

(Unofficial)

Announcement of the Food and Drug Administration

Re: Criteria, Procedures and Conditions for Registration of Bodies Providing Audit and Certification for Food Production Premises under Regulated Criteria

It is appropriate to revise Announcement of the Food and Drug Administration Re: Criteria, Procedures and Conditions for Registration of Inspection Bodies for Food Production Premises under Regulated Criteria, by improvement of registration to be consistent, clear and comply with international principle and be able to have efficient operation. The Food and Drug Administration has issued the announcement as follows:

Clause 1 Announcement of the Food and Drug Administration Re: Criteria, Procedures and Conditions for Registration of Inspection Bodies for Food Production Premises dated 27th February B.E. 2555 (2012) shall be repealed.

Clause 2 Registration of bodies providing audit and certification for food production premises under regulated Criteria shall comply with criteria, procedures and conditions shall be as specified in List no. 1 enclosed to this announcement.

Clause 3 Application for registration of bodies providing audit and certification for food production premises under regulated criteria, an application form in List no.2 enclosed to this announcement shall be submitted.

So that from now onwards

Announced on 29th May B.E 2558 (2015)

(Signed) Boonchai Somboonsook

(Mr. Boonchai Somboonsook)

Secretary-General of Food and Drug Administration

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

List No.1

Criteria, Procedures and Conditions in Registration of Bodies providing audit and certification of Food Production Premises under Regulated Criteria

1. Scope

This document prescribes definitions, qualification of an applicant, procedures in registration of bodies providing audit and certification for food production premises under regulated criteria, conditions, monitoring, decreasing of scope and withdrawal, appeal, confidentiality and others that concerning with an approval for competency of a body providing audit and certification for food production premises that have been registered with the Food and Drug Administration to perform audits of varieties of food production premises under regulated criteria, and to be as information for the Food and Drug Administration to further proceeding under a legislation. The registration of the scopes under regulated criteria is as follows:

1.1 Audit of food production premises under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments, and Food Storages.

1.2 Audit of food production premises of drinking water in sealed containers under Notification of the Ministry of Public Health, Re: Drinking Water in Sealed Containers.

1.3 Audit of food production premises of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments, and Storage of Ready-To-Consume Milk Products in Liquid Form which Passed Through Pasteurization Heat Treatment.

1.4 Audit of food production premise of processed foods packed in packaging ready to sale under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments, and Storage of Processed Foods Packed in Packaging Ready to Sale.

1.5 Audit of food production premise of low and acidified low acid canned food under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments, and Storage of Low and Acidified Low Acid Canned Food.

1.6 Audit of method, equipment in irradiation and storage of irradiated food under the Notification of Ministry of Public Health Re: Irradiated Food.

1.7 Audit of food production premises of edible salt under Notification of the Ministry of Public Health, Re: Edible Salt.

1.8 Criteria for audit of food production premises of other kinds of food as prescribed by the Administration.

2. References

2.1 Food Act B.E. 2522 (1979).

2.2 Criteria and conditions for an approval of competency of certification bodies of food and agricultural commodities in scope of GMP/HACCP (ACFS-CSSA-R-SD-01), the National Bureau of Agricultural Commodity and Food Standards.

2.3 Criteria and conditions for an approval of competency of certification bodies in scope of Food Safety Management System (ACFS-CSSA-R-SD-15), the National Bureau of Agricultural Commodity and Food Standards.

2.4 ISO/TS 22003:2013 Food Safety management system – Requirements for bodies providing audit and certification of food safety management systems.

2.5 ISO/IEC 17021:2011 Conformity assessment –Requirements for bodies providing audit and certification of management systems.

2.6 Criteria and condition for qualification and experience of auditors for food production premises under regulated criteria of the Food and Drug Administration (RL-F5-14).

2.7 Criteria, procedures and conditions for registration of curriculum and training bodies in area of criteria of food law of the Food and Drug Administration (RL-F5-15).

3. Glossary of terms

Definitions of terms in this document are as follows:

3.1 Office means the Food and Drug Administration.

3.2 Secretary-General means the Secretary-General of the Food and Drug Administration or authorized person by the Secretary-General of the Food and Drug Administration.

3.3 Audit means systematic, independent and documented process to attain audit evidence and having decision openly in consideration of conformity assessment against criteria under the Food Act B.E. 2522 (1979), relevant Ministerial regulation, and audit criteria of the Food and Drug Administration.

3.4 Applicant means a legal entity who intends to register with the office as “Certification body for food production premises under regulated criteria”.

3.5 Certification body means an applicant that passed through an evaluation of attached evidence documents submitted with an application form and has been approved by the Office for competency to function for audit and certification of food production premises under regulated criteria.

