaged packaging or prolonged storage, food products shall be



re-inspected to ensure that they have not been contaminated and the deterioration of quality is still acceptable.

- 11.1.5 When temperature and humidity control are necessary, control methods and parameters limit shall be established, documented and recorded.
- 11.1.6 Food items rotation shall should be based on the "first in first out" principle; products shall be stable and ventilated when stacked.
- 11.1.7 There shall be measures to prevent cross-contamination of any item that may contaminate raw materials, semi-finished products, <u>materials to be reworked</u> or finished products; those that can not effectively prevent cross-contamination shall be prohibited from being stored or transported together with raw materials, semi-finished products, <u>reworked products</u> or finished products.
- 11.1.8 Incoming delivery containers and vehicles transporting purchased goods into the plant shall be inspected, so as not to cause raw materials or plant site environmental contamination. Outgoing delivery containers and vehicles used for food product shipping or dispatch shall be also inspected before loading to assure food safety, sanitation and hygiene conditions. Good transportation requiring temperature control shall have an effective temperature control system, and be documented and recorded. The food factory shall require logistic operations to be in accordance with the temperature conditions of the products. Low temperature foods shall be promptly loaded and unloaded at a temperature of 15 degrees Celsius and product temperature shall be detected and recorded.
- 11.1.9 All records related to the production process of the food product shall be reviewed and checked prior to shipment to ensure the integrity of information including that control limits are in compliance, and corrective action taken and product handling was appropriate. This inspection shall be performed by a trained and experienced personnel, with signed and dated.
- 11.2 Storage and transport records: Inventory and shipping records shall be established, including lot number, time, location, destination, quantity etc., in order to be recalled quickly when any problem comes up.

12 Labelling

- 12.1 Product labelling shall be in compliance with the "Act Governing Food Safety and Sanitation". When that regulation is not applicable, other relevant laws and regulations of central competent authorities shall be applied. The label of products for export shall comply with the requirements of laws and regulations of the intended country.
- 12.2 Retail products label shall be presented in Chinese and generic symbols with the following information and must be set off in a frame text box (in the below order):
 - 12.2.1 Product name.
 - 12.2.2 List of ingredients. When it is a mixed ingredient, each component shall be also listed.
 - 12.2.3 Weight, volume or quantity.
 - 12.2.4 List of food additives.



- 12.2.5 Name, <u>phone number and</u> address, <u>customer service line or phone number</u> of the manufacturer or <u>domestic</u> company in charge. When only the name of the <u>domestic</u> company in charge is indicated, the use of the TQF product certification mark is not permitted. Having obtained the national traceable agricultural products shall indicate the traceable source; Having obtained the production system enacted by central agricultural authority, shall indicate the production system.
- 12.2.6 Country of origin.
- 12.2.7 Nutrition label.
- 12.2.8 Genetically modified food ingredients.
- 12.2.9 Expiration date. When required by the central competent authority, date of manufacture, shelf life or preservation conditions shall be also indicated. This information shall be printed on the packaging rather than tagged.
- 12.2.10 Lot number: Product lot shall be indicated by explicit or implicit code, which enables tracing back the raw materials and ingredients records involved in the manufacturing of a product.
- 12.2.11 Instructions for consumption or cooking and any special storage conditions, if necessary.
- 12.2.12 Other information required as indicated by the central competent authority.
- 12.3 It is recommended that finished products be labelled with bar code.
- 12.4 Product's outer packaging shall be labelled with the lot number to facilitate storage management and product recall.
- 12.5 Allergen information: Allergen labelling shall comply with the regulations of the country of origin and the allergen management of sales area.
- 12.6 If there is no label on the product, the product information shall be provided to the customer to ensure their safety use of the product.

13 Customer Complaint Procedure and Product Recall

- 13.1 Customer complaint system shall be established for written or verbal complaints and suggestions. The quality control personnel (and when necessary, with the coordination of other relevant departments) shall investigate the root cause and make improvements, and assign a personnel to contact the customer who filed the complaints or suggestions for explanation (or apologies) or in appreciation for his/her comments.
- 13.2 A system for product recall and destruction of finished products shall be established, including degree of product recall, scope and due date, mock recall shall be conducted at least once a year.
- 13.3 The written or oral complaints and suggestions made by the customer and the finished product recall shall be recorded, indicating product name, lot number, quantity, reason, handling date and final resolution method. It is recommended that the records be statistically analysed and reviewed periodically, and the result distributed to related departments as a reference for improvement.



13.4 Food factories shall establish anomalies or defect handling procedures to address significant and potential problems that may arise from external or internal problems or customer complaints.

14 Record Management

14.1 Records

- 14.1.1 Sanitation management specialist personnel shall record the result of regular sanitary inspections, fill out the hygiene management log, which include daily sanitizing work and personnel hygiene conditions and detailed records of the corrective actions and preventive measures.
- 14.1.2 The Quality Assurance Department shall record and review the results of quality control of raw materials, semi-finished products and finished products and even the customer complaints and product recall results. Corrective action and preventive measures shall be recorded in detail.
- 14.1.3 The Production Department shall complete the production records and process operation control records, and also corrective action and preventive measures shall be recorded in detail.
- 14.1.4 All food factory records and documents shall be presented in Chinese and truly recorded.
- 14.1.5 Stationaries that not easy to be erased shall be used for record writing. Every record shall be signed and dated by responsible persons and supervisor, signature shall be use in principle, when seal are used instead then special control procedure shall be established. If the content of the record are modified, the original text shall not be completely illegible so that the original text cannot be read, the person who made the modification shall sign next to revised text.
- 14.2 Record verification: All production and quality control records shall be reviewed respectively by the Production and Quality Control Departments to ensure that all operations are in compliance, and immediate actions shall be taken whenever an anomaly or deviation is found.

14.3 Recordkeeping

14.3.1 The food factory shall keep the relevant records (including shipping records) regulated under this provision until the terms required by the clients and/or by the regulations of the place of manufacture and sale are satisfied. If there is no regulation, the records shall be kept exceeding expiration date, and all the information shall be readily accessible when needed. All food factory records including inventory regulated under this provision, shall be kept at least 5 years and readily accessible.

15 Establishment of Management System and Auditing

15.1 Food factory shall establish an integral effective TQF management system. The design and control of the organization and implementation system, including food safety policy and food safety culture shall have structural integrity and coordination.



- 15.1.1 Senior site manager shall sign and implement their policy <u>and culture</u> of food safety commitment <u>promised by the food factory</u>. It shall cover the requirements from clients and <u>regulations</u>, the range of business activities. The food safety cultures shall contain the communication, training, employee feedback and the food safety-related <u>performance assessment</u>, and shall keep the food safety <u>TQF</u> management system updated.
- 15.1.2 Establish the reviewing procedure for the commitment to maintain the food safety performance.
- 15.1.3 This The food safety policy shall be documented and published in the language that all the personnel can understand, and shall be placed in the obvious location. This policy shall be announced and communicated to all the personnel in the food factory

15.2 Management system audit

- 15.2.1 Food factory shall establish an effective internal auditing system to conduct both regular and non-scheduled audits. The assessment shall be carried out by all levels of management staffs in order to identify potential problems of the plant and to give a reasonable solution, corrective action and tracking.
- 15.2.2 An internal auditor shall be properly trained, and it shall be documented and recorded.
- 15.2.3 Food factory shall establish an effective internal audit plan and specify the frequency of audits (all the certificated scopes and certification scheme shall be integrity audited at least once a year or in batches), and shall be effectively implemented and recorded.

 When the changes in the food factory affect food safety, the frequency of internal audits shall be increased to ensure the effectiveness of the food safety system.
- 15.2.4 All the records shall be kept in safe. Electronic documents included local backup and back-up off-site record can only be review with permission. If the record is hard copy, it shall be kept in a proper manner by designated personnel.

15.3 Document management system

- 15.3.1 Shall establish procedure document which cover the requirements of applied certification scopes and products, according to safety and quality management policy.
- 15.3.2 The issuance, renewal and abrogation of the documentation shall be signed and approved by responsible person or authorized person for implementing and recorded.
- 15.3.3 This is also applicable for revisions that will ensure that the staffs responsible for the quality operation have the valid version of the operation document and is placed in the workplace for the operator to be implemented.

