THE MINISTRY OF HEALTH

Circular No. 19/2012/TT-BYT of November 9, 2012, guiding the regulation conformity announcement and food safety regulation conformity announcement

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 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 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 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 Ministry of Health promulgates the **Circular** guiding the regulation conformity announcement and food safety regulation conformity announcement.*

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular provides the order and dossiers for regulation conformity announcement and food safety regulation conformity announcement (below referred to as product announcement) for prepackaged processed food, food additives, food processing aids, packaging materials and tools in direct contact with food (below referred to as products); responsibilities of agencies receiving and registering regulation conformity announcement and food safety regulation conformity statements (below referred to as registration-receiving agencies) and product announcing organizations and individuals (below referred to as organizations and individuals); and post-product announcement inspection.

Article 2. Interpretation of terms

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

1. Food safety regulation conformity announcement means an organization's or individual's announcement that its/his/her product is conformable with food safety regulations, for products having no corresponding technical regulations.

2. Major quality norms means the levels or quantities of substances decisive to the nutritious value and typical properties of a product, which are used to identify, classify and distinguish the product from another food of the same type.

3. Detailed product information sheet means a document on technical requirements of a product (containing the same product name, brand, major quality norms and chemical, physical and microorganic standards) set and announced by an organization or individual as conformable with corresponding national technical regulations or with Vietnamese food safety regulations (in case such product has no technical regulations) or with regulations of the Codex Alimentarius Commission (Codex) in case Vietnamese regulations are not available.

4. Designated testing laboratory means a testing laboratory which is designated by a competent agency in Vietnam.

5. Accredited independent testing laboratory means a testing laboratory which is recognized by an accreditation institution and is independent from product makers.

6. Recognized testing laboratory means a product maker's testing laboratory which is recognized by an accreditation institution or a testing laboratory which is designated by a competent foreign agency.

Article 3. Contents of assessment of announced products' conformity with corresponding technical regulations or with food safety regulations

1. For assessment of conformity with corresponding technical regulations (below referred to as regulation conformity assessment) for announced products having technical regulations: Assessment contents applicable to each specific product are provided in corresponding technical regulations.

2. For assessment of conformity with food safety regulations (below referred to as food safety regulation conformity assessment) for products having no technical regulations: Assessment contents applicable to each specific product are based on food safety norms prescribed by the law on food safety. In case Vietnamese regulations are not available, Codex regulations apply.

Chapter II

ORDER AND DOSSIERS OF PRODUCT ANNOUNCEMENT

Article 4. Order and dossiers of regulation conformity announcement

1. Order of regulation conformity announcement

a/ Step 1: Regulation conformity assessment

Organizations or individuals may conduct regulation conformity assessment by themselves under Clause 1, Article 3 of this Circular and have their products tested at a designated, accredited independent or recognized testing laboratory; or through a regulation conformity certification institution designated by the Ministry of Health.

b/ Step 2: Registration of regulation conformity statements

An organization or individual makes and submits an announcement dossier under Clause 2 of this Article to a registration receiving agency provided in Article 7 of this Circular.

2. Regulation conformity announcement dossier:

a/ The papers and documents provided in Articles 5 and 7 of the Government's Decree No. 38/2012/ND-CP of April 25, 2012, detailing a number of articles of the Law on Food Safety (below referred to as Decree No. 38/2012/ND-CP);

b/ Particularly for product testing results: The product testing result issued by a designated, accredited independent or recognized testing laboratory within 12 months (the original or notarized copy together with the original for comparison, or consularly legalized copy), covering the norms required by corresponding technical regulations.

Article 5. Order and dossiers of food safety regulation conformity announcement

1. Order of food safety regulation conformity

announcement:

a/ Step 1: Food safety regulation conformity assessment

An organization or individual has its/his/her product tested at a designated, accredited independent or recognized testing laboratory; and assesses the product's conformity with food safety regulations based on testing results and under Clause 2, Article 3 of this Circular.

b/ Step 2: Registration of food safety regulation conformity statements.

An organization or individual makes and submits an announcement dossier under Clause 2 of this Article to a registration receiving agency provided for Article 7 of this Circular.

2. Food safety regulation conformity announcement dossier:

a/ The papers and documents provided in Articles 6 and 7 of Decree No. 38/2012/ND-CP;

b/ Particularly for product testing results: The product testing result issued by a designated, accredited independent or recognized testing laboratory within 12 months (the original or notarized copy together with the original for comparison or consularly legalized copy), covering major quality norms and safety norms.

c/ The product use testing result for functional food with new uses or processed from new substances or with new technology, which is marketed in Vietnam for the first time and has not been proved to be safe and effective.

