

Regulations for Approving and Supervising Organic Accreditation Bodies

Legislative history

1. Full text of 17 articles was promulgated by the Council of Agriculture on May 8, 2019 per Order Nung-Liang-Tze 1081069113A, and was set to be effective on May 30, 2019.

Article 1

These Regulations have been established in accordance with paragraph 5 of Article 11 of the Organic Agriculture Promotion Act (hereinafter referred to as the Act).

Article 2

Any institution or legal entity engaging in accreditation activities shall have the following qualifications:

1. Have a system of conformity assessment of certification bodies set up and implemented in accordance with ISO/IEC 17011 and a Mutual Recognition Arrangement for the accreditation scope of product certification bodies signed.
2. Be a member of International Accreditation Forum (IAF).

Article 3

Any institution or legal entity that engages in accreditation activities shall submit the following documents to the Central Competent Authority to apply for permission:

1. Copies of supporting documents regarding the establishment or registration of the institution or legal entity.
2. Copies of the arrangement in subparagraph 1 of the previous article.
3. Relevant documents for conducting accreditation activities.
4. Other documents required by the Central Competent Authority.

The documents in subparagraph 3 of the previous paragraph are as the following:

1. Quality manual.
2. Scope of accreditation.
3. Areas and countries where the accreditation is to be performed.
4. Accreditation standards: the standards for evaluating the qualifications to provide certification services; the required items are shown in the Appendix.
5. Assessment procedures: including initial assessment procedures, surveillance procedures, renewal assessment procedures, and extensional assessment procedures.
6. Assessment personnel: including internal regulations regarding selecting, training, dispatching, and appraisal of personnel, and requirements that eligible assessment personnel shall receive the training held by the Central Competent Authority or its designated body (institution) or legal entities at least once every two years and obtain

the certificate of completion.

7. Rules for assessment operation.
8. Accreditation contract template.
9. Pricing standard.

Article 4

For institutions or legal entities that have passed the permission review after applying according to the previous article, the Central Competent Authority shall issue the accreditation body permission, which shall include the following items:

1. Name and address of the accreditation body.
2. Scope of accreditation.
3. Areas and countries where the accreditation may be performed.
4. Valid period.

The scope of accreditation stipulated in subparagraph 2 of the previous paragraph is as the following:

1. Organic crops.
2. Organic livestock products.
3. Organic aquatic products.
4. Non-edible organic forest products.
5. Organic processing, packaging, and distribution.

The validity in subparagraph 4 of paragraph 1 is five years; one year prior to expiration, the accreditation body may submit copies of the arrangement in paragraph 1 of Article 2 to the Central Competent Authority to apply for permission renewal. The validity of the renewed permission shall not exceed 5 years.

Article 5

In case of any amendment to the permissions stipulated in subparagraphs 1 to 3 of paragraph 1 of the previous article, the accreditation body shall submit relevant documents to the Central Competent Authority to apply for such amendment permission.

Accreditation body shall apply for the amendment permission of subparagraph 1 of paragraph 1 of the previous article from the Central Competent Authority within 30 days after occurrence of the event.

Article 6

Upon the accreditation body's amendment to or abolishment of the documents stipulated in paragraph 2 of Article 3, the accreditation standards stipulated in subparagraph 4, paragraph 2 of Article 3 shall be submitted to the Central Competent Authority for approval, and other documents shall be kept record with the Central Competent Authority.

Article 7

Upon accepting the accreditation application from an institution, school or legal entity, the accreditation body shall sign the accreditation contract with the applicant who is reviewed eligible according to the accreditation standards in initial assessment procedures to provide certification service, and shall issue the accreditation certificate to the certification body.

The accreditation certificate in the above paragraph shall include the following items:

1. Name and address of the certification body.
2. Name of accreditation standards.
3. Scope of accreditation and certification type.
4. Areas and countries where the certification activity is allowed to be performed.
5. Accreditation certificate number.
6. Name of accreditation body.
7. Issuing date and valid period.

Article 8

The certification type in subparagraph 3 of paragraph 2 of the previous article refers to individual certification and group certification.