15.4 Traceability system

15.4.1 Food factory shall establish, implement and maintain a product traceability system according to "food and its related products traceability system management approach" enacted by TFDA, with lot number or other trace back method that can identify the name and address of the production manufactory. The system should shall be able to trace back the product from the customer end to the raw material supplier or service, and to track forward to the purchased clients and transporting location, from the raw material to the finished product and have them recorded.



- 15.4.2 The OEM products shall also comply with the requirements of traceability system in this scheme.
- 15.5 Emergency procedure: Food factory shall stablish procedures and contingency plans for potential emergencies and conduct regular drills.
- 15.6 Corrective action and update
 - 15.6.1 During the course of operation, improvements shall be made based on the sanitation issues, and reviewed and discussed with the sanitation control team. Continuous operation corrective action and update shall be done when necessary, in accordance with regulations and TQF requirements.
 - 15.6.2 During the course of operation, the food factory shall identify corrective action opportunities when problems occurred in the production process, quality control, management system, customer complaint, deviation responses, product recall, labeling, supplier assessment, internal audit and food safety management system implementation, and reviewed and discussed with the Quality Management Committee. Continuous operation corrective action and update shall be done when necessary in accordance with this provision. In the event of a major or sudden food safety incident, or for any reason the product was removed from the shelf and recalled, the supplier shall notify Taiwan Quality Food Association and the certification body with priority.

16 Supplementary Specifications

- 16.1 When the content of these technical specifications are in conflict with existing national laws and regulations, then the existing laws and regulations shall prevail. Compliance dates for the implementation of the Food Safety Control System (HACCP) is subject to the announcements of the central authority. Manufacturers shall establish the HACCP system before any announcement of the central authority.
- 16.2 These technical specifications and its amendment shall come into force from the date of publication.



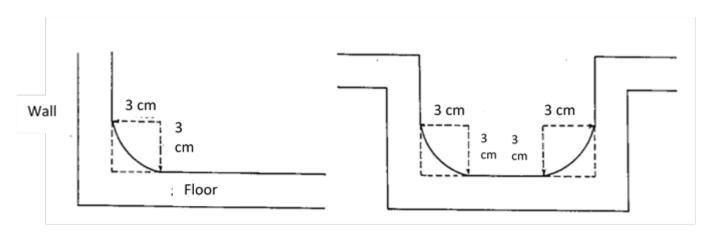
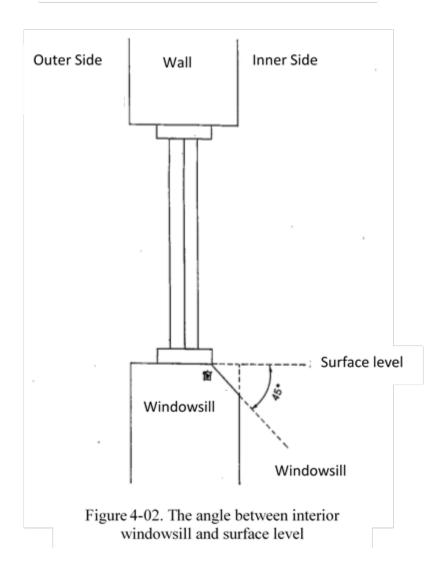


Figure 4-01. The corner and column feet of the wall shall have an appropriate arc





Chapter 5 Food Safety Management Specifications

1 Food Safety Management Control System

- 1.1 A food factory shall have a committee to promote the TQF system (see 7.1.3, Chapter 4); establish a food safety management control system; define all hazards in processes including the validation of ingredients and packaging materials, processing, manufacturing, packaging, storage, and transportation of products; implement hazard analysis; determine critical control points; set control limits; perform surveillance; take corrective and preventive actions; conduct verification; and document records.
 - 1.1.1 A hazard analysis shall identify the frequency rate and severity rate of potential biological, physical, and chemical hazards (including allergens) with respect to the product description, onsite processes consistent with the product's intended use, and flow diagram the quality control plan (QC flowchart).
 - 1.1.2 Critical control points shall be determined with respect to the data obtained from hazard analysis.
 - 1.1.3 Control limits shall be set and validated for each critical control point.
 - 1.1.4 The items, methods, frequency, and handlers for monitoring each critical control points shall be defined to prevent out of the control limit in real time.
 - 1.1.5 Corrective actions for handling deviations from control limits shall be planned for each critical control point to ensure the cause(s) of deterioration is(are) corrected.
 - 1.1.6 Procedures for verifying HACCP plan shall be established, and an internal audit shall be performed at least once annually. When any alteration occurs during validation of ingredients and packaging materials, processing, manufacture, packaging storage and transportation which may impact the safety of product, the food factory shall re-verify its HACCP plan.
 - 1.1.7 A food safety control system shall have documented data recorded by onsite handlers, signed for approval and dated by a responsible person. All related document shall be retained for at least five years.
- 1.2 Products with similar food safety hazard analysis, critical point analysis, and control limits may be categorized in the same HACCP plan.
- 1.3 In the event that the food safety regulations of a place (country) of origin and a distribution region contain requirements outside of the CODEX Codex Alimentarius Commission specifications and HACCP guidelines, the food safety control system team shall take actions to meet such requirements.

2 Allergen Management

A food factory shall conform with the labelling principles of allergen management of the place (country) of origin and the distribution region, include them in the hazard analysis plan, and establish related management methods to control allergens and prevent allergen sources from cross contamination with products. Allergen management shall include:

2.1 Establish a list of allergens appropriate to a place (country) of origin and a distribution region for the reference management of ingredients, semi-finished products, materials to be



reworked and finished products-supplements, and food additives containing allergens.

- 2.2 Manage the above allergens through the food safety control system.
- 2.3 Assess the potential indirect <u>cross-contact of</u> allergen sources outside the premises, such as a quality control room, an office, a canteen, or a visitor.
- 2.4 Establish specifications for identifying, handling, storing, and separating allergencontaining ingredients and <u>materials to be reworked</u> to prevent cross-contact of other ingredients, semi-finished products, and finished products in the operating process, and monitoring measures for verification.
- 2.5 When producing a different product with equipment used to produce allergen-containing ingredients, the equipment surface shall be effectively cleaned to remove all potential target allergens on equipment surface. Procedures to prevent cross-contact shall be documented and records of product switch shall be maintained.
- 2.6 Procedures for hazard analysis shall be documented to verify and validate the effectiveness of cleaning of the equipment and premises producing allergen-containing products. If the effective cleaning of equipment to prevent allergen sources are unachievable, shared use of premises and equipment is prohibited.
- 2.7 Allergen-containing products or products produced in a production containing allergens shall comply with the relevant regulatory requirements. Certification bodies shall ensure that the allergen cross-contact management measure is the same as the document that supplied from the site on annual surveillance. The allergy warning sign including allergen information and allergens causing potential cross-contact due to unintended mixing are suggested to be clearly labeled on the package label. The following control procedures of allergen product labels shall be established: material incoming, manufacturing, usage, destruction, and records shall be maintained to ensure accuracy.
- 2.8 A product traceability system shall consider the processing condition of allergen-containing products and the use of ingredients, <u>semi-finished products</u>, <u>materials to be reworked supplements</u>, and food additives. Records shall be maintained to ensure traceability.
- 2.9 Ingredients, semi-finished products, <u>materials to be reworked rework products</u>, and finished products containing allergens shall be clearly labeled and segregated to prevent crosscontact. Records shall be maintained to ensure traceability.
- 2.10 When performing an audit in the supplier's premises, a food factory shall verify its allergen management procedures and request suppliers to notify the food factory of any formula change.
- 2.11 At least one allergen-related training course shall be arranged for workers to clearly understand management procedures and implementation methods of allergen management.

3 Food Defense Management

A food factory shall refer to the risk assessment principles to establish, implement, and maintain a scientific basis Food Defense Management Plan, documented processes relating to food defense management on a scientific basis, which including the methods such as analysis of the critical control points for the vulnerabilities in threats on food production safety. Such documented processes The food defense management plan shall be established based on the food safety management system, and the food factory shall list the risks relating to of food defense to



minimize or eliminate all identified hazards. Besides, the food defense management plan shall be regularly reviewed to maintain the operation. A system to minimize or eliminate all identified hazards shall be established, and a food defense plan shall be established and implemented to implement and verify food defense periodically.