3.6 Working Group for Evaluation of Certification bodies’ competency including of personnel in food area means a group of person authorized by the Secretary- General to consider qualifications of applicants under scope they have applied for registration, decreasing and increasing scope and cancellation.

3.7 Working Group of Monitoring means a group of person authorized by the Working Group for Evaluation of Certification bodies' competency including of personnel in food area to monitor operating results of bodies providing audit and certification.

3.8 Appellate Committee means a group of person authorized by the Secretary-General to consider an appeal.

4. Qualifications of Applicants

4.1 An applicant shall have the following qualifications:

4.1.1 Be a legal entity registered in Thailand, in case of an alien legal entity shall receive a business license under the Alien Business Act by the Department of Business Development, Ministry of Commerce.

4.1.2 Be accredited by International Accreditation Forum (IAF) in accordance with either one among the following standards:

a) Criteria / conditions for an approval of competency of certification bodies of food and agricultural commodities in scope of GMP, HACCP, ACFS (SSA-R-SD-01).

b) Criteria / conditions for an approval of competency of certification bodies in scope of Food Safety Management System (ACFS-SSA-R-D-15).

c) ISO/TS 22003:2013 Food Safety management system – Requirements for bodies providing audit and certification of food safety management systems.

d) ISO/IEC 17021:2011 Conformity assessment –Requirements for bodies providing audit and certification of management systems.

e) Other equivalent standards.

4.1.3 Not be a withdrawal registration person under the applied scope, except for the withdrawal of longer than 6 months.

4.1.4 Not be a person or having a representative under prosecution of offences relating to certificate and alteration for registration of certification body, except that either such prosecution has been terminated resulting from the person or representative is not guilty, or the court has the final judgment for such prosecution.

4.1.5 Not be a person under examination process for truly certified any documents due to having behavior or reason to believe that such certification body or representative either alters an official document regarding certification or conspires to the alteration or relevant direct and indirect offences.

4.2 Personnel

4.2.1 An applicant shall have competent and experienced personnel in audit of food production premises in scope of registered standards that complied with criteria and conditions of qualifications and experience of auditors of regulated criteria for food production premises and passed training courses and also from training bodies that have been recognized and registered by the Food and Drug Administration.

4.2.2 An applicant shall have at least 4 persons per agency to provide audit of food production premise requested for services and at least 2 persons for each scope of regulated criteria registered with the office.

5. Procedures for registration of Certification Body for food production premises under regulated criteria

5.1 For application, an application form for registration of certification body for food production premises under regulated criteria shall be submitted to the office with attached documents and evidences as specified in List no. 2. Applicants shall submit all accurate and updated information.

5.2 Once application form is received, the office will preliminarily consider for accuracy and completeness of an application form and submitted documents, if their details are not completed or additional documents are needed, the office will notify the applicants to proceed as in a notice and the officers will consider after receiving of completely additional documents.

5.3 When all documents are complete, Working Group for Evaluation of Certification bodies' competency including of personnel in food area which authorized by the office will consider qualifications of applicants under scope they have applied for registration. In case of evidence and qualifications are not met, applicants will be informed by written notice to correct or submit additional documents for further consideration.

5.4 A qualified applicant will be "a certification body for food production premises under regulated criteria" whenever auditors and lead auditors shall pass an assessment by an approval of Working Group for Evaluation of Certification bodies' competency including of personnel in food area, of on-site audit performance on food production premises under regulated criteria at least 2 times or duration not less than 2 days.

5.5 The office will register the qualified applicants whom proceed as stated in 5.4 as "a certification body for food production premises under regulated criteria" under specific registered scope and will further publish to stakeholders.

5.6 List of registered certification bodies for food production premises under regulated criteria will be valid for 3 years from the date of being registered.

6. Conditions

Applicants registered as a certification body shall operate as the following conditions:

6.1 Maintain for a whole period of registration a quality system as standards certified and criteria or regulation as prescribed by the office.

6.2 No conflict of interest or involve in any business that affect impartiality and honesty of agency's operation such as

6.2.1 A certification body and its operation unit under the same legal status shall not propose or provide service on consultation of any food management systems.

6.2.2 Shall not do marketing or propose its activities linked to activities of food management system consultation firms.

6.2.3 Shall not hire personnel who provide food management system consultation for auditing and other certifying activities for such customer at least 2 years after finishing of such consultation.

6.2.4 If a certification body proposes for internal audit in any organization, such certification body shall not make an audit of such organization within 2 years after finishing of such internal audit.

6.2.5 Shall not subcontract any audit relevant with food to other organizations or agencies.

6.3 A certification body shall cooperate with the office in the following areas:

6.3.1 Shall audit food production premises with audit procedures/manuals prescribed or approved by the office as follows:

a) Criteria and conditions of auditing for permission of food production premises and/or certifying as regulated criteria.

b) Food production premise audit manual.

c) Other regulations relevant to audit of food production premises.

