

THE MINISTRY OF HEALTH

Circular No. 11/2013/TT-BYT of April 8, 2013, guiding the designation of regulation conformity certification organizations for prepackaged processed foods; food additives; food processing aids; and packagings and utensils in direct contact with foods

Pursuant to the June 29, 2006 Law on Standards and Technical Regulations, and the Government's Decree No. 127/2007/ND-CP of August 1, 2007, detailing the implementation of a number of articles of the Law on Standards and Technical Regulations;

Pursuant to the November 21, 2007 Law on Product and Goods Quality, and the Government's Decree No. 132/2008/ND-CP of December 31, 2008, detailing the implementation of a number of articles of the Law on Product and Goods Quality;

Pursuant to the June 17, 2010 Law on Food Safety, and the Government's Decree No. 38/2012/ND-CP of April 25, 2012, detailing the implementation of 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 Head of the Food Safety Department;

The Minister of Health promulgates the Circular to guide the designation of regulation conformity certification organizations for prepackaged processed foods; food additives;

food processing aids; and packagings and utensils in direct contact with foods.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

1. This Circular guides the requirements, order and procedures for designation of regulation conformity certification organizations for prepackaged processed foods; food additives; food processing aids; and packagings and utensils in direct contact with foods subject to relevant technical regulations (below referred to as products); responsibilities of receiving agencies and designated regulation conformity certification organizations.

2. In case treaties, conventions and agreements on mutual recognition between Vietnam and countries and territories concerning the recognition of conformity assessment results by designated conformity assessment organizations have provisions different from those of this Circular, provisions of such treaties, conventions and agreements prevail.

Article 2. Interpretation of terms

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

1. Designated regulation conformity certification organization is an organization meeting the requirements prescribed in Article 3 of this Circular and designated by the Ministry of Health to certify products conformable with respective technical regulations in order to serve state management.

2. The recognition of regulation conformity certification results means acceptance by competent state agencies, organizations and

individuals operating in Vietnam of results of regulation conformity certification performed by conformity assessment organizations of other countries or territories.

Chapter II

REQUIREMENTS, ORDER, PROCEDURES FOR REGISTRATION AND DESIGNATION OF REGULATION CONFORMITY CERTIFICATION ORGANIZATIONS

Article 3. Requirements for a designated regulation conformity certification organization

1. Having been established in accordance with law and having functions in the certification area.

2. Having registered and been granted a certificate of registration of certification activities by the Directorate for Standards, Metrology and Quality of the Ministry of Science and Technology in accordance with the law on product and goods quality.

3. Having at least five state payroll assessment experts (public employees or employees under contracts of a term of at least 12 months or labor contracts of an indefinite term) and satisfying the following requirements:

a/ Possessing a university or higher degree and having professional qualifications relevant to assessment and certification fields, of whom at least three have at least three years' work experience;

b/ Possessing certificates of annual training courses on food safety organized by the Food Safety Department.

4. Having sufficient technical materials and documents compliant with regulations applicable to to-be-certified products and a certification process relevant to applicable technical regulations.

Article 4. Order and procedures for registration of designation of regulation conformity certification organizations

1. When wishing to conduct regulation conformity certification for products, an organization meeting the requirements prescribed in Article 3 of this Circular shall compile a registration dossier and send 1 (one) set of dossier to the Food Safety Department of the Ministry of Health.

2. The registration dossier includes:

a/ A written request for designation of regulation conformity certification organization for products, made according to the form provided in Appendix 1 to this Circular;

b/ A copy of the establishment decision or the business registration certificate;

c/ A certificate of registration of certification field granted by the Directorate for Standards, Metrology and Quality of the Ministry of Science and Technology (a certified copy or a copy enclosed with the original for comparison);

d/ A list of assessment experts made according to the provided form in Appendix 2 to this Circular and their professional training certificates;

dd/ A certificate form;

e/ A list of technical materials, standards and technical regulations to products registered for designation, made according to the form provided in Appendix 3 to this Circular.