- 3.1 Vulnerability Assessment includes identifying the vulnerabilities prone to assault of attack in all food categories, production and processing processes, packaging and storage methods, and establishing and enforcing defensive measures.
- 3.2 Vulnerability Assessment covers willful public health hazards, such as the threat of terrorist operations; the willful attack of discontented employees/food factories/competitors; and the possibility of internal attack and non-economically motivated adulteration. Mitigation strategies shall be established for vulnerabilities to ensure the food defense system is appropriate to reduce or prevent loopholes, including necessary descriptions.
- 3.3 The items, methods, frequency, and handlers of vulnerability monitoring in a mitigation strategy shall be defined to ensure the mitigation strategy is effectively implemented.
- 3.4 Corrective Actions to compensate for the inadequacy of the mitigation strategy shall be established to ensure the cause(s) of deviation is(are) corrected.
- 3.5 Documented processes for tracking and verifying a food defense plan, vulnerability mitigation strategy, and the progress of corrective actions shall be established. Records of monitoring and corrective actions shall be reviewed periodically to ensure that corrective actions are effectively implemented.
- 3.6 A food defense plan shall be recorded by the executor and signed for approval and dated by a responsible person. All related documents shall be retained for at least five years.
- 3.7 A food defense plan shall be reviewed and analyzed at least every year with respect to the change in external defense (e.g. factory and peripheral buildings and vehicle access), internal defense (e.g. facility, public facility and laboratory of the factory, and production automation systems), logistics and warehousing, suspicious and dangerous items, chemicals, and personnel. If a food defense plan can't be implemented, corrective action methods must be determined.
- 3.8 Food defense training courses shall be arranged periodically to ensure that handlers clearly understand the food defense management plan and its implementation.

4 Food Fraud Management

- 4.1 A food factory shall uphold integrity to establish an internal management regulations based on the food safety management system to prevent deliberate or unintentional food frauds.
- 4.2 Food frauds include adulteration, counterfeiting, dilution, false labeling, use of ingredients from an unknown source, and making untrue or misleading label and claims of products to obtain economic benefits.
- 4.3 A food fraud prevention plan shall be established, including the identification of products within the scope of certification, production, and processing processes, packaging and storage methods, to analyze potential vulnerabilities of food fraud and implement the prevention plan.



- 4.4 The supply chain shall be audited periodically to ensure the ingredients and packaging materials from suppliers are trusted.
- 4.5 The food fraud prevention plan shall be reviewed and analyzed every year, and documented operating procedures shall be in place to facilitate validation and traceability.



Chapter 6 Food Quality Management Specifications

In addition to conforming to the specifications of TQF level 1 certification, a food factory applying for TQF level 2 certification shall comply with the requirements relating to food quality management under these specifications. When applying for the TQF level 2 certification, a food factory shall establish an Integrated Quality Program (IQP) to further establish a quality management system in order to ensure that the customer requirements and regulatory requirements for product quality are met and in accordance with the "TQF Certification Scheme—Specifications and Standards for Product Inspection Items" (TQF-PCS-101~127, 199). A food factory will establish its own quality and testing specifications and standards, and the production of certified products shall comply with such specification and standards.

1 Principles of IQP Management

- 1.1 Senior executives shall make commitments to provide valid resources to fulfill IQP operation.
- 1.2 Define quality management responsibilities.
- 1.3 Establish a "Plan-Do-Check-Action" management model to make continual corrective action and prevent nonconformities through effective system operation.
- 1.4 A food factory should shall establish quality specification of a product which meets the customers' and retailers' satisfaction. According to the product's characteristics, taking the belonged "TQF Specifications and Standards for Product Test Items" (TQF-PCS-101~127, 199) into consideration when establishing the specification. When the testing item is the same as listed in the TQF specification, the standard cannot lower than TQF specification, CNS and related regulations. If the aforementioned cannot be met due to certain specific specification, the food factory shall provide the relevant information to the certification body, without causing any food safety concern, the certification body shall make a professional decision.
- 1.5 Identify the control requirements for quality specifications, analyze the critical control points, establish control methods and adopt appropriate measures, and implement progressive monitoring and prevention through process and system management to produce products in conformity with the quality specifications.
- 1.6 Inspect and verify product quality specifications with respect to the established inspection methods or methods specified by distributors and customers. Only qualified products shall be shipped.

2 Key IQP Elements for implementation

- 2.1 The food factory shall have a food quality policy signed and announced by the senior executives and shall be regularly reviewed to ensure the establishment, implementation, maintenance and continuous improvement of IQP.
- 2.2 Take customers and suppliers requirements for product quality, in accordance with the quality specifications in the "TQF Specifications and Standards for Product Test Items" (TQF-PCS-101~127, 199), the "Chinese National Standard" (CNS), related government regulation, standard or other international quality standards, trade standards, and other



- supporting documents to define a product quality standard.
- 2.3 The scope of IQP implementation shall cover any roles relating to the sources of ingredients and packaging materials of products; regional characteristics (environmental impacts and characteristics of the place of origin) factory site (multi-site, specific site); product category; and outsourcing contractors.
 - 2.4 Under IQP, a food factory shall analyze the critical control points affecting quality specifications with reference to the <u>Codex Alimentarius Commission's CODEX's</u> HACCP principles. These critical control points may include the management of ingredients and packaging materials, process control, resource ability, technology, packaging, storage, or transportation. IQP can be integrated with or independent from the food safety control system, provided that the quality threats and their critical control points shall be identified separately.
 - 2.4.1 Units responsible for the management of ingredients and packaging materials, production and manufacture, and storage and transportation shall establish and implement relevant procedures, and records shall be maintained to achieve the quality objectives.
 - 2.4.2 Committees promoting the TQF system shall establish fair objectives for the validation of ingredients and packaging materials, processing, manufacture, packaging, storage, and transportation; review the quality monitoring control points of each responsible unit; and manage the status of implementation to ensure that the overall quality objectives are achieved.

2.5 Product quality control

- 2.5.1 Quality specifications, sampling criteria, testing items, standards, and methods for certification products shall be established in conformity with the Act Governing Food Safety and Sanitation and refer to the "TQF Specifications and Standards for Product Test Items" (TQF-PCS-101~127, 199).
- 2.5.2 Product shall be inspected and analyzed based on the quality specifications before shipping, such as sensory evaluation performed by a trained staff in accordance with the established methods or the distributor requirements.
- 2.5.3 Supporting details shall be submitted for products claimed as organic foods, Kosher, Halal, or conforming to other certification specifications.



Addendum 1. Glossary

Term	Definition					
Certification scheme	Documents related to the requirements, systems, specifications, regulations, marks, and the intellectual property rights of marks; and references that shall be followed by accreditation bodies, certification bodies, and suppliers.					
Food factory	Responsible for proving to certification bodies that the certification requirements are met, including the product requirements. Unless otherwise stated, where the term "food factory" is used in this scheme, which also means "applicant". Factories refer to the actual place of production.					
ISO/IEC 17065:2012	The ISO / IEC17065 is a standard for Conformity assessment — Requirements for bodies certifying products, processes and services issued by ISO / CASCO in September 2012. The implementation of products, processes and services, certification body shall comply with its regulated quality control requirements and the structure of the products' certification body.					
Annual Surveillance Audit	Annual surveillance audit is the unannounced Refers to the audit conducted by certification bodies at least twice a year for the compliance of production system and products, which includes annual on-site audit, annual on-site sampling (for level II only) and post market sampling. The annual surveillance audit is implemented without announcement (irregularly implemented without prior notice to a food factory).					
Food Good Manufacturing Practices (FGMP)	In 1989, the Industrial Development Bureau of the Ministry of Economic Affairs set forth an voluntary management system for the quality, hygiene and safety of food in the manufacturing process.					
The Regulations on Good Hygienic Practices for Food (GHP)	Based on the Ministry of Health and Welfare regarding the Food Safety					
Regulation on Food Safety Control System	Based on the Food Safety and Health Administration Law by the Ministry of Health and Welfare, refers to a system for the identification, assessment and control of food safety hazards, the application of the principle of critical points of hazard analysis and the acceptance, processing, manufacture, storage and transportation of raw materials and ingredients.					
Codex Alimentarius Commission	Codex Alimentarius Commission was established by Food and Agriculture Organization and World Health Organization, is an organization that set food standards in aiming to protect the health of consumers and the fairness of international food trade.					
Hazard Analysis and Critical Control Points (HACCP)	Hazard Analysis Critical Control Point (HACCP) system is based on an appendix of CAC/RCP 1 -1969 (revised 4-2003)					