Non-natural person operators who meet the following conditions can apply for group certification:

1. The management center is established to be responsible for business planning and implementing.
2. Group members adopt the quality management system established by the management center, continuously operate under the supervision of the management center, and meet the requirements and rules thereof.
3. The produced organic agricultural products and in-conversion agricultural products are labeled and sold in the name of the group.

Article 9

For the accredited certification body, the accreditation body shall conduct surveillance at least once a year to ensure that the certification body constantly meets the accreditation standards in the valid period of the accreditation certificate.

Article 10

The valid period of the accreditation certificate of the certification body is three years. Six months prior to expiration, the certification body may apply for renewal assessment; in case of an overdue application, re-application for accreditation is required.

For the certification body that applies for renewal assessment and is found eligible through

renewal assessment procedures, the accreditation body shall approve the renewal and issue the accreditation certificate, provided that each renewal period shall not exceed three years.

Article 11

The certification body may apply to the accreditation body for an extensional assessment regarding the scope of accreditation, and the area and country in which the accreditation activities are performed.

For the application stipulated in the previous paragraph, if the applicant is found eligible through extensional assessment procedures, the accreditation body shall update the accreditation certificate.

Article 12

If the certification body can no longer engage in its scope of certification or certain certification activities in the area and country, the certification body shall immediately notify the accreditation body in writing.

After receiving the aforementioned notice, the accreditation body shall reduce the incapacitated part of that certification body and update the accreditation certificate.

Article 13

If the certification body is under any of the following circumstances, the accreditation body may terminate its certification qualification or certain scope of certification activity:

1. Lacking the ability required for all certification activities within the scope of the accreditation according to accreditation standards.
2. Lacking the ability required for some certification activities within the scope of accreditation according to accreditation standards and failure to notify the accreditation body as required in paragraph 1 of the previous article.
3. Organizational functioning and perspective fail to maintain impartiality and independence stipulated in accreditation standards.
4. Failing to conduct certification activities in accordance with the relevant provisions of the accredited scope in a serious manner.
5. Its certified operator fails to meet certification standards stipulated in paragraph 3 of Article 12 of the Act in a serious manner and failure to subsequently handle it effectively.
6. Failing to manage its certified operator regarding the use of the organic mark as stipulated in paragraph 2 of Article 20 of the Act in a serious manner.
7. Engages in certification activities beyond the scope of accreditation.
8. Provides false certification records or relevant documents in a serious manner.
9. Other serious inconformity to accreditation standards according to the assessment

results of the accreditation body.

Article 14

Accreditation contracts signed with the certification body and following records of the accreditation body's engagement in accreditation activities shall be retained for at least five years:

1. Records of formulation, amendment, and abolishment of the documents in paragraph 2 of Article 3.
2. Assessment records of the certification body according to assessment process.
3. Records of the accreditation decision according to assessment results.
4. Records regarding selecting, training, dispatching, and appraisal of assessment personnel.
5. Other records required by the Central Competent Authority.

Article 15

Based on the engaged accreditation activities, the accreditation body shall submit a written performance report of the previous year to the Central Competent Authority by March 31 every year.

The Central Competent Authority may form an examination team to conduct examination of the accreditation body and its accredited certification body.

Article 16

The accreditation body shall disclose the name, address, contact number, scope of accreditation, area and country of accreditation, valid accreditation period, and information about its disposals of its accredited certification body on the accreditation body's website.

Article 17

These Regulations shall enter into force on May 30, 2019.

