

the Regulations Governing Accreditation and Outsourced Accreditation Management of Food Testing Institutions

Chapter 1 General Principles

Article 1 These regulations are promulgated pursuant to the Paragraph 3 of Article 37 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the Act).

Article 2 Definition of the terms herein employed are as follows:

1. Testing institution: It refers to a testing body (institution), corporation, or group possessing the capacity to implement food testing.
2. Accreditation: It refers to the procedure established under this set of regulations instituted to validate the testing competence of a testing institution for a particular testing item.
3. Sanitation Standards: It refers to the permissible tolerance , standards, limitation standards, or provisional standards defined in Paragraph 2 of Article 15, Article 17, Paragraph 1 of Article 18, or Article 19 of the Act.

Chapter 2 Accreditation Requirements and Procedure for Testing Institutions

Article 3 Testing institutions applying for accreditation shall meet the following requirements:

1. Equipped with the essential test equipment, space, and quality management system.
2. Complete with an official responsible person, a report signatory, a testing department manager, a quality control manager, and the pertinent test personnel possessing the following qualifications:
 - (1) graduates of a domestic or a foreign college, university or higher educational institution recognized by the Ministry of Education holding degrees in medicine, chemistry, biology, or food science;
 - (2) for test personnel, completed testing work related training, and for other personnel, completed quality management related professional training and at least 3 years of testing related work experience.

Article 4 Testing institutions applying for accreditation shall submit an application form, together with the following supporting documents and information to the central competent authority:

1. the certifications and documents manifesting the compliance with the requirements stipulated in the preceding article;
2. the quality manual and test operational procedures;
3. an assessment report of uncertainty of measurements in case of an application filed for quantitative test item. However, this requirement does not apply under emergency circumstances or insufficiency of test resources and where test procedure under application has been declared by the central competent authority.
4. documents certifying testing capacity and quality control chart of the test results;
5. a method validation assessment report if the central competent authority does not prescribe a testing method for a test item under accreditation application pursuant to Article 38 of the Act.

Article 5 Where the documents and information stipulated in the foregoing article do not comply with regulations or is found incomplete, the central competent authority shall issue a supplementation request and deadline to the applicant; where requirement is not fulfilled within the prescribed deadline, application shall be denied.

Article 6 The central competent authority shall conduct a document review and on-site assessment on the applications of testing institutions.

Where the on-site assessment finds a deficiency, the testing institutions shall submit a corrective plan to the central competent authority for re-assessment after the end of on-site assessment within 60 days.

Article 7 Where the application passes the assessment stated in Article 4, the central competent authority shall announce the scope of accreditation, including specifics of the test item(s) and testing method(s) approved, and thereafter an accreditation certificate shall be issued in acknowledgment thereof.

Article 8 The accreditation certificate shall contain the following information:

1. The name and address of the testing institution;

2. The full name of the responsible person of the testing institution;
3. Accreditation item, testing method, test scope, and report signatory;
4. Year, month, date, and serial number of the accreditation certificate.
5. Validity period of the accreditation certificate.

The testing institution shall display the accreditation certificate in a highly visible place of the premises.

Article 9 The accreditation certificate has a validity period of 3 years. An application for extension may be filed within the six-month period preceding date of expiration. The maximum period of extension per application is 3 years. The provisions of Articles 4 to 6 shall apply mutatis mutandis to the document, information and procedures required for accreditation period extension application.

Chapter 3 Management of Accredited Testing Institutions

Article 10 In the event of changes in any of the items enumerated under Subparagraphs 1 to 3 of Paragraph 1 of Article 8, the testing institution shall submit an application to the central competent authority for approval pursuant to the following provisions; amendment may be instituted after approval is granted:

1. Change of address: application shall be filed within 30 days of event.
2. Change of testing methods or changes in consequence of amendment of the sanitation standards as prescribed in the official announcement of the central competent authority: application shall be filed within 90 days of event.
3. Changes other than the matters stated in the preceding two paragraphs: application shall be filed within 90 days of event.

Article 11 A testing institution accepting a commission to conduct test on the accredited test item shall comply with the following provisions:

1. Sign a contract with the client; contract shall specify the test item, method, and scope of the test.
2. Accurately record the detailed information of the client and the use purpose of the test report.

3. Accurately record the condition of specimen(s) received, including the name, batch number, manufacturing date or expiry date, source, packaging, and quantity of the product. No space or column shall be left blank; moreover, photographs of the specimens submitted for testing shall be kept on file.
4. The test report shall indicate the product information, test item, testing method, test scope, and test results of the specimen(s). All information shall be true and accurate. Where report shall also contain results outside the scope of accreditation (including test item, testing method, and test scope), results shall be distinguished and factually stated.
5. Non-accredited testing methods may not be used for testing; however, this limitation shall not apply where such is requested in a specifically signed contract with the client or in a written request of the client, and such is specified in the test report.
6. The test report shall clearly note the following: "The test report merely reflects the test results of the consigned matters of the client and is not a certification of the legitimacy of the related products."
7. The test report and records of quality control information and raw data shall be kept on file together for at least 3 years.
8. Test reports shall be designed to thwart forgery.