6.3.2 Shall not disclose result of audit to other persons except having a written consent from the auditee and the office.

6.3.3 Shall deliver report of audit result of food production premises under regulated criteria every month.

In case audit result of food production premises do not comply with regulated criteria or data changing are not consistent to that have been approved, certification body shall immediately notify the office with relevant evidences.

6.3.4 Provide collaboration with the Working Group of Monitoring in monitoring of operation results including deliver any documents and evidences to the Office when has been requested.

6.4 Shall not use the registration in detriment or misleading of such registration.

6.5 If defects or errors of audit results are discovered and notified by the office, such defects or errors shall be corrected without undue delay, and if additional inspection is needed because of such causes, additional expenses cannot be charged from the auditee or the Office.

6.6 If a renewal of registration is desired, written notification to the office shall be made in advance at least 90 days before expired date.

6.7 If decreasing of scope or cancellation of the registration is desired, written notification to the office shall be made in advance at least 45 days.

6.8 If expanding the scope of registration is desired, a certification body shall submit an application form and operate as the first time of application.

6.9 If there are some changes of details in application documents or any other changes that will affect ability of the inspection body, the applicant shall notify to the office within 15 days.

6.10 The office may review the registration of certification bodies if there are any changes that affect to ability or competent of audit.

7. Monitoring

The Working Group of Monitoring will make on-site audit at least once a year for registered certification bodies by consideration from history of their operations and complaints at food production premises or may audit the entire system at the office of the certification bodies. If results of the monitoring does not comply with the criteria, procedures and conditions as prescribed by the office, corrective action shall be notified and proceeded within 30 days and 60 days respectively as the case maybe.

8. Decreasing of scope and cancellation

8.1 If a certification body cannot maintain the system as prescribed in Clause 6 or do not implement criteria, procedures and conditions as prescribed, the office may take the following actions:

8.1.1 Decreasing of scope of registration

If any major change occurred in the agency that affect to ability on operation of such agency or when the certification body made written notification to the office.

8.1.2 Cancellation of registration will occur in the following cases:

(a) Monitoring audit of the office indicates that the operations of such certification body are not complied with major contents of requirements of registration as in Clause 4.1 and Clause 4.2 and cannot implement criteria, procedures and conditions as prescribed at determined duration by having no appropriate reason or correction implemented have no efficient.

(b) Implementations are not followed conditions in Clause 6 and 7 including other criteria and conditions prescribed by the office.

8.2 The office may consider to decrease the scope or cancellation of the registration when receiving information, evidence or suggestion from accreditation body that has accredited the certification body to decrease the scope or cancellation as the case maybe.

8.3 In case of decreasing of the scope or cancellation of the registration, the office will publish to public when receiving information or evidence from clause 8.2 or it is finalized in clause 9.

8.4 In case that decreasing of the scope or cancellation of registration has been made, the certification body shall cease its operation or claim for carry on certification of food production premises under regulated criteria and shall cease immediately on use of printed matter, advertising media that referred to the registration.

9. Appeal

9.1 An applicant for registration or certification bodies that have been decreased in scope or cancelled as in Clause 8.1 may make a written appeal to the Secretary-General within 15 working days as from the date of the office inform result of consideration or such measure to the applicant or certification bodies.

9.2 The office will authorize appellate committee to consider and will inform the result to appellant within 30 working days from the date of receiving an appeal by the office. If such duration of time is not sufficient, twice extensions by 15 working days each time may be made.

9.3 In case that an appellant do not agree with a decision of the appellate committee, the appellant can make a second appeal to the Secretary-General within 15 working days as from the date of the Office inform the result of consideration of the appellate committee.

9.4 During consideration of appeal is not finalized, it shall be deemed that the former result is still effective.

9.5 It shall be deemed that decision of the Secretary-General is finalized.

10. Confidentiality

10.1 The office and all stakeholders will keep any data and information received from applicants or registered certification bodies confidential and will not disclose to other persons except having written permission from applicants or registered certification bodies.

10.2 The office will not responsible for any detriment occurred with applicants or registered certification bodies due to disclosure of confidence to outsiders except for the case that having a proven evidence which indicate such detriment occurred because of the office error.

11. Others

11.1 In case that some changes have been made to any criteria or conditions relevant to registration, the office will inform applicants or registered certification bodies to revise and correct within a specified time as the case maybe.

11.2 The office will not responsible for any dishonest action or disobedience to prescribed criteria or conditions by applicants or registered certification bodies.