Term	Definition			
Food Safety Modernization Act (FSMA)	On January 4 th , 2011 by President Obama signed the entry to start.			
Integrated Quality Program (IQP)	Established from the requirements of food factories, distributors and consumer regarding product quality features, according to the raw materials, semi-finished products, product specifications and related manufacturing operations standards, as for the food factory to verify the quality of products and specifications.			
Certification Body	A public or private entity which has entered into a license agreement with the TQFA authorizing it to certify its supplier's TQF System in accordance with the ISO/IEC 17065 and general requirements.			
Certification scope	Refers to the production field with the same certificated category under the food factory registration scope which client applied for certification. The scope of certification in this scheme refers to certification to be carried out on the production lines of same categorised products within the scope of registration of the factory applied for certification by the suppliers. Production management within the scope of certification shall meet the system requirements specified in this scheme. For use of TQF mark on 83 abelling of products within the scope of certification shall meet the product requirements specified in this scheme.			
Certified production	Refers to the number which is issued after the production system pass the			
system number	TQF certification, also called production line number.			
Certified product mark	Refers to the number which is produced after the product pass the TQF			
<u>number</u>	certification, also called product number.			
Same categorised product	A food factory meets the production system requirements that set in this scheme, the products that produced under the same certification scope, but does not apply for the TQF certification mark.			
Certified product When the food factory complies to the certification requirements scheme regarding system, food product safety and quality, the prallowed to use TQF certification mark.				

Term				
	The on-site evaluation and audit conducted, including initial on-site audit, annual on-site audit and nonconformity on-site audit for food factory by the certification body.			
	1. Initial on-site audit: refers to when a food factory applies for TQF certification, the first on-site audit conducted by a certification body. It is an announced on-site audit.			
On-site audit	2. Annual on-site audit: refers to unannounced on-site audits conducted by a certification body during the certification period for certified food factory.			
	3. Nonconformity on-site audit: is a part of annual surveillance auidts, when there are three nine or more points of the sum of "major nonconformities" in accumulation in an annual on-site audit, a certification body shall conduct an on-site audit focusing on the nonconformities.			
Post market sampling	To ensure the hygiene and safety of the products, and that its quality meets the certification requirements. A random sampling of products on the market will be tested.			
National standard	Chinese National Standards; CNS.			
Scheme owner	An organization, which is responsible for the development, management and maintenance of a specific certification scheme. TQF scheme is owned by the Taiwan Quality Food Association.			
International Accreditation Forum (IAF)	Established by the American National Standards Institute (ANSI) and the United States Registry Accreditation Board (RAB) to ensure an effective mutual recognition internationally by recognizing accreditation bodies and other conformity assessment agencies.			
International Mutual Recognition Agreement International Mutual Recognition Agreement International Accreditation Forum and together with the International Mutual and conformity assessment throughout the world to promote recognition agreement between the accreditation bodies signed upon IAF MLA.				
Taiwan Accreditation Foundation	Representing the Republic of China (Taiwan) in the IAF and have signed the IAF MLA, promoting international certification in various fields of certification bodies, testing agencies and laboratories in the country to establish its quality and technical evaluation standards to ensure that the certification operation complies with international Specification ISO / IEC 17011 requirements.			



Term	Definition		
	An objective existence. Objectivity is understood and means that a conflict		
	of interest does not exist or has been resolved. It does not have an adverse		
T., 4 4	impact on the activities of the entity. The other nouns that can help to		
Integrity	express this key elements includes: fairness independent, free from conflict		
	of interest, without prejudices, unbiased, neutral, fair, open and impartial,		
	independent and balanced.		
D ' C '1 11	Production of animal products, including dairy products (04.dairy		
Processing of perishable	products) and others (14.processed seafood, 15.frozen foods, 18.processed		
animal products	meat products, 19.chilled prepared foods).		
	Production of plant products, including beverages (01.baverages), gains		
Processing of perishable	and grain processed products (02.baked foods, 08.noodles), and others		
vegetal products	(12.preserved fruits and vegetables, 13.processed soybean products,		
	15.frozen foods, 19.chilled prepared foods).		
	Production of animal and plant products, including beverages,		
Processing of perishable	fermentation and brewing products (01. beverages, 17.spices and		
animal and vegetal	condiments), gains and grain processed products (02.baked foods,		
products	08.noodles), dairy products (04.dairy products, 07.ice and novelties), and		
(mixed products)	others (10.ready to eat meals, 15.frozen foods, 19.chilled prepared foods).		
	Production of any products stored and sold at ambient temperature,		
	including beverages and fermentation and brewing products (01.beverages,		
	06.soy sauce, 11.MSG, 17.spices & condiments, 25.alcohol & liquor) gain		
	and grain processed products (02.baked foods, 08.noodles,		
	09.confectionary, 22.flour, 23.refined sugar, 24 starch sugar), oils and fat		
Processing of ambient	(03.edible oils), dairy products (04.dairy products, 05.powdered infant		
stable products	formula), canning and thermal-processed products (12.preserved fruits and		
	vegetables, 16.canned foods), dried products and others (13.processed		
	soybean products, 14.processed seafood 18.processed meat products,		
	20.dehydrated foods, 21.tea leaf, 26.functional food, 27.food additives,		
	food in general).		
	The products manufactured and processed belong to the Groups of Section		
	C Manufacturing of the "Standard Industrial Classification System of the		
Main product	Republic of China" compiled by the Directorate General of Budget,		
	Accounting and Statistics, Executive Yuan, R.O.C		
	The combination of the selection and determination of a conformity		
Assessment	assessment activity, the selection and determination process are described		
7 KSSCSSITICITE	in clause A.2 and clause A.3 of the ISO / IEC 17000: 2004.		
Critical Control Points It refers to a point, step, or procedure which control can be app			
(CCP)	prevent, eliminate or reduce a food safety hazard to an acceptable level.		
On-site audit working	Formed by one auditor or more auditors implementing on-site audit,		
group	including support technical experts, where necessary.		
Auditor	A person working for a licensed certification body to audit a food factory.		
Addition A person working for a needsed certification body to addit a food factory.			



Term	Definition		
NA 141 14 C 4	The same food factory applying for a scope of certification, where the		
Multi-site factory	production line is located in different plant.		
	The lead auditor assigned to implement on-site audit. Work items include		
0	kick-off meeting, facility audit, desk audit, internal discussion, assessment		
On-site audit leader	conclusions, preparation of the on-site assessment report, and submission		
	of the report to the certification body.		
Process and quality	The steps taken in all stages of the process including receiving,		
control plan	manufacturing, shipping and periodic testing are described in detail to		
(QC flowchart)	ensure that outputs are under control at all stages of the process.		
	It refers to the completely non-execution of an evaluation item in the on-		
Major Non conformity	site audit checklist, and this is highly likely to cause immediate hazards or		
Major Non-conformity	and risk on food safety or quality. The audit fails when there are three or		
	more "major nonconformity" in accumulated in an on-site audit.		
	It refers to the partial non-execution of an evaluation item in the on-site		
Minor Non conformity	audit checklist, and this is less likely to cause food safety hazards or quality		
Minor Non-conformity	problems immediately. The score of three "minor nonconformity" equals		
	to one "major nonconformity."		
	Significant hazards on consumers after consumption; adulterated or		
	counterfeited products; provision of false documents or records		
Anomaly	(documented information), risk of food safety offence the government		
	regulations to an extent that meet the recall standard or rules of the		
	government agency.		
Certification system	Conformity assessment system related to documented requirements,		
Certification system	specifications and procedures.		
	Refers to the basic conditions and activities necessary to maintain a		
Pre-requisite Program	hygienic environment throughout the food supply chain and is applicable		
(PRP)	to the production, handling and provision of safe finished products and safe		
	food for human consumption.		
	Using hazard analysis to identify prerequisite programs (PRPs), based on		
Operating Pre-requisite	the principle of controlling the likelihood of food safety hazards being		
Program (OPRP)	introduced and / or controlling the contamination or spread of food safety		
	hazards in the product or processing environment.		
	It refers to the non-execution of a small part of an evaluation item in the		
Opportunity for	on-site audit checklist; The non-executed part will not cause food safety		
improvement	hazards or quality problems, but can be the improvement for site. No mark		
	will be deducted for opportunities for improvement.		
Re-evaluation	An additional on-site evaluation for food factory who fails the initial on-		
TC Cvariation	site audit.		
Re-testing	An additional product testing for failing to meet the product specification		



