

THE MINISTRY OF HEALTH

Circular No. 26/2012/TT-BYT of November 30, 2012, on grant of certificates of establishments eligible for food safety for producers and traders of functional food, micronutrient-fortified food, food additives or food processing aids; natural mineral water or bottled drinking water; and food packaging tools and materials and food containers under the Ministry of Health's management

Pursuant to the 2010 Law on Food Safety;

Pursuant to the Government's Decree No. 38/2012/ND-CP of April 25, 2012, detailing a number of articles of the Law on Food Safety;

Pursuant to the Government's Decree No. 63/2012/ND-CP of August 31, 2012, defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the proposal of the director of the Vietnam Food Administration;

The Minister of Health promulgates the Circular providing the grant of certificates of establishments eligible for food safety in food production and trading under the Ministry of Health's management.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular provides dossiers, procedures and competence to grant certificates of establishments eligible for food safety (below referred to as certificates) to producers and traders of functional food, micronutrient-fortified food, food additives or food processing aids; natural mineral water or bottled drinking water; and packaging and tools in direct contact with food under the Ministry of Health's management (below referred to as establishments).

Article 2. Interpretation of terms

In this Circular, the terms below are construed as follows:

1. Small preliminary producer means an establishment growing, breeding, harvesting, catching or exploiting food materials on a household scale.

2. Small food trader means an establishment trading in food on a household scale with or without a food business registration certificate.

3. Street vendor means an establishment selling instant or cooked food on streets (without a fixed shop).

Chapter II

DOSSIERS, ORDER AND COMPETENCE TO GRANT CERTIFICATES

Article 3. Certificate application dossiers

A certificate application dossier must be bound

into a book, comprising the following documents:

1. Application for a certificate (made according to a set form).

2. Copy of the business registration certificate indicating the food business line, which is certified by the establishment.

3. Illustrations of physical foundations, facilities, equipment and tools meeting food safety requirements (certified by the establishment), comprising:

a/ Drawing of the site plan of the establishment and its surrounding areas;

b/ Diagram of the food production process or product preservation and distribution process and illustrations of the establishment's physical foundations, facilities, equipment and tools.

4. Written certification of food safety training for the establishment owner and employees directly engaged in food production and trading:

a/ For an establishment with less than 30 employees: To submit a copy of the certification (certified by the establishment);

b/ For an establishment with 30 employees or more: To submit a list of trained employees (certified by the establishment).

5. Health certificates of the establishment owner and employees directly engaged in food production and trading: notices of negative feces testing of intestinal diseases (cholera, dysentery and typhoid) of employees directly engaged in food production, for diarrhea-hit areas as announced by the Ministry of Health:

a/ For an establishment with less than 30

employees: To submit a copy of the certificate (certified by the establishment);

b/ For an establishment with 30 employees or more: To submit a list of health check-up results and feces testing results of the establishment owner and employees directly engaged in food production and trading (certified by the establishment).

Article 4. Competence to grant certificates

1. The Vietnam Food Administration shall grant certificates to:

Producers and traders of functional food, micronutrient-fortified food, food additives and food processing aids other than small producers and traders; and other food producers and traders at special request (request of countries importing products of these establishments).

2. Provincial-level food administrations shall grant certificates to:

a/ Producers and traders of natural mineral water or bottled drinking water, packaging materials and tools in direct contact with food under the health sector's management in their localities;

b/ Small producers of functional food, micronutrient-fortified food, food additives and food processing aids;

c/ Small traders of functional food, micronutrient-fortified food, food additives and food processing aids subject to special preservation requirements.

Article 5. Certificate grant procedures

Dossier-receiving agencies shall examine

dossiers, appraise establishments and grant certificates to eligible establishments. Certificate grant procedures are as follows:

1. Dossier examination:

a/ Within 5 working days after receiving a complete dossier, the dossier-receiving agency shall consider and examine the validity of that dossier and notify the establishment in writing if the dossier is invalid;

b/ Sixty days after receiving a notice of its dossier's invalidity, if the establishment fails to make response or supplement and complete the dossier as requested, the dossier-receiving agency shall cancel such dossier.

