

I. GENERAL PROVISIONS

Article 1. Scope of regulation

1. This Circular stipulates the assay, circulation registration, advertisement, labeling and use of quick food test kits.

2. Before circulation in Vietnam, all quick food test kits, produced at home and produced overseas and imported into Vietnam (excluding those temporarily imported for re-export), must be granted circulation registration certificates and numbers by the Ministry of Health for testing food hygiene and safety assessment indicators.

Article 2. Subjects of application

This Circular applies to enterprises producing, trading in, importing or distributing testing chemicals and instruments (below referred to as enterprises) when they request circulation registration of quick food test kits in Vietnam.

Article 3. Interpretation of terms

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

1. A quick food test kit consists of tools, chemicals or culturing media which are ready-made and complete for testing one or several given food hygiene and safety indicators and giving a result within a shorter time compared to standard testing methods.

2. Circulation registration means a process of carrying out prescribed procedures for appraising the scientificity, practicality and preciseness of a quick test kit and the lawfulness of the dossier of request for registration in order to permit circulation by issuing a circulation registration certificate and number.

3. Assay means a process of experimentation to prove the actual properties of a quick food test kit.

THE MINISTRY OF HEALTH**Circular No. 13/2010/TT-BYT of May 12, 2010, guiding the management of quick food test kits**

Pursuant to the July 26, 2003 Ordinance on Food Hygiene and Safety;

Pursuant to the Government's Decree No. 163/2004/ND-CP of September 7, 2004, detailing a number of articles of the Ordinance on Food Hygiene and Safety;

Pursuant to the Government's Decree No. 188/2007/ND-CP of December 27, 2007, defining the functions, tasks, powers and organizational structure of the Ministry of Health;

The Ministry of Health guides the management of quick food test kits as follows:

Article 4. Charge and fee for circulation registration of quick food test kits

Enterprises shall pay charges and fees when registering for the circulation of quick food test kits under regulations of the Minister of Finance.

II. ASSAY OF QUICK FOOD TEST KITS

Article 5. Assay requirements

1. All quick food test kits must be assayed in Vietnam before they are registered for circulation on the Vietnamese market, except those mentioned in Clause 2 of this Article.

2. No re-assay is required for quick food test kits already accredited by WHO, FAO or JECFA or permitted for circulation by countries which have signed protocols on mutual recognition with Vietnam.

Article 6. Assay agencies

All technical units meeting conditions stipulated in Article 7 of this Circular may technically assay quick food test kits at the request of enterprises.

Article 7. Conditions on assay agencies

To conduct assay, an agency must meet the following conditions:

1. Having the function of testing food hygiene and safety;

2. Having a laboratory recognized to comply with ISO/IEC 17025 standards and operating in a domain in which it is recognized to have conducted food tests related to indicators to be assayed;

3. Having adequate equipment and professional personnel meeting assay requirements.

Article 8. Procedures for conducting assay

1. The Ministry of Health (the Food Safety Administration) shall annually announce a list of technical units capable of assaying the quality of quick food test kits for enterprises to select.

2. Enterprises shall bear all assay expenses under law.

3. Enterprises shall send to the Ministry of Health (the Food Safety Administration) written requests for consideration of assay results, enclosed with results of assays conducted by three technical units selected by themselves from the list of technical units annually announced by the Ministry of Health under Clause 1 of this Article.

4. After receiving complete dossiers stated in Article 10 of this Circular, the Food Safety Administration shall form an appraisal council to evaluate quick food test kits for advising the Director of the Food Safety Administration on considering and signing circulation registration certificates.

III. CIRCULATION REGISTRATION FOR QUICK FOOD TEST KITS

Article 9. Forms of circulation registration

1. Circulation registration: Enterprises shall submit dossiers of request under Clause 1 or 2, Article 10 of this Circular.

2. Registration of change or addition:

a/ For quick food test kits which already have circulation registration certificates, during the validity term of their certificates, approval of registration certificate-issuing agencies is required for change or addition of any of their registered contents;

b/ When changing or adding any of the following contents, an enterprise shall submit a dossier of request under Clause 1 or 3, Article 10 of this Circular; the registration certificate-

issuing agency shall consider keeping unchanged the circulation registration number and renewing the circulation certificate:

- Change of the registration-requesting enterprise;
- Change of the life time or preservation conditions;
- Change (addition) of label contents;
- Change of name of the kit;
- Change of scope of application;
- Change of limit of finding;
- Change (addition) of use instructions;
- Change of information on preciseness (or error);
- Change (addition) of composition of the kit and packaging specifications.

c/ When changing or adding any of the following registered contents, procedures shall be carried out as in the case of circulation registration; enterprises shall submit dossiers of request under Clause 1 or 2, Article 10 of this Circular; registration certificate-issuing agencies shall withdraw the issued permits and registration numbers and carry out procedures for considering the issuance of new ones:

- Change (addition) of testing indicators;
- Change of operational principles;
- Change of testing characteristics.

Article 10. Dossiers of request for circulation registration and registration of change or addition

1. An enterprise shall submit to the registration certificate-issuing agency 2 sets of dossier of request for circulation registration (below referred to as dossier). In such dossier, documents of legal validity must be originals or lawful copies while foreign-language documents must be accompanied by Vietnamese translations

already consularly legalized or notarized. A dossier must have a list of documents.