Appendix

Required Items for the Accreditation Standards of Accreditation Bodies

1. Certification body
 - 1.1 With the accreditation qualifications stipulated in the Accreditation Requirements for Product Certification Bodies (ISO/IEC 17065).
 - 1.2 Conduct audit according to the Guidelines for Auditing Management Systems (ISO 19011).
 - 1.3 Testing required for certification shall be conducted by a test laboratory accredited according to the General Requirements for the Competence of Testing and Calibration Laboratories (ISO/IEC 17025). However, for specific test items, when a laboratory cannot completely meet the requirements and no other laboratories have such capacity, the accreditation body may witness how the certification body confirms laboratory capabilities through witness assessment.
 - 1.4 Organizational functioning and perspective maintain impartiality and independence.
 - 1.5 Capable of managing the use of the organic mark by its certified operators.
 - 1.6 Capable of handling businesses and issues between and among the Central Competent Authority, the accreditation body, the certification applicant, its certified operator, and consumers.
 - 1.7 Capable of training and appraising its personnel to meet basic personnel requirements.
 - 1.8 Starting from the date of the accreditation application, the accreditation qualifications have not been terminated by the accreditation body within the last three years.
 - 1.9 Contents of the certification contract shall meet the Items Required to be Stated in the Contract between Organic Certification Bodies and Agricultural Operators stipulated by Central Competent Authority.
2. Basic personnel requirements
 - 2.1 Certification auditor
 - 2.1.1 Shall meet one of the following qualifications:
 - 2.1.1.1 Passed the relevant national occupational test.
 - 2.1.1.2 With work experience in the production, processing, research, development, technology, transportation and sale, test, and quality management of agricultural products (crops, livestock products, aquatic products, forest products, processed products), or in the formulation (establishment), amendment, or review of relevant standards or regulations.
 - 2.1.1.2.1 If graduated from an agriculture and food-related

department: one year.

2.1.1.2.2 If not graduated from an agriculture and food-related department: two years.

2.1.2 Shall obtain a certificate of qualifying conformity assessment training for auditors and have experience participating in at least five on-site audits according to the category of agricultural products (crops, livestock products, aquatic products, forest products, processed products), which shall be accomplished within two years before obtaining auditor qualifications.

2.1.3 Shall undergo the following training and obtain the corresponding certificates:

2.1.3.1 At least eight hours of training on the applicable laws of organic agricultural products and domestic and foreign certification systems.

2.1.3.2 At least 16 hours of training on knowledge related to the processes and technologies for the production, storage and distribution of agricultural products.

2.1.3.3 At least 16 hours of training on audit skills, methods and case analysis.

2.1.4 The training participation stipulated in 2.1.3 shall be limited to the following:

2.1.4.1 Training held by the Central Competent Authority and its affiliated body.

2.1.4.2 Training held by an institution entrusted by the Central Competent Authority.

2.1.4.3 Training held by institutions of college.

2.1.4.4 Training held by a professional institution approved by the Central Competent Authority.

2.1.5 If not graduated from an agriculture and food-related department, the hours of training received according to 2.1.3 shall be no less than 60 hours.

2.1.6 An eligible auditor shall receive at least 20 hours of advanced training every two years, whose contents are the same as those stipulated in 2.1.3, and at least 10 on-site audits shall be conducted to maintain qualification.

2.1.7 For the number of on-site audit stipulated in 2.1.2 and 2.1.6, if the number of on-site audit on the specific category of agricultural products cannot be accomplished due to special circumstances, the number thereof may be reduced with the Central Competent Authority's consent.

2.2 Certification decision maker

2.2.1 Knowledgeable about regulations related to organic agriculture.

2.2.2 Knowledgeable about certification body operating procedures and scopes of certification activity.

- 2.2.3 Knowledgeable about audit principles and techniques.
- 2.2.4 With more than three years of cumulative experience in fields related to organic agriculture, the production or certification of organic agricultural products, or assessment of accreditation body.

3. Basic certification criteria

3.1 Certification procedure and operation period

- 3.1.1 Upon accepting an application for the certification of organic agricultural products and in-conversion agricultural products, the certification body shall carry out the procedures of the document review, on-site audit, product sampling for testing and certification decision, and the applicant shall be notified of the results in writing. However, if according to risk assessment or no products are available for testing due to the factor of force majeure, the certification body may test other part of the plant thereof.
- 3.1.2 The certification body shall determine the operation period of each procedural stage stipulated in 3.1.1, and the duration of the operation periods of all stages shall not exceed six months. However, this period shall not include the time period to make corrections or improvements notified to the applicant.