Article 6. Announcement for products (other than functional food) imported for use only within production establishments, supermarkets or four-star or higher rank hotels

1. A product announcement dossier comprises:

a/ The product manifest:

For food materials, packaging materials and tools in direct contact with food imported for production only within enterprises: The product manifest complies with Form No. 2 attached to this Circular *(not translated)*.

- For food additives and food processing aids imported only for production within enterprises: The product manifest complies with Form No. 3 attached to this Circular *(not translated)*.

For food products imported only for business within supermarkets or four-star or higher-rank hotels: The product manifest complies with Form No. 4 attached to this Circular *(not translated)*.

b/ The business registration certificate (copy appended with the seal of the organization or individual)

c/ The product testing result within 12 months or detailed product information sheet of the manufacturer; or the product testing result of a designated, accredited independent or recognized testing laboratory.

2. Organizations or individuals shall make and

submit an announcement dossier provided in Clause 1 of this Article to a registration-receiving agency provided in Article 7 of this Circular.

Article 7. Competence to receive registration dossiers and grant receipts of regulation conformity statements and certificates of food safety regulation conformity announcement

1. The Ministry of Health assigns the Vietnam Food Administration to receive registration dossiers; grant receipts of regulation conformity statements (below referred to as receipts) and certificates of food safety regulation conformity announcement (below referred to as certificates) for functional food, food additives, food processing aids, and imported prepackaged processed food, packaging materials and tools in direct contact with food; and make written certification of products (other than functional food) imported for use only within production establishments, supermarkets and four-star or higher rank hotels.

2. Provincial-level Health Departments assign provincial-level Food Administrations to receive registration dossiers and grant receipts and certificates for domestic prepackaged processed food (other than functional food), packaging materials and tools in direct contact with food produced or traded by organizations and individuals based in their localities.

3. For domestic products for export, their statements may be registered at the Vietnam Food Administration or provincial-level Food Administrations of the localities in which organizations or individuals are headquartered when so requested by importing countries.

4. For products of the same quality for which a single organization or individual takes responsibility, which are produced in 2 (two) or more provinces or cities, their statements may be registered at the Vietnam Food Administration or the provincial-level Food Administration of the locality in which such organization or individual is headquartered.

5. The registration-receiving agencies provided in Clauses 1 and 2 of this Article shall receive registration dossiers and grant receipts and certificates in accordance with Clauses 3, 4 and 5, Article 4 of Decree No. 38/2012/ND-CP.

Within 2 (two) months after receiving a notice of the reason for not issuing a receipt and certificate from a registration-receiving agency, if an organization or individual fails to supplement and complete the dossier as requested, the registration receiving agency shall cancel such dossier.

6. Registration-receiving agencies shall grant and manage serial numbers of receipts and certificates.

a/ Receipts and certificates granted by the Vietnam Food Administration will be respectively presented in the following order: serial number/year of grant/ATTP-TNCB and serial number/year of grant/ATTP-XNCB.

b/ Receipts and certificates granted by

provincial-level Food Administrations will be respectively written in the following order: serial number/year of grant/YT+abbreviated name of province or city-TNCB; and serial number/year of grant/YT+abbreviated name of province or city-XNCB.

Rules on abbreviation of names of provinces and cities in receipts and certificates are provided in Form No. 5 attached to this Circular *(not translated)*.

Article 8. Announcement for food additives and food processing aids

1. For food additives and food processing aids on the Ministry of Health-promulgated list of substances permitted for use, organizations and individuals shall announce products in accordance with Articles 4, 5, 6 and 7 of this Circular.

2. For food additives and food processing aids outside Vietnam's list of substances permitted for use; products containing food additives and food processing aids outside Vietnam's list of substances permitted for use but on the list under Codex's regulations or permitted for use in countries of manufacture, the Vietnam Food Administration shall consider permission for product announcement.

Article 9. Re-grant of receipts and certificates

1. Receipts and certificates may be re-granted in accordance with Article 8 of Decree No. 38/2012/ND-CP by competent state agencies which have granted receipts and certificates for the first time for those products.

2. If organizations or individuals file requests re-grant of receipts and certificates for products fail to fully and properly implement the periodical testing regime, registration-receiving agencies shall inspect their production and business establishments. Based on violation handling results and remedial actions, registration-receiving agencies shall decide on re-grant or re-announcement.

Chapter III

RESPONSIBILITIES OF REGISTRATION-RECEIVING AGENCIES AND ORGANIZATIONS AND INDIVIDUALS

Article 10. Responsibilities of registration-receiving agencies

A registration-receiving agency has the following rights and responsibilities:

1. To receive regulation conformity announcement or food safety regulation conformity announcement dossiers of organizations and individuals.