Term	Definition
	The following situations occur during the certification period are taken as special food safety incidents:
Special food safety	1. The production system or product is regarded to be an anomaly by a certification body.
incident	2. The production system or product has food safety concerns and is subjected to inspection required to remove the product from the shelf by the health authorities.
Termination Withdraw	In the case of the below situations, a certification body may terminate a food factory's certification qualification and shall change the site's certification status to termination on TQF-ICT platform with the reason and the effective date: 1. The certification qualification has been suspended by a certification body, and the food factory fails to make corrections within the given timeframe. 2. In violate of relevant laws and regulations, with an intentional conduct of malicious falsehood or other serious food safety event. The terminated food factory shall return its contract and certificate to the certification body from the effective date of the termination, and shall not use cease the usage of the TQF certification mark on its products immediately, which the products manufactured prior to the termination are
Re-assessment Re-ass	

Term	Definition			
	1. In the case of the below situations, a certification body MAY suspend a food factory's certification qualification:			
	(1) When there are three nine or more points of the sum of "major nonconformities" in accumulation in an annual on-site audit;			
	(2) Failing to pay the TQF certification mark annual fee within the required time;			
	(3) Other violations of TQF Scheme requirements.			
Suspension	2. In case of the below situations, a certification body SHALL suspend a food factory's certification qualification:			
	(1) An anomaly happens in the production system or products. The certification certificate shall become temporarily invalidated during a suspension, the <u>usage of TQF</u> certification mark <u>shall be ceased</u>			
	immediately, which the products manufactured prior to the suspension are not limited by this regulation. is no longer allowed to be used on products. Certification body shall change the site's certification status to suspension on the TOE ICT pletform with the reason and the effective data.			
	on the TQF-ICT platform with the reason and the effective date. Activities other than monitoring, that determine the validity of the HACCP			
Verification	plan and that the system is operating according to the plan, to confirm its			
	effectiveness.			
	A food factory voluntarily withdraws its certification qualification, shall			
Withdrawal	return its contract and certification certificate to a certification body. The			
withdrawar	certification mark is no longer allowed to be used from the effective date. The certification body shall change the certification status to withdrawal on the TQF-ICT platform.			
Strict vegetarian food	It refers to food product based on vegetables without any egg or dairy products and the allium family (namely, onion, garlic, scallions, leeks,			
	chives, or shallots). This includes ovo-vegetarian, lactovegetarian, ovo-lactovegetarian and vegan food.			
	1. Ovo-vegetarian: it refers to strict vegetarian food and egg products.			
Vegetarian Food	2. Lactovegetarian: it refers to strict vegetarian food and dairy products.			
	3. Ovo-lactovegetarian: it refers to strict vegetarian food, egg products and dairy products.			
	4. Vegan food: it refers to food with vegetables only.			
	it refers to non-vegetarian foods made from sacrificed animals or added			
Non-Vegetarian Food	with animal ingredients during the manufacturing process, except ovovegetarian, lactovegetarian, ovo-lactovegetarian.			



Term	Definition		
	The process of collecting and evaluating information on hazards associated		
Hazard analysis	with the food under consideration to decide which are significant and must		
	be addressed in the HACCP plan.		
	That element of confirmation focused on collecting and evaluating		
Validation	scientific and technical information to determine if the HACCP plan, when		
	properly implemented, will effectively control the hazards.		
Cantal Line	Any action or activity that can be used to prevent, eliminate or reduce a		
Control Limits	significant biological, chemical, or physical hazard.		
Cama atian	Action to eliminate the cause of a detected non-conformity or other		
Corrective	undesirable situation when non-compliance regarding food safety and		
Action	quality is found during production.		
	The TQF-certified products shall be a packaged food. Apart from		
	complying with the provisions specified in relevant food safety and		
Product Requirement	sanitation laws and regulations, TQF-certified products should shall also		
	meet the "Specifications and Standards of the Testing Items of TQF		
	Certification Scheme" for respective food categories.		
	The steps that the food factory took to trace the source of product supply		
T. 1.11.	or track the flow of products through labeling in all aspects of the food and		
Traceability	related product supply process, including establishing its information and		
	management measures.		
	As defined by the U.S. Food and Drug Administration (FDA), food defense		
F 116	is the protection against intentional contamination of food by biological,		
Food defence	physical, chemical or radiation hazards and is unlikely to be reasonably		
	occurred in the food supply.		
	Food fraud is the deliberate and intentional substitution, addition,		
	tampering or misrepresentation of food, food ingredients or food		
Food fraud	packaging, labelling, product information or false or misleading statements		
	made about a product for economic gain that could impact consumer		
	health.		
T	Verification of the compliance with the control point compliance criteria		
Inspection	(CPCC) at production site level.		
37.1 1.11.	Identifying the vulnerabilities prone to assault of attack in all food		
Vulnerability	categories, production and processing processes, packaging and storage		
assessment	methods, and establishing and enforcing defensive measures.		
Mitigation			
strategy implementing an action plan.			
	The process of collecting and evaluating information on quality hazards		
O1'4- A 1 ' 1	associated with the food under consideration to decide which control point		
Quality Analysis and	have significant impact on the product along the production chain,		
Critical Control Point	including raw material management, operation control, resource capability,		
(QACCP)	technology, packaging, storage or transport. Mainly to prevent, eliminate		
	or reduce a food quality hazard to an acceptable level.		



Term	Definition			
	Refers to the market concerned testing items that are not regulated by the "Specifications and Standards of the Testing Items of TQF Certification			
Concerned items	Scheme" and sampled by the certification body for inspection depends on the situation when the concern about safety or violation of regulations occur.			



Addendum 2. Taiwan Quality Food Certification Scheme Food Sector Categories

1 The 28 Categories of Products in Taiwan Quality Food Certification Scheme

The scope of Taiwan Quality Food Certification Scheme (hereinafter referred to as "TQF Scheme") covers the specifications established with food safety fundamentals (Chapter 4 of TQF Scheme), food safety management (Chapter 5 of TQF Scheme), and food quality management (Chapter 6 of TQF Scheme). This is based on the requirements for the manufacturing, processing, and logistic processed of food for human consumption (including food ingredients and food additives). Therefore, as mentioned in the food safety fundamentals in Chapter 4 of TQF Scheme, specific technical specifications of TQF Scheme 28 food sector categories (from No. 1 to 27 and 99) are established separately. The 28 food sector categories of TQF Scheme is tabulated below:

01. Beverages	02. Baked foods	03. Edible oils	04. Dairy products	05. Powdered infant formula	06. Soy sauce
07. Ice & novelties	08. Noodles	09. Confectionary	10. Ready to eat meals	11. MSG	12. Preserved fruits and vegetables
13. Processed soybean products	14. Processed seafood	15. Frozen foods	16. Canned foods	17. Spices & condiments	18. Processed meat products
19. Chilled prepared foods	20. Dehydrated foods	21. Tea leaf	22. Flour	23. Refined sugar	24. Starch sugar
25. Alcohol & liquor	26. Functional food	27. Food additives	99. Foods in general		

2 The list of GFSI scope covered by TQF Scheme food sector categories

Based on product properties, the TQF Scheme has covered the manufacturing of processed food defined by GFSI Scope as follows:

ECI. Processing of perishable animal products

ECII. Processing of perishable vegetal products

ECIII. Processing of perishable animal and vegetal products (mixed products)

ECIV. Processing of ambient stable products



3 The Table of TQF Scheme Food Sector Categories

GFSI Scope	Audit Field	TQF Scheme Food Sector Categories		
E CI. Processing of	Dairy products	04. Dairy products		
perishable animal products	Others	14. Processed seafood, 15. Frozen foods, 18. Processed meat products,19. Chilled prepared foods		
E CII. Processing of	Beverages	01. Beverages		
perishable vegetal	Grains and grain processed products	02. Baked foods, 08. Noodles		
products	Others	12. Preserved fruits and vegetables, 13. Processed soybean products, 15. Frozen foods, 19. Chilled prepared foods		
ECIII. Processing of perishable animal	Beverages, fermentation and brewing products	01. Beverages, 17. Spices & condiments		
and vegetal	Grains and grain processed products	02. Baked foods, 08. Noodles		
products (mixed	Dairy products	04. Dairy products, 07. Ice & novelties		
products)	Others	10. Ready to eat meals, 15. Frozen foods, 19. Chilled prepared foods		
E CIV. Processing of ambient stable	Beverages, fermentation and brewing products	01. Beverages, 06. Soy sauce, 11. MSG, 17. Spices & condiments, 25. Alcohol & liquor		
products	Continue and audit and and hards	02. Baked foods, 08. Noodles, 09. Confectionary, 22. Flour, 23. Refined sugar,		
	Grains and grain processed products	24. Starch sugar		
	Oils and fats	03. Edible oils		
	Dairy products	04. Dairy products, 05. Powdered infant formula		
	Canning and thermal-processed products*	12. Preserved fruits and vegetables, 16. Canned foods		
		13. Processed soybean products, 14. Processed seafood, 18. Processed meat products,		
	Dried products and others	20. Dehydrated foods, 21. Tea leaf, 26. Functional food, 27. Food additives,		
		99. Foods in general		

^{*}Auditors performing the audit field of "Canning and thermal-processed products" shall comply with the competency requirement of thermal-processing technology through canning foods.



