

**Circular No. 28/2011/TT-BYT of June 24, 2011, amending and supplementing a number of articles of Circular No. 13/2010/TT-BYT of May 12, 2010, guiding the management of quick food test kits**

*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;*

*In performing the simplification of administrative procedures in the spirit of the Government's Resolution No. 62/NQ-CP of December 17, 2010, on simplification of administrative procedures under the Ministry of Health's management;*

*The Minister of Health issues the circular amending and supplementing a number of articles of Circular No. 12/2010/TTBYT of May 12, 2010, guiding the management of quick food test kits, as follows:*

**Article 1.** To amend and supplement a number of articles of Circular No. 12/2010/TTBYT of May 12, 2010, guiding the management of quick food test kits

**1. To amend and supplement Article 9 as follows:**

“**Article 9.** Forms of circulation registration; modified and supplemented circulation registration, and extension of circulation

registration of quick food test kits

1. Circulation registration of quick food test kits

Enterprises shall submit dossiers of request under Clause 1, Article 10 of this Circular.

2. Modified and supplemented circulation registration

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 supplementation 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 2, Article 10 of this Circular; the registration certificate-issuing agency shall consider retain the circulation registration number and the granted circulation registration certificate:

- Change of the life time or preservation conditions;
- Change (supplementation) of label contents;
- Change of scope of application;
- Change of limit of finding;
- Change (supplementation) of use instructions;
- Change of information on preciseness (or error);
- Change (supplementation) of packaging specifications.

c/ When changing or supplementing 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, Article 10 of this Circular; registration certificate-issuing agencies shall revoke the granted certificates and registration numbers and carry out procedures for considering the issuance of new ones:

- Change (supplementation) of testing indicators;
- Change of operational principles;
- Change of testing characteristics;
- Change of name of the quick test kit;
- Change of the enterprise requesting the registration.

3. Extension of circulation registration of quick food test kits

Within 3 months before the expiration of its circulation registration certificate, an enterprise shall submit a dossier of request for circulation registration extension according to Clause 3, Article 10 of this Circular if their quick food test kits continue being circulated in Vietnam.

Past that time limit, if the enterprise fails to complete procedures for extension, it shall submit a dossier of request for circulation registration under Clause 1, Article 10 of this Circular.”

**2. To amend and supplement Article 10 as follows:**



**“Article 10.** Dossiers of request for circulation registration and modified and supplemented circulation registration, or extension of circulation registration of quick food test kits

1. A dossier of request for circulation registration of a quick food test kit

An enterprise shall submit to the registration certificate-issuing agency 1 set of dossier of request for circulation registration (enclosed with a list of attached documents) which comprises:

a/ An application for circulation registration of a quick food test kit (made according to the form provided in Appendix I to this Circular);

b/ A copy of the business registration certificate (with the enterprise’s certification);

c/ Research and testing documents related to the quick food test kit. Foreign-language documents must be enclosed with their Vietnamese translations (with the enterprise’s certification);

d/ Instructions for use of the quick food test kit. Foreign-language use instructions must be enclosed with their Vietnamese translations (with the enterprise’s certification);

e/ Reports on results of testing of the quick food test kit of three technical units selected by the enterprise itself from the list of technical units annually announced by the Ministry of Health;

f/ One sample of labels of the quick food

test kit, including the direct label on the smallest package unit and the label on the indirect package (bearing the enterprise’s seal);

g/ A copy of the circulation permit in the country of manufacture or exportation, granted by a competent state agency of this country (for case of registration of an imported quick food test kit) and legalized by a consulate, in English or Vietnamese. For a circulation permit in another foreign language, it must be enclosed with its notarized Vietnamese translation;

h/ Two samples of the quick food test kit.

2. Dossiers of request for change or supplementation of registered contents of quick food test kits

When there is a change of or supplement to a content specified in Clause 2, Article 9 of this Circular, the enterprise shall submit to the certificate-issuing agency one dossier set (enclosed with a list of attached documents), which comprises:

a/ A written request for change of a content of the circulation registration of the quick food test kit (made according to the form provided in Appendix II to this Circular);

b/ A copy of the circulation registration certificate (including the first-time certificate and extended certificates);

c/ Documents related to the change or supplementation of the registered content. Foreign-language documents must be enclosed with their Vietnamese translations (with the enterprise’s certification);

d/ Two samples of the quick food test kit.

3. Dossiers of request for extension of circulation registration of quick food test kits

The enterprise shall submit to the certificate-issuing agency one dossier set of request for extension of the circulation registration (enclosed with a list of attached documents), which comprises:

a/ A written request for extension of the circulation registration certificate (made according to the form provided in Appendix III to this Circular);

b/ A copy of the circulation registration certificate (including the first-time certificate and extended certificates);

c/ One sample of the quick food test kit;

d/ Documents certifying the stability and special effect of at least one technical unit having used the quick food test kit.”

**3. To amend and supplement Article 11 as follows:**

“**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 examine 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/ Set up a specialized appraisal council to evaluate the kit:

- To examine, appraise 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 making 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 quick food test kit by issuing a circulation registration certificate to the kit or renewing its certificate (for cases of change or supplementation);

- 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 enterprises:

- Twenty working days after the date of submission of a valid dossier, for dossiers of circulation registration of quick food test kits;

- Ten working days after the date of submission of a valid dossier, for dossiers of modified and supplemented circulation registration of quick food test kits;

- Five working days after the date of submission of a valid dossier, for dossiers of registration of extension of quick food test kits.

3. Validity term of certificates of circulation registration of quick food test kits:

a/ A certificate of circulation registration of a quick food test kit is valid for 5 years after the date of its signing;

b/ A certificate of circulation registration of a quick food test kit may be extended many times with each extension valid for 5 years after the date of its signing;

c/ For quick food test kits already have certificates of circulation registration issued under the Minister of Health's Decision No. 18/2007/QĐ-BYT of February 27, 2007, promulgating the Regulation on management of quick testing of food hygiene and safety, enterprises shall carry out procedures for extending these certificates upon the expiration of their 5-year validity term.

**Article 2. Effect**

This Circular takes effect on August 10, 2011.-

*For the Minister of Health*  
Deputy Minister  
TRINH QUAN HUAN

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