2. To grant and re-grant receipts and certificates according to the time limits provided in Clauses 3, 4 and 5, Article 4 of Decree No. 38/2012/ND-CP.

3. Within 7 (seven) working days after granting a receipt or certificate, to notify products

obtaining such receipt or certificate on its website.

4. To append its seal on every two adjoining pages of detailed product information sheets and on product labels to certify compulsory labeling contents in accordance with law. Such seal appending is not valid for certification of industrial property. To return organizations and individuals a product dossier set and file dossiers under regulations.

5. To manage and use collected fees and charges for the grant of receipts and certificates under the Ministry of Finance's guidance.

Article 11. Responsibilities of organizations and individuals

Organizations or individuals have the following rights and responsibilities:

1. To announce and re-announce products at registration-receiving agencies provided in Article 7 of this Circular; to fully pay fees and charges in accordance with law.

2. To control quality and food safety of their own products. To implement the periodical inspection and testing regime under regulations and take full responsibility for conformity of announced products.

3. To clearly announce product names which properly reflect product nature (ingredients, uses, processing technology). A product name which does not clearly reflect the product nature must be accompanied by the name of the product group and compulsory labeling contents.

4. To submit official labels one (1) month after obtaining a receipt or certificate, if they have only submitted the draft labeling contents upon announcement.

5. When detecting a product which violates the law on product quality and food safety or is untruthfully labeled, advertised or announced:

a/ To promptly report on the product's unconformity to competent state management agencies and the registration-receiving agency;

b/ To remedy such unconformity

c/ When necessary or so requested by competent state management agencies, to suspend production and rolling out of and recall unconformable products currently circulated in the market;

d/ To report to competent state management agencies and the registration-receiving agency on results of remedying such inconformity before resuming the production and trading of that product.

6. To keep product announcement dossiers according to prescribed time limits as a basis for examination and inspection or for proving conformity of their products with announced and committed contents of the dossiers.

7. In case of changing label appearance, packing method, quality indicators, optional labeling contents, office addresses of

organizations or individuals or places of production, names of organizations or individuals (in case of changing business registration certificate), to submit a written request for supplementation together with the certification of changed and supplemented contents of organizations or individuals responsible for products in order to retain the serial numbers of granted or re-granted receipts or certificates.

Chapter IV

POST-PRODUCT ANNOUCEMENT INSPECTION

Article 12. Post-announcement inspection

Registration receiving agencies and provincial-level Food Administrations of localities in which production and business establishments are based are competent to inspect the implementation of the law on food safety and periodical testing regime with respect to announced products of these establishments.

Article 13. Sampling for periodical testing

1. The periodical testing regime is provided as follows:

a/ Once a year, for products of establishments possessing a certificate of one of the following advanced quality control systems: GMP, HACCP, ISO 22000 or equivalent.

b/ Twice a year, for products of establishments without a certificate of the above systems.

2. Sampling for periodical testing shall be conducted by organizations or individuals or by competent agencies as requested by organizations or individuals.

3. Indicators to be periodically tested are major quality norms announced in the detailed product information sheet or on the label of the marketed product; and a number of chemical, physical and microorganic indicators announced in the detailed production information sheet or prescribed by law.

4. Organizations and individuals may use testing results of irregular and periodical inspection and examination teams or results of state examination of imported food safety as results of periodical testing if meeting the requirements provided in Clause 3 of this Article.

Chapter V

IMPLEMENTATION PROVISIONS

Article 14. Transitional provision

Product standard certificates granted under the Health Ministry's Decision No. 42/2005/QD-BYT of December 8, 2005, issuing the regulation on announcement of food product standards, remain valid till the end of their validity duration.

Article 15. Effect

1. This Circular takes effect on December 25, 2012.

2. The Health Ministry's Decision No. 42/2005/QD-BYT of December 8, 2005, issuing the regulation on announcement of food product standards, ceases to be effective on the effective date of this Circular.

Article 16. Organization of implementation

1. The Ministry of Health assigns the Vietnam Food Administration to organize and examine the implementation of this Circular nationwide.

Biannually, the Vietnam Food Administration shall report on the grant of receipts and certificates to the Minister of Health.

2. Provincial-level Health Departments assign provincial-level Food Administrations to organize and examine the implementation of this Circular within their localities.

Provincial level Food Administrations shall monthly report on the grant of receipts and certificates to provincial level Health Departments and the Vietnam Food Administration.-

For the Minister of Health
Deputy Minister
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