4 The Description and Example Table of TQF Scheme 28 Food Sector Categories

GFSI Scope	Audit Field	TQF Scheme Food Sector Categories	Description	Example of Products
ECI. Processing of perishable animal	Dairy products	04. Dairy products	Applies to the processing, transport and storage of refrigerated or frozen dairy products which are primarily based on milk of cows or other animals and may be supplemented with appropriate additives. This product shall be treated with appropriate method before human consumption.	Refrigerated or frozen flavored milk, fermented milk, pudding, cheese, panna cotta, etc.
products		14.Processed seafood	Applies to the processing, transport and storage of refrigerated or frozen surimi seafood products with fish or other aquatic meats as the main ingredient prepared by mincing with salt, mixing with sugar, starch, and quality improvement agents; then molding and heating to coagulate protein, and rapid cooling or freezing and packaging appropriately.	Refrigerated or frozen surimi seafood products such as surimi (e.g. fish mice), fish ball, fish cake (e.g. kamaboko), imitated products (e.g. imitation crab meat, imitation scallops), tian bu la, tempura, squid ball, etc.
	Others	15. Frozen foods	 Applies to the processing, transport and storage of frozen poultry, meat, seafood or prepared food with one or more types of poultry, meat, aquatic as main ingredient prepared by appropriately processing, quickly freezing, properly packaging, and transported and sold at -18°C or below. Frozen poultry and/or meat food: products with poultry and/or meat as main ingredient which was prepared by cleaning, grading, trimming, and cutting before quick freezing and properly packaging, transported and sold at -18°C or below. Frozen seafood products: products with aquatic products as main ingredient which is prepared by cleaning, shucking, gutting, sorting, trimming, or heating before quick freezing and properly packaging, transported and sold at -18°C or below. Frozen prepared foods: products with aquatic, poultry and/or meat 	Frozen Poultry or meat foods seafood products Prepared foods: frozen dishes, combo dishes, frozen mixed foods (e.g. pizza, dim sum, dumpling), etc.

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			processing and preparations; and is ready to eat after simple	
			processing or heating.	
		18. Processed meat products	 Applies to the processing, transport and storage of refrigerated or frozen processed meat and/or poultry products. Cured meat products: products with poultry and/or meat as main ingredient which was prepared by deboning (optional), trimming, curing, filling in casing, stretchable films or molds (optional), or smoking cooked (optional) before packaging appropriately. Emulsion-type meat products: products with poultry and/or meat as main ingredient which was prepared by mince (emulsion), forming, smoking (optional), and cooking before packaging appropriately. 	 Refrigerated or frozen Cured meat products: Chinese and Western sausages, ham, bacon, etc. Emulsion-type meat products: meat ball, hotdog, etc.
		19. Chilled prepared foods	Applies to the processing, transport and storage of refrigerated prepared foods with one or more types of aquatic product, poultry, and/or meat as main ingredient processed and prepared before appropriately packaging and storing between freezing point and 7°C. This product is ready to eat with or without simple processing or heating.	Refrigerated side dishes, dishes, soup, snacks or combo dishes, etc.
ECII. Processing of perishable vegetal products	Beverages	01. Beverages	Applies to the processing, transportation and storage of refrigerated packaged beverages made by fresh fruit, vegetable and those reconstituted juice, tea and its extracted beverage or coffee beverage, etc. which are sealed and filled in can, bottle, carton or other containers and can be drunk after dilution or directly.	 Non-carbonated beverages: general beverages, fruit and vegetable juice/beverages and those reconstituted juice/beverages, tea beverages, coffee beverages, beverages with vegetable protein other than soybean (e.g. coconut milk, grain milk, rice milk, peanut milk, almond milk, oat milk), vinegar based beverages, etc. Other beverage with less than 0.5% alcohol

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Grains and		Applies to the processing, transport and storage of refrigerated or frozen extruded breads, cakes and deserts with mixed vegetable formula.	
	02. Baked foods	 Bread: products obtained from mixing, blending, and fermenting of major ingredients and forming or wrapping with special auxiliary ingredients to make into the required shape for proofing, leavening, baking, cooling, and packaging. 	Refrigerated or frozen bread, cake, Western pastries, etc.
grain processed products		 Cake: products obtain from mixing and blending various ingredients before baking, shaping, cooling, decorating, and packaging. 	
		 Western pastries: Western non-staple flour-made snacks usually without fermentation. 	
	08. Noodles	Applies to the processing, transport and storage of refrigerated or frozen noodles which is made by flour as main ingredient mixing with water.	Refrigerated or frozen high water activity flour noodles and bean/rice noodles such as uncooked fresh noodles, alkalinized yellow noodles, Udon, flat dough
	12. Preserved fruits and vegetables	Applies to the processing, transport and storage of refrigerated or frozen preserved fruits and vegetables which is made by fruits or vegetables, based on its variety, with the preservation of curing with salt, organic acid and/or sugar, or by direct seasoning, fermentation, or ageing process.	Refrigerated or frozen salted fruits and vegetables, pickled fruits and vegetables, sugaring preservation fruits and vegetables (applies to soluble solids below 60°Brix), preserved fruits, kimchi, etc.
Others	13. Processed soybean products	 Applies to the processing, transport and storage of refrigerated or frozen products: Soymilk, formulated soymilk, soybean-based beverages which is a milky beverage processed with soybean or soy protein as main ingredient, and when necessary, supplemented with nutritional additives and flavorings. Soybean curd/tofu: products made from soymilk preparation and coagulated by adding coagulant. 	 Refrigerated or frozen UHT soymilk, formulated soymilk, soybean-based beverages, etc. Soybean curd/tofu: soft tofu/ silken tofu, firm tofu, frozen dried tofu, packaged tofu, etc. Soybean pudding

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			 Soybean pudding: products made from soymilk preparation and coagulated by adding coagulant. Compressed soybean curd/dried tofu/dried bean curd: products 	 Compressed soybean curd/dried tofu/dried bean curd Fried tofu
			made from soymilk preparation and coagulated by adding coagulant, and have been moulded and pressed for a harder texture and dried afterward.	
			Fried tofu: bean curd prepared by deep frying.	
			Applies to the processing, transport and storage of frozen agricultural or prepared food with one or more types of agricultural product as main ingredient prepared by appropriately processing, quickly freezing, properly packaging, and transported and sold at -18°C or below.	Frozen
		15. Frozen foods	 Frozen agricultural foods: products with agricultural products as main ingredient prepared by cleaning, sorting, trimming or blanching before quick freezing and properly packaging, transported and sold at -18°C or below. 	 Agricultural foods Prepared foods: frozen dishes, combo dishes, frozen dough, frozen noodles/pasta, frozen bean/rice noodles, frozen mixed foods, etc.
			 Frozen prepared foods: products with one or more types of agricultural product as main ingredient which is prepared after appropriate processing and preparations; and is ready to eat after simple processing or heating. 	noodies, irozen mixed ioods, etc.
		19. Chilled prepared foods	Applies to the processing, transport and storage of refrigerated prepared foods with one or more types of agricultural product as main ingredient processed and prepared before appropriately packaging and storing between freezing point and 7°C. This product is ready to eat with or without simple processing or heating.	Refrigerated side dishes, dishes, soup, snacks or combo dishes, etc.
ECIII. Processing of perishable	Beverages, fermentation and brewing products	01. Beverages	Applies to the processing, transport and storage of refrigerated packaged beverages which are sealed and filled in can, bottle, carton or other containers and can be drunk after dilution or directly.	Refrigerated Non-carbonated beverages: general beverages, beverages containing milk below 50% or acidic beverages, etc.