Article 12 The central competent authority shall regularly audit the equipment, personnel organization, quality management, operating procedures, testing capacity, and test records of the accredited testing institutions and may require the testing institutions to submit reports of the testing procedures conducted within the accreditation scope. When necessary, the central competent authority may conduct irregular audit.

Moreover, the central competent authority may require the testing institutions to participate in the central competent authority organized or outsourced proficiency testing activities.

Testing institutions are not entitled to evade, obstruct, or refuse the audit procedure, report submission, and proficiency testing participation requirement prescribed in the foregoing two paragraphs.

Article 13 Where the testing institution undergoing the proficiency testing required in the second paragraph of the preceding article fails to pass the proficiency assessment, it shall be obliged to institute corrective actions within 15 days

following the date of acceptance of the test assessment notice; moreover, a corrective action report shall be submitted to the central competent authority. The testing institution shall be required to receive the follow-up proficiency testing as per date scheduled by the central competent authority.

Article 14 In the event of a major unforeseen food related event, testing institutions receiving an emergency mobilization notification from the central competent authority shall be obliged to process the food testing within the prescribed deadline; thereafter, testing institutions shall submit complete product information and testing results to the central competent authority.

Chapter 4 Procedure for the Outsourcing of Accreditation Work

Article 15 The central competent authority intending to outsource the accreditation work to a related body (institution), corporation, or group (hereafter referred as independent provider) pursuant to the provisions of Paragraph 2 of Article 37 of the Act shall process assignment through an open selection process.

Article 16 The independent provider shall meet the following requirements:

1. Possession of the experiences required for the accreditation of testing institutions and the necessary documents supporting said eligibility;
2. Employment of personnel meeting the following qualifications:
 - (1) graduates of a domestic or a foreign college, university or higher educational institution recognized by the Ministry of Education holding degrees in food science, nutrition, medicine, chemistry, or biology, with previous employment experience in the testing institution's testing competence validation related work;
 - (2) study of at least 15 credits of legal subjects involving criminal law, civil law, code of criminal procedure, code of civil procedure, and administrative law in a domestic university, with a transcript of records reflecting said credits.
3. Fulfillment of all other requirements announced by the central competent authority.

Chapter 5 Management of Independent Providers

Article 17 An independent provider shall have an established management system and the related operating procedures established in coordination with its accreditation procedures and produce an information manual; the information manual shall contain at least the following information:

1. organization chart;
2. document control;
3. records;
4. nonconformities and corrective actions;
5. preventive actions;
6. internal audit;
7. management review;
8. complaints.

The aforementioned manual shall be reviewed regularly to ensure appropriateness with operations and updated or revised from time to time to suit actual operating conditions. The internal audit and management review procedures shall be conducted at least once a year.

Article 18 An independent provider shall ensure that the personnel implementing the accreditation procedures possess the necessary food testing related knowledge and proficiency; moreover, the independent provider shall keep a record of the initial and regular assessments conducted on said personnel.

The personnel stated in the preceding paragraph shall attend at least 12 hours of continued education and training course conducted by an institution (body) or civilian institution or group recognized by the central competent authority. Education or training curriculum shall include audit techniques, testing knowledge and skills, and related laws.

Article 19 Any information acquired by an independent provider in the course of the accreditation process or any accreditation related information provided by the testing institution shall be retained on file for at least 15 years; whereas records of accreditation work related documents and information shall be permanently retained on file.

Upon the conclusion of the independent provider's outsourcing service, the aforementioned documents and information retained on file shall be turned over to the central competent authority.

Article 20 An independent provider shall be obliged to maintain the confidentiality of all information acquired in the course of implementing accreditation work, and shall refrain from disclosing said information.

Article 21 An independent provider implementing an on-site assessment pursuant to Paragraph 1 of Article 6 shall submit the prepared assessment schedule to the central competent authority a week before the assessment date; on the other hand, the central competent authority may appoint a representative to attend the assessment. The independent provider shall not evade, obstruct, or refuse such attendance.

Article 22 An independent provider shall inform the central competent authority of the accreditation results of every case processed; moreover, related documents and information shall be attached.

Article 23 The central competent authority may notify the independent provider of its requirement to submit operation-related documents and information and may conduct irregular audit procedures on the venue of operations of the independent provider.

The independent provider shall not evade, obstruct, or refuse the foregoing notice, requirement or audit.

Article 24 All documents and information provided to the central competent authority by the independent provider pursuant to the provisions of the Regulations shall be true and accurate.

Article 25 An independent provider and its personnel entrusted with the processing of accreditation work shall observe the “conflict of interest” regulations as dictated in the Administrative Procedure Law.

An independent provider shall desist from instituting any violent acts, threats, demands or post factum bribery, from accepting bribes or other improper benefits, from forging and altering documents, or from making false reports or statements. Any such violation shall be subject to legal action.

Article 26 The central competent authority shall sign a work consignment contract with the independent provider. Contract shall clearly define matters and other details, related rights and obligations, breach of contract penalty and reasons, dispute processing, and factors for the revocation or temporary suspension of the consigned work covered in the contract.

Chapter 6 Supplementary Provisions

Article 27 Where an accredited testing institution or an independent provider violates the provisions herein stipulated, the central competent authority shall resort to the actions stipulated in Article 48-1 of the Act.

Article 28 These regulations shall be effective as of the date of promulgation.