2. Establishment appraisal:

a/ If the dossier is valid according to the examination result, the competent agency shall appraise the establishment within 10 working days. In case of authorizing a competent subordinate agency to conduct appraisal, it shall make a written authorization:

b/ Establishment appraisal team:

- An establishment appraisal team is formed under the decision of an agency competent to grant certificates or an authorized agency;

- An establishment appraisal team consists of between 5 and 9 members (or between 3 and 5 members, for small food producers and traders) at least two-thirds of whom are food safety professionals (specialists with relevant expertise may be invited to join this team);

- The establishment appraisal team head shall take responsibility for the establishment appraisal results;

c/ Establishment appraisal contents:

To compare information and appraise the legality of the certificate application dossier against the original dossier filed by the establishment under regulations; to appraise food safety conditions at the establishment under regulations and make a written record according a set form.

3. Certificate grant:

a/ For an establishment satisfying food safety conditions under regulations, the dossier-receiving agency shall grant a certificate, made according to a set form. For a seasonal food producer or trader, the operation duration must be indicated in the certificate;

b/ For an establishment not yet satisfying food safety conditions and required to complete those conditions, the contents and time limit of such completion must be indicated, which must not exceed 60 days. The appraisal team shall conduct re-appraisal when the establishment makes a written certification of its completion of food safety conditions required by the appraisal team;

c/ For an establishment failing to satisfy food safety conditions, the dossier-receiving agency shall issue a notice to the local management agency for supervision and request the establishment not to operate until it obtains a certificate. The establishment shall re-submit a certificate application dossier under regulations.

Article 6. Renewal of certificates

1. A certificate may be renewed when:

a/ It remains valid; and,

b/ The enterprise's name and/or the

establishment owner changes or its address changes without change in the location and in the entire food production and trading process:

2. A dossier of application for renewal of a certificate (1 set) comprises the following documents certified by the establishment:

a/ Application for renewal of a certificate (made according to a set form);

b/ Copy of the latest appraisal record, which is certified by the establishment;

c/ Original certificate;

d/ Notarized copy of the lawful document proving the change;

e/ Health certificate and food safety and hygiene training certificate of the new establishment owner, for change of the establishment owner (copy certified by the establishment).

3. Within 7 working days after receiving a dossier of application for renewal of a certificate, the dossier-receiving agency shall renew a certificate for the establishment. In case of refusal, it shall issue a notice to the establishment stating the reason.

Article 7. Revocation of certificates

1. A certificate is revoked when:

a/ The producer or trader fails to commence operation in the registered food business line;

b/ A competent state agency issues a decision on transformation of business line of the establishment;

c/ The food producer or trader is deprived of the right to use the certificate under the law on

food safety-related administrative sanctioning.

2. Revocation competence:

a/ An agency having granted a certificate may revoke that certificate;

b/ A competent superior agency may revoke a certificate granted by its subordinate agency.

Article 8. Post-certificate grant inspection

Dossier-receiving agencies and competent functional agencies shall conduct post-certificate grant inspection:

1. Maximum twice a year for establishments having obtained certificates and GMP, HACCP, ISO 22000 or equivalent certificates granted by competent agencies.

2. Maximum three times a year for establishments having obtained certificates granted by competent agencies.

Chapter III

PROVISIONS APPLICABLE TO FOOD
PRODUCERS AND TRADERS NOT
REQUIRED TO OBTAIN CERTIFICATES

Article 9. Establishments not required to obtain certificates

Producers and traders of functional food, micronutrient-fortified food, food additives, food processing aids, mineral water, bottled drinking water and packaging and tools in direct contact with food under the Ministry of Health's management, including:

1. Small producers of functional food.
2. Small traders not subject to special product

preservation requirements.

3. Street vendors.

4. Traders of packaging not subject to special preservation conditions.

5. Traders of packaging and tools in direct contact with food.

Article 10. Inspection of establishments not required to obtain certificates

1. Establishments not required to obtain certificates shall make their own plans to conduct internal inspection and supervision of food safety conditions at least once a year.

2. Provincial-level food administrations and competent agencies shall inspect establishments not required to obtain certificates in their localities.

3. Inspection of establishments not required to obtain certificates is limited at four times a year.

Chapter IV

IMPLEMENTATION PROVISIONS

Article 11. Effect

1. This Circular takes effect on January 15, 2013.

2. To annul the Health Minister's Decision No. 11/2006/QĐ-BYT of March 9, 2006, promulgating the Regulation on grant of certificates of eligibility for food hygiene and safety for producers and traders of high-risk food, the effective date of this Circular.

Article 12. Organization of implementation

1. The Vietnam Food Administration - the

Ministry of Health shall guide the implementation of this Circular nationwide.

2. Provincial-level Health Departments and food administrations shall guide and organize the implementation of this Circular in their localities.-

For the Minister of Health
Deputy Minister
NGUYEN THANH LONG