2. A dossier of request for circulation registration of a quick food test kit comprises:

- a/ A written request for circulation registration of a quick food test kit (made according to a set form);
- b/ The business registration certificate;
- c/ Documents on researches and tests related to the kit;
- d/ User manual attached to the kit;
- e/ Reports on assay results made by assay agencies;
- f/ Specimen labels of the kit, including the label directly on the smallest packaging unit and the label on the indirect package;
- g/ The certificates of protection of the trademark and intellectual property rights, and the paper of authorization by the manufacturer (if any);

h/ The permit for circulation in the manufacturing or exporting country, issued by a competent state agency of this country (for registration of imported kits);

i/ Three kits requested for circulation registration.

3. A dossier of request for change or addition of a registered content of a quick food test kit comprises:

- a/ A written request for change of a registered content of a kit (made according to a set form).
- b/ Documents related to the change or addition of the registered content.
- c/ Three kits requested for circulation registration.

Article 11. Competence and procedures for considering the issuance of certificates and

circulation registration numbers for quick food test kits

1. The Ministry of Health authorizes the Food Safety Administration to appraise dossiers and issue circulation registration certificates and numbers to quick food test kits.

2. The Food Safety Administration shall:

a/ Receive dossiers of request for registration;

b/ Form an appraisal council to evaluate the kit:

- To examine and evaluate and make conclusions on scientific grounds and practicality of the quick food test kit and advise the Ministry of Health (the Food Safety Administration) on considering and evaluating the kit;

- To propose the way of dealing with the request for circulation registration for the kit.

c/ On the basis of conclusions and proposals of the council, the Director of the Food Safety Administration shall decide to:

- Permit the circulation of a kit by issuing a circulation registration certificate (according to a set form) to the kit or renewing its certificate (for cases of change or addition);

- Request addition of information and documents before permitting circulation by notifying such in writing to the enterprise, clearly stating the request;

- Disallow the circulation registration by notifying such in writing to the enterprise, clearly stating the reason.

d/ Time limit for replying to enterprises:

- Thirty working days from the date of issuing a paper of appointment for receiving replies, for requests for circulation registration;

- Fifteen working days from the date of issuing a paper of appointment for receiving replies, for requests for change or addition of

registered contents.

3. A circulation registration certificate for a quick food test kit is valid for 5 years from the date of its signing. Three months before the certificate expires, an enterprise that wishes to make re-registration for further circulation in Vietnam shall submit a dossier for this purpose. Past six months from the date of expiration of this certificate, an enterprise that fails to submit a dossier for re-registration shall compile a dossier as in the case of new registration.

IV. TRADING IN, ADVERTISMENT, LABELING AND USE OF QUICK FOOD TEST KITS

Article 12. Trading in quick food test kits

1. Enterprises may trade in quick food test kits only after they obtain a circulation registration certificate.

2. Enterprises may only trade in quick food test kits of registered types that meet registered criteria.

3. Enterprises shall take responsibility for any harm caused by their quick food test kits that fail to meet registered criteria.

Article 13. Advertisement of quick food test kits

1. Enterprises may advertise quick food test kits only after obtaining circulation registration certificates for these kits.

2. Advertisements on quick food test kits must comply with the advertisement law.

Article 14. Labeling of quick food test kits

1. Labels of quick food test kits must comply with the current law on labeling of domestically circulated goods and imports and exports.

2. In addition, the compulsory contents of a

label are:

- a/ Circulation registration number;
- b/ Safety cautions in the circulation and use of the kit.

Article 15. Use of quick food test kits during the time of food hygiene and safety experimentation

Depending on the scope of application, quick food test kits may be used in the following cases:

1. Testing in support of food hygiene and safety examination and inspection work. Results of tests using a quick food test kit are just initial, helping screening and orienting subsequent affirmative tests in a laboratory. Results obtained from tests using a quick food test kit may not be used as a basis for handling violations;
2. Testing to help control hygiene and safety in the process of food production, processing and trading;
3. Testing to help consumers select food.

Article 16. Termination of circulation

1. Circulation of a quick food test kit shall be terminated under decision of the registration certificate-issuing agency when an enterprise commits any of the following violations:

- a/ Changing or adding a content specified in Article 9 of this Circular without approval of an administration agency;
- b/ Advertising information on a quick food test kit not true to the registered contents;
- c/ The quick food test kit circulated on the market is different from the registered sample or does not have registered properties.

2. The circulation registration-issuing agency shall decide to terminate circulation of the quick

food test kit and announce its decision nationwide.

3. Upon receiving the circulation termination decision, an enterprise shall:

- a/ Take without delay measures to recall the kits currently circulated on the market: from its agents and customers;
- b/ Make a recall dossier;
- c/ Report on recall results to the administration agency.

4. For a serious violation that affects product quality, the state management agency may consider withdrawing the circulation registration number.

5. An enterprise shall bear all expenses for recalling its quick food test kits.

V. IMPLEMENTATION PROVISIONS

Article 17. This Circular takes effect on July 1, 2010.

The Health Minister's Decision No. 18/2007/QĐ-BYT of February 27, 2007, on the management of quick food hygiene and safety tests, ceases to be effective on the effective date of this Circular.

Article 18. The Chief of the Office, the Director of the Food Safety Administration, the chief inspector and concerned units under the Ministry of Health, directors of provincial-level Health Departments, health agencies within all branches, and concerned agencies shall implement this Circular.-

For the Minister of Health
Deputy Minister
TRINH QUAN HUAN