~~Cancel~~

List No.2

Application form for registration of Certification Body for Food Production Premises
under regulated criteria

At

Date..... Month.....B.E.

1. Name Ageyears Nationality.....

Identity card No..... Issued at.....

Address..... Trok/Soi Street Moo.....

Sub-districtDistrict Province Post code

Telephone Mobile phone Fax E-mail address

2. Apply for registration of certification body on behalf of.....
(Name of applicant legal person)

By having..... is as a business operator

Address Trok/Soi Street Moo.....

Sub-districtDistrict Province Post code

Telephone Mobile phone Fax E-mail address

3. Branch or Regional Office desire for registered certification bodies (if any)

Name of agency..... Branch.....

Address Trok/Soi Street Moo.....

Sub-district District Province Post code

Telephone Mobile phone Fax E-mail address

4. Objectives

To register certification body under following scope To increase the scope of registration

To renew registration in the following scopes (can select more than 1 scope)

(1) Audit of food production premises under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments and Food Storages.

(2) Audit of production premises of drinking water in sealed containers under Notification of the Ministry of Public Health, Re: Drinking Water in sealed containers.

(3) Audit of production premises of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments, and storage of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment.

(4) Audit of production premises of processed food in packaging ready to sale under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments and Storages of processed food in packaging ready to sale.

(5) Audit of production premises of low and acidified low acid canned food under Notification of the Ministry of Public Health, Re: Production Processes, Production Equipments and Storages of low and acidified low acid canned food.

(6) Audit of production premises of edible salt under Notification of the Ministry of Public Health, Re: Edible Salt.

(7) Audit of methods and equipments for irradiation and storage of irradiated food under Notification of the Ministry of Public Health, Re: Irradiated Food.

(8) Criteria for audit of food production premises of other kinds of food as prescribed by the Administration..... (Please specify).....

Request for correction of details such as modification of auditor level, changing address of certification body, addition of evidence registration etc. (specify the details of changing clearly and completely)

5 Apply for registration of certification bodies to provide service (can select more than 1 item)

issue certificate for legal GMP inspect premise for renewal production license

6. Legal status

Government agency Private agency Other (please specify).....

7. Accredited by accreditation body (AB)

| Name of AB | No. of certificate | Scope of accreditation | Date of accredited | Expiry date |
|------------|--------------------|------------------------|--------------------|-------------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

8. Total number of auditorspersons **Number of lead auditors**.....person and **auditors**.....persons

9. contact person (should be a representative of management section or organization well understood person)

1) Name.....Position.....
 Tel.....Fax.....
 Mobile phone.....E-mail address.....

2) Name.....Position.....
 Tel.....Fax.....
 Mobile phone.....E-mail address.....

10. Together with this application form, I attached the following documents :

10.1 Certified document of registration of legal entity or document specified status of a legal entity and authorized person to do business of legal entity of the applicant in case of an alien legal entity shall receive a business license under the Alien Business Act by the Department of Business Development, Ministry of Commerce.

10.2 Copy of house registration and copy of identification card of an applicant. If an applicant has not been an authorized to sign, the following additional documents shall be submitted;

| | |
|---|--|
| <p>(1) Power of attorney (with Duty Stamp 30 Baht).</p> <p>(2) Copy of house registration and copy of identification card of a grantor and a grantee or equivalent documents which recognized by government agencies such as copy of passport, driver license or officer identification card or alien business license.</p> <p>10.3 A copy of location of head office or branch office in Thailand is being applied for registration in details.</p> <p>10.4 Organization structure of applied agency with job description of personnel in the agency including inspectors of the agency.</p> <p>10.5 A Copy of accreditation evidence with scope applied in Clause 6 of an application form from an international recognized Accreditation Body.</p> <p>10.6 A Copy of evidences presenting qualification of inspectors that complied with criteria and conditions about qualification and experience of inspectors for regulated food production premises as follows;</p> <p>(1) Education.</p> <p>(2) Training (Certificate or training certificate).</p> <p>(3) Copy of production premises Audit log certified by supervisor or auditees' agencies</p> <p>10.7 A copy of Quality Manual or equivalent (Criteria for Estimation of Manday, if any).</p> <p>10.8 A copy of Procedure from applying system planning of audit, auditor authorization, audit and certification monitoring during certification through valid of certification.</p> <p>10.9 Publication of the inspection body promotion (if any).</p> | |
| <p>I certify that</p> <p>(a) A person who signs has been granted to do any business as a representative of the agency.</p> <p>(b) Whatever presented in the application form is true and update, if the documents are not completed, I will provide for completeness of the agency in accordance with the requirements of the registration.</p> | |
| <p>Sign by an applicant (authorized person):</p> <p>Position:</p> | <p>Seal:</p> <p>Day/Month/Year:</p> |