animal and				• Other beverage with less than 0.5%
vegetal				alcohol
products (mixed products)		17. Spices & condiments	Applies to the processing, transport and storage of refrigerated or frozen spices and condiments sauces which are primarily made with agricultural, poultry, meat, or aquatic products or their processed products and with other ingredients by function or by characteristics through fermentation or blending.	Refrigerated or frozen thin sauces, thick sauces, particle-containing sauces, dips, dressings, etc.
	Grains and grain processed products	02. Baked foods	 Applies to the processing, transport and storage of refrigerated or frozen extruded breads, cakes and deserts with mix formulations of animal and vegetable formula. Bread: products obtained from mixing, blending, and fermenting of major ingredients and forming or wrapping with special auxiliary ingredients to make into the required shape for proofing, leavening, baking, cooling, and packaging. Cake: products obtain from mixing and blending various ingredients before baking, shaping, cooling, decorating, and packaging. Western pastries: Western non-staple flour-made snacks usually without fermentation. 	Refrigerated or frozen breads, cakes, Western pastries, meat pies, etc.
		08. Noodles	Applies to the processing, transport and storage of refrigerated or frozen products which are consisted of noodles as the main course and adding with animal or vegetable ingredients, and/or adding food suggestions as appropriate.	Refrigerated or frozen prepared noodles containing animal or vegetable ingredients
	Dairy products	04. Dairy products	Applies to the processing, transport and storage of refrigerated or frozen dairy product which is primarily based on milk of cows or other animals and other vegetable ingredient. This product may be supplemented with appropriate additives and shall be treated with appropriate method before human consumption.	Refrigerated or frozen flavored milk, fermented milk, other dairy product, beverages containing milk above 50%, etc.
		07. Ice & novelties	Applies to the processing, transport and storage of frozen product which is made with milk, milk product or drinking water as main ingredient and the addition of sugar and other ingredients and/or food	Frozen ice cream, soft ice cream, sherbet, ice cream bars, popsicles, edible ice cubes, etc.

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		additives with the appropriately freezing process for human consumption.	
		• Ice cream: a frozen food which is solidified and made from a liquid mixture by milk or milk product as main ingredient and the addition of sugar and food additives (e.g. emulsifiers, stabilizers and flavors).	
		 Popsicles: a frozen food which is solidified and made from a liquid mixture by drinking water, sugar and food additives (e.g. emulsifiers, stabilizers and flavors). 	
		 Edible ice cubes: a frozen and solidified drinking water made from cube mold. 	
		Foods prepared form instant consumption by a group and packaged in boxes or transported directly in bulk-packed containers.	
		 Boxed foods: foods prepared as a main meal with rice or noodles as the staple food and assembled with entrees prepared from agricultural, poultry, meat, aquatic products and is appropriately packed in boxes or small packages for storage and consumption within a short period time. 	
Others	10. Ready to eat meals	 Institutional food service foods: foods prepared with rice as the staple food and assembled with entrees prepared from agricultural, poultry, meat, aquatic products and without being packed in boxes or small packages but directly transported in bulk-packed containers for immediately consumption within a short period time. 	Boxed foods, institutional food service foods, cooked entrees, etc.
		 Cooked entrees: food prepared with agricultural, poultry, meat, and aquatic products (excluding rice or other staple foods) and appropriately packed in boxes or small packages for a short storage and immediately consumption within a short period time. 	
	15. Frozen foods	Applies to the processing, transport and storage of frozen agricultural, poultry, meat, seafood or prepared food with one or more types of agricultural, poultry, meat, aquatic as main ingredient prepared by	Frozen prepared foods such as frozen dishes, combo dishes, frozen mixed foods

				 appropriately processing, quickly freezing, properly packaging, and transported and sold at -18°C or below. Frozen prepared foods: products with agricultural, aquatic, poultry and/or mea products as main ingredient which is prepared after appropriate processing and preparations; and is ready to eat after simple processing or heating. 	
			19. Chilled prepared foods	Applies to the processing, transport and storage of refrigerated prepared foods with one or more types of agricultural product, aquatic product, poultry, and/or meat as main ingredient processed and prepared before appropriately packaging and storing between freezing point and 7°C. This product is ready to eat with or without simple processing or heating.	Refrigerated side dishes, dishes, soup, snacks or combo dishes, etc.
o	ECIV. Processing f ambient stable products	Beverages, fermentation and brewing products	01.Beverages	Applies to the processing, transport and storage of shelf stable packaged beverages with the treatment of sterilization, UHT, high temperature or high pressure process (HPP) or other effective methods. This product is sealed and filled in can, bottle, carton or other containers which can be drunk after dilution or directly.	 Shelf stable products: Carbonated beverages Non-carbonated beverages: general beverages, fruit and vegetable juice/beverages and those reconstituted juice/beverages, sport drinks, beverages containing milk below 50% or acidic beverages, beverages with vegetable protein other than soybean (e.g. coconut milk, grain milk, rice milk, peanut milk, almond milk, oat milk), vinegar based beverages, packaged water (including packaged drinking water and mineral water), etc. Other beverage with less than 0.5 % alcohol
			06. Soy sauce	 Applies to the processing, transport and storage of shelf stable Soy sauce: a condiment containing hydrolyzed protein made by traditional fermentation, chemical hydrolysis (non-brewed 	Shelf stable products:

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		 method), or a combination of those two methods. It may be prepared with salt, carbohydrates, alcohol, chemical flavors, and preservatives when necessary. Crude soy sauce: untreated liquid obtained from pressing fermented and aged soy sauce mash. 	 Soy sauce: fermented (brewed) soy sauce, chemical hydrolysis soy sauce and blended soy sauce Crude soy sauce
	11. MSG	Applies to the processing, transport and storage of shelf stable fermented mash, a nonessential amino acid (glutamic acid) and its sodium salt (monosodium glutamate, MSG). These material can be applied as a seasoning agent to enhance flavor.	Shelf stable fermented mash, glutamic acid, monosodium glutamate (MSG)
	17. Spices & condiments	Applies to the processing, transport and storage of shelf stable spices and condiments sauces which are primarily made with agricultural, poultry, meat, or aquatic products or their processed products and with other ingredients by function or by characteristics through fermentation or blending.	Shelf stable products such as thin sauces, thick sauces, particle-containing sauces, dips, dressings, etc.
	25. Alcohol & liquor	 Applies to the processing, transport and storage of shelf stable beverages containing alcohol by volume level above 0.5 %, other natural alcohol for making or blending such beverages, and their products. Brewed wines: alcoholic beverages made with grains, fruits, and other plants containing starch or saccharides through saccharification. Distilled wines: distilled alcoholic beverages made with grains, fruits, and other plants containing starch or saccharides by saccharification (optional) and fermentation. Compound wines: wines, with an extract over 2% alcohol by volume, made by compounding alcohol or distilled wines or brewed wines as the base liquor with animal or plant ingredients, medicinal herbs, minerals, or other food additives. 	 Shelf stable products: Brewed wines: beers, yellow wines, fruit wines, etc. Distilled wines: brandies, whiskies, distilled spirits, rice wine, other spirits (e.g. rum and tafia, gin, vodka and others) Compound wines: liqueur, steeped wines cooking wines others
Grains and grain	02. Baked foods	Applies to the processing, transport and storage of shelf stable extruded breads, cakes, Chinese snakes, Western pastries, biscuits (e.g. cookies), dried deserts and roasted nuts with mix formulations	Shelf stable breads, cakes, Chinese snakes (e.g. Chinese style cakes), Western pastries, biscuits (e.g. cookies),



processed		of animal and vegetable formula. The covered area of this category	dried deserts (e.g. seaweeds, potato
products		can be extended to all bakery operations	chips), roasted nuts, etc.
		 Bread: products obtained from mixing, blending, and fermenting of major ingredients and forming or wrapping with special auxiliary ingredients to make into the required shape for proofing, leavening, baking, cooling, and packaging. 	
		 Cake: products obtain from mixing and blending various ingredients before baking, shaping, cooling, decorating, and packaging. 	
		 Chinese snacks: traditional steamed, cooked, baked, fried, and pan-fried Chinese flour-foods. 	
		 Western pastries: Western non-staple flour-made snacks usually without fermentation. 	
		• Biscuits (cookies): foods obtained from mixing major ingredients with other ingredients (e.g. fats and oils, carbohydrates, dairy products, eggs and other food additives), shaped through fully kneading, baking, drying, cooling, and packaging.	
		 Dried desserts: snacks containing little water content obtained from mixing ingredients, shaping, seasoning, and baking or frying. 	
		• Roasted nuts: all kinds of edible seeds or kernels processed by roasting, frying, and seasoning to change their shape the type and flavors.	
			Shelf stable products:
		Applies to the processing, transport and storage of shelf stable	Instant noodles
	08. Noodles	noodles and bean/rice noodles made by mixing main ingredients (e.g. flour, edible starch, green bean starch or rice) with water and required a dehydration process such as deep fried or drying.	 Dried noodles and bean/rice noodles (Taiwanese fedelini, dried noodles, macaroni, spaghetti, bean noodles and rice noodles etc.)