Article 5. Designation, redesignation, temporary suspension or revocation of decisions on the designation of regulation conformity certification organizations

1. The Food Safety Department shall manage the receipt and processing of dossiers of registration for designation of regulation conformity certification organizations, designate, redesignate, temporarily suspend and revoke decisions to designate organizations to make regulation conformity certification for products (below referred to as the receiving agency).

2. Within 30 working days after receiving a complete and valid dossier, the receiving agency shall examine the dossier and evaluate the real capability at site (if necessary) and issue a decision to designate a regulation conformity certification organization, made according to the form provided in Appendix 4 to this Circular.

In case of refusing the designation, the receiving agency shall notify in writing the the reason for refusal to the dossier-submitting organization.

3. Three months before the expiration of the decision on designation of a regulation conformity certification organization, the regulation conformity certification organization shall carry out procedures for re-registration prescribed in Article 4 of this Circular if it needs to be further designated.

4. In the course of operation, the designating agency shall periodically and irregularly inspect and supervise the certification agency's activities. When the certification organization violates the law, the designating agency shall

issue a decision to temporarily suspend the certification organization's activities until the certification organization remedies its violations. Within three months from the date of being temporarily suspended, if the certification organization fails to remedy its violations, the designating agency shall issue a decision to revoke the granted designation decision.

5. Six months after the designation decision is revoked, the certification organization may re-register its operation if it so wishes.

6. Information on the designation, re-designation, temporary suspension and revocation of decisions on the designation of regulation conformity certification organizations must be updated on the website of the Food Safety Department.

Chapter III

RESPONSIBILITIES OF THE RECEIVING AGENCY AND DESIGNATED REGULATION CONFORMITY CERTIFICATION ORGANIZATIONS

Article 6. Responsibilities of the receiving agency

1. To receive and process dossiers of registration for designation of regulation conformity certification organizations, designate, redesignate, temporarily suspend and revoke decisions to designate regulation conformity certification organizations.

2. To notify organizations and individuals of the list of designated regulation conformity certification organizations on its website within 3 (three) days from the date of signing designation decisions.

3. To manage, inspect and assess activities of designated regulation conformity certification organizations. To apply the methods prescribed in Clauses 4 and 5 of this Circular when a regulation conformity certification organization violates the provisions of this Circular or Article 20 of the Law on Product and Goods Quality.

4. To publicize the names of regulation conformity certification organizations designated, redesignated, temporarily suspended, or having their designation decisions revoked on its website and report to the Directorate for Standards, Metrology and Quality (the Ministry of Science and Technology) for coordinated management.

5. To review the situation and results of activities of designated regulation conformity certification organizations on a quarterly basis or at requests and report them to the Minister of Health and notify them to the Directorate for Standards, Metrology and Quality (the Ministry of Science and Technology) for coordinated management.

Article 7. Responsibilities of designated regulation conformity certification organizations

Apart from the responsibilities prescribed in Articles 19 and 20 of the Law on Product and Goods Quality, designated regulation conformity certification organizations shall:

1. Promptly report to the Food Safety Department on the narrowing of the scope or temporary suspension or revocation of their conformity certificates and the right to use regulation conformity seals.

2. Make quarterly or irregular reports when requested, to the Food Safety Department on results of their regulation conformity certification activities for products, according to the form provided in Appendix 5 to this Circular.

3. Report all changes affecting their regulation conformity certification capacity in the registered fields to the Food Security Department within fifteen (15) days after such changes occur.

Chapter IV

ORGANIZATION OF IMPLEMENTATION

Article 8. Effect

This Circular takes effect on May 23, 2013.

Article 9. Organization of implementation

1. The Ministry of Health assigns the Food Safety Department to guide and implement this Circular.

2. In necessary cases to meet the state management requirements, the Food Safety Department shall report to the Minister of Health for consideration and temporary designation of regulation conformity certification organizations that are not up to the requirements prescribed in Article 3 of this Circular.

Any problems arising in the course of implementation should be promptly reported to the Ministry of Health (the Food Safety Department) for consideration and settlement.-

For the Minister of Health

Deputy Minister

NGUYEN THANH LONG