3.2 Group certification

- 3.2.1 For a group certification application case, prior to on-site audit, the certification body shall first evaluate whether the operation of its management center meets the requirements of its own regulations and operating procedures; if the results indicate that sampling may be applicable for the following on-site audit, the number of members sampled shall be no less than the square root of the total number of members.
- 3.2.2 If sampling is adopted for on-site audit of group members according to 3.2.1, the certification body shall audit all lands of the sampled members that applied for certification.
- 3.2.3 When the certification body conducts product sampling for testing in a group certification case, the number of sampling for testing thereof shall be no less than the square root of the total number of members.

3.3 For the sampling carried out by the certification body, the procedure and quantity thereof shall give consideration to the objectivity, representativeness, and purpose of risk management and be capable of avoiding contamination.

3.4 Certification certificate

- 3.4.1 For those who apply for organic agricultural products and in-conversion agricultural products certification and are found eligible through certification, the certification body will issue the certification certificate for organic agricultural products and in-conversion agricultural products according to the

relevant product categories.

3.4.2 The certification certificate shall include the following items:

3.4.2.1 The name and address of the operator, and the name of its statutory person responsible.

3.4.2.2 Address or land number of the certification site.

3.4.2.3 Category and item of agricultural products and certification type thereof.

3.4.2.4 Valid period.

3.4.2.5 Name and address of the certification body.

3.4.2.6 Certificate number.

3.4.3 The validity period of a certification certificate for organic agricultural products and in-conversion agricultural products shall be no more than three years; three months prior to expiration of the valid period, the certification body shall ask the operator to fill in the application form to apply to the certification body for renewal; overdue renewal applications shall not be accepted.

3.4.4 After the renewal application according to 3.4.3 has been reviewed and approved, the certification certificate will be renewed.

3.5 Amendment to certification certificate

3.5.1 If an operator has any of the following circumstances, the certification body shall ask it to submit relevant materials to apply for the amendment to the certificate of organic certification or in-conversion certification:

3.5.1.1 Change of the name or address of the operator, or the name of its statutory person responsible.

3.5.1.2 The certification scope is reduced in terms of the certified site or certified product items.

3.5.1.3 Reduction of group certification members.

3.5.2 After the application according to 3.5.1 has been reviewed and approved, a replacement certificate with the same period of validity as the original certificate shall be issued.

3.6 Report to the certification body for review

3.6.1 If changes are made to the production and processing of organic agricultural products and in-conversion agricultural products, or in the operating system maintaining organic integrity, the operator shall take the initiative to report such changes to the certification body for review.

3.6.2 If the certification body reviews the change and determines that it is likely to affect the results of the original certification, the certification shall be conducted on the change by the certification body.

3.7 Application for extensional audit

3.7.1 Under any of the following circumstances, the certification body shall ask the operator to submit relevant materials to apply for extensional audit:

3.7.1.1 An extension of the certification site.

3.7.1.2 An extension of the agricultural product items to be certified.

3.7.1.3 An extension of group certification members.

3.7.2 After the extensional audit according to 3.7.1 has been reviewed and approved, a replacement certificate with the same period of validity as the original certificate shall be issued.

3.8 Surveillance

3.8.1 The certification body shall perform surveillance on all of its operators with the certified products at least once a year. However, the frequency of surveillance may be increased as necessary.

3.8.2 For the surveillance conducted by the certification body according to 3.8.1, the proportion of surveillance without notice or by serving notice within 24 hours before surveillance shall account for at least five percent of the total number of its certified operators.

3.9 The procedures prescribed in 3.1.1 shall apply *mutatis mutandis* to the renewal audit stipulated in 3.4.3, the review and certification stipulated in 3.6, the extensional audit stipulated in 3.7.1 and the surveillance audit stipulated in 3.8.1, the certification body shall refer to procedures, or the certification body may implement necessary procedures in view of the certification risk of the individual case.

3.10 The certification body shall conduct sample testing of its certified agricultural products in the market every year, and the number thereof shall account for at least three percent of the total number of its certified operators.

3.11 The certification body shall publish relevant information of its certified operators, such as the name, address, contact number, categories and items of certified agricultural products, valid period and disposals in the information system designated by the Central Competent Authority within 10 days after making a certification decision or reviewing, as well as quarterly publish the relevant information on issuing organic marks in the same system.