	09. Confectionary	Applies to the processing, transport and storage of shelf stable sugar confections prepared by mixing, tempering or boiling, molding, and cooling of sugars (edible carbohydrates such as sugar, starch sugar, glucose, and invert sugar) or added with other ingredients such as dairy products, fats, nuts, starch, pectin/gelatin, cocoa powder, seasoning, flavorings, emulsifiers, colorings, and gum base.	Shelf stable hard candy, semi-soft candy, soft candy (jelly), chocolate, chewing gum, and tablet candy, etc.
	22. Flour	Applies to the processing, transport and storage of shelf stable flour, bran, wheat germ, etc. which has been produced with wheat by the process of separated, milled or other methods.	Ambient stable flour bran, wheat germ, etc.
	23. Refined sugar	Applies to the processing, transport and storage of shelf stable sugar which has been refined or processed from raw sugar by melting, purifying, filtering, concentration and/or crystallization, crushing, recrystallization, and forming.	 Shelf stable products: Refined sugar: sugar including refined white sugar, granulated sugar, fine granulated sugar, castor sugar, refined golden sugar (dark and light brown sugar), liquid sugar (clear or colored), ultra-fine granulated sugar, etc. Processed sugar: crystal, rock, powdered, cube sugar, etc.
	24. Starch sugar	Applies to the processing, transport and storage of shelf stable starch sugar which has been produced with starch by melting, liquefication, saccharification, inversion, bleaching, isomerization, separation, desalination, concentration and/or crystallization.	Shelf stable maltose, high fructose corn syrup, glucose, oligosaccharides, etc.
Oils and fats	03. Edible oils	Applies to the processing, transport and storage of shelf stable animal and vegetable oils and fats. The manufacturing of clarifying and refining processes are included.	 Shelf stable products: Margarine Fat spreads Shortening: aquatic animal, animal and vegetable Oils: olive, peanut, corn, vegetable, sunflower, safflower, canola, nut, seed, etc.



			Dregs of fat
	04. Dairy products	Applies to the processing, transport and storage of shelf stable sterilized (retorted) UHT milk of cows or goats, and dairy products with the treatment of high temperature or high pressure processes (HPP).	Shelf stable long-life milk, condensed milk, milk powder, butter, cream, beverages containing milk above 50% and other dairy products, etc.
Dairy products	05. Powdered infant formula	supplemented with appropriate nutrients for the growth and development needs of babies and infants under 12 months of age when necessary.	Shelf stable powdered infant formula
Canning and thermal-	12. Preserved fruits and vegetables	Applies to the processing, transport and storage of shelf stable preserved fruits and vegetables which are primarily made by fruits and vegetables and cured with salt, organic acid and/or sugar by the treatment of direct seasoning, fermentation, or ageing process as preservation methods.	Shelf stable salted fruits and vegetables, pickled fruit and vegetables, sugaring preservation fruits and vegetables (applies to soluble solids below 60°Brix), preserved/candied fruit, kimchi, etc.
thermal- processed products*	16. Canned foods	Applies to the processing, transport and storage of shelf stable canned foods which are sealed in hermetic containers with the treatment of commercial sterilization before and after seaming to ensure long-term storage.	 Shelf stable products: Low-acid canned foods Acidified canned foods Acid canned foods Low water activity canned foods
Dried goods and Others	13. Processed soybean products	 Applies to the processing, transport and storage of shelf stable UHT soy milk, formulated soy milk or soybean-based beverages which are processed with soybeans or soy protein and supplemented with nutritional additives or flavorings when necessary. Seasoned compressed tofu (soybean curds) which is seasoned and partially dried. 	Shelf stable UHT soy milk, formulated soy milk or soybean-based beverages and seasoned compressed tofu, etc.
	14. Processed seafood	Applies to the processing, transport and storage of shelf stable	Ambient stable products:

	 Dehydrated and seasoned seafood products: products with aquatic animals and plants as the main ingredient and prepared with food additives, such as salt, sugar, and quality improvement agents, by means of processing, drying, oven frying, or smoking to reduce its moisture content to an appropriate amount and maintain suitable water activity and packaging appropriately. Pickled seafood products: products with aquatic animals and plants as the main ingredient and prepared by adding salt, sugar or organic acids to reduce water activity and for seasoning and preservation. 	 Dehydrated and seasoned seafood products: dried seafood products, dried and seasoned seafood products, dried raw seafood products, dried seafood products (cooked) Pickled seafood products: salted seafood products, dried and salted seafood products
18. Processed meat	Applies to the processing, transport and storage of shelf stable	Shelf stable seasoning dried meat
products	dehydrated and ready-to-eat meat product.	products such as meat floss, meat jerky
20. Dehydrated foods	Applies to the processing, transport and storage of shelf stable dehydrated foods that the foods are dehydrated by either heating or vacuum hydroextraction to reduce moisture lesser than the safe water activity level. Waterproof packaging shall use appropriately to prevent deterioration by pests, enzymes, and hazardous microorganisms for a period of time when stored at room temperature. Biological, biochemical and chemical changes without affecting food safety and sanitation taking place during moisture removal are allowed, except for modifying the composition of the food ingredient solids with soluble ingredients or additives or for dehydration after extraction or concentration.	Shelf stable dried vegetables, dried fruits, etc.
21. Tea leaf	Applies to the processing, transport and storage of shelf stable dehydrated and processed tea leaves for drinking or as food ingredients.	Shelf stable dried tea leaf products.
	Applies to the processing, transport and storage of shelf stable	Shelf stable products:
26. Functional food	 Functional food: a dietary food or food supplement offering physiological regulation functions with scientifically proven functional composition(s). 	 Functional foods containing: CoQ10, γ- aminobutyric acid, phytosterols, dietary fibers, resistant maltodextrins, lactic acid bacteria (LAB), catechins,



	 Food in tablets: a food formulation made of one or multiple compressed powdered food ingredient(s) with or without food additives. Food in capsule: a type of solid or liquid food contained in a hard or soft capsule (shell). Powdered food: a food formulation processed with two or more substances in powdered form. 	 lycopene, spirulina, anthocyanidins, proanthocyanidins, glucosamine, fructans, cereal β-glucans, or green algae Mushroom functional foods containing β-glucan or water soluble crude polysaccharides Fish oil functional foods containing ω-3 fatty acids Foods containing soybean lecithin or soybean isoflavones Ganoderma tsugae functional foods
27. Food additives	Applies to the processing, transport and storage of shelf stable food additives which is added to or brought into contact with food in the course of manufacturing, processing, mixing, packing, transport and storage of food, with the purpose of coloring, seasoning, preserving, bleaching, emulsifying, flavoring, stabilizing the quality, fermentation, increasing viscosity, nutrition fortification, preventing oxidation or other necessary purpose and added to or come in contact with food unit or compound. Single food additive: products listed in the "Specifications for the Range and Limit of Use of Food Additives", complying with such specifications, and carrying a food additive permit. Compound food additive: compound products for use in food processing made with single food additives formulated with food ingredients and other single food additives.	containing triterpenoid Shelf stable food additive products include: Preservatives Sanitizing agents Antioxidants Bleaching agents Color fasting agents Leavening agents Food quality improvement, fermentation and food processing agents Nutritional additives Colors Flavoring agents Seasoning agents



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				• Sweeteners
				Pasting agents
				Coagulating agents
				Chemicals for food industry
				• Carriers
				• Emulsifiers
				Other food additives
		99. Foods in general	Applies to the processing, transport and storage of other shelf stable foods in general.	Shelf stable products:
				Powder/ concentrated powder
				Powder cereal
				• Fermented foods
				Edible algae
				Capsule/ tablet foods
				Tapioca balls

^{*}Auditors performing the audit field of "Canning and thermal-processed products" shall provide the evidence of thermal-processing technology training.