

## **DECREE**

### **Detailing a number of articles of the Law on Food Safety<sup>1</sup>**

*Pursuant to the June 19, 2015 Law on Organization of the Government;*

*Pursuant to the June 17, 2010 Law on Food Safety;*

*At the proposal of the Minister of Health;*

*The Government promulgates the Decree detailing a number of articles of the Law on Food Safety.*

#### Chapter I

#### GENERAL PROVISIONS

##### **Article 1.** Scope of regulation

This Decree details a number of articles of the Law on Food Safety regarding:

1. Procedures for product self-declaration.
2. Procedures for registration of product declarations.
3. Assurance of safety of genetically modified foods.
4. Grant of certificates of food safety eligibility.
5. State inspection of safety of imported and exported foods.
6. Food labeling.
7. Food advertisement.
8. Food safety conditions in the production of health supplements.
9. Food safety conditions in the production, trading and use of food additives.

10. Tracing of food origin.

11. Assignment of state management responsibilities for food safety.

**Article 2. Subjects of application**

This Decree applies to Vietnamese agencies, organizations and individuals; foreign organizations and individuals engaged in food production and trading in Vietnam; and organizations and individuals carrying out food safety-related activities in Vietnam (below collectively referred to as organizations and individuals).

**Article 3. Interpretation of terms**

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

1. Dietary supplement (or health supplement) means a product used as a supplement to the daily diet to maintain, reinforce and improve the functions of human body and reduce risks of suffering disease. A dietary supplement may contain one or more of the following substances or mixtures thereof:

a/ Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other biologically active substances;

b/ Substances derived from animals, minerals and plants in the form of extracts, isolates, concentrates or metabolites;

c/ Substances synthesized from the ingredients referred to at Points a and b above.

Dietary supplements may take the form of soft gel, pellet, tablet, granule, powder, liquid and other dosage forms divided (for use) into small doses.

2. Medical food, also called food for special medical purposes, means a food that can be consumed orally or with a feeding tube, prescribed to regulate the patient's diet, and that may be used only under medical supervision.

3. Food for special dietary uses means a food for people on a diet, elderly people and other special people defined by the Codex Committee, processed or formulated according to a special formula to satisfy particular dietary requirements based on a particular physical or pathological conditions and specific disorders of the user. The composition of this food must differ significantly from that of ordinary foods of the same nature, if any.

4. Scientific evidence means scientific information and documents from scientific researches accepted by competent state management

agencies in charge of scientific research or published in Vietnamese or foreign science journals, or documents on traditional medicine and herbal plants or medicaments published in science publications.

5. Goods owner means an organization or individual responsible for the goods specified in the dossier of product declaration or self-declaration, or an organization or individual authorized to import or export food products.

6. Imports or exports are food products of the same category and having the same name, label, producer and packaging material.

7. Import or export lot means the entire food products of an export or import shipment (transported under the same bill of lading). A lot may comprise one or more than one type of goods.

8. Small food producer means a household or individual that cultivates, raises, gathers, fishes or exploits food materials with or without an enterprise registration certificate.

9. Small food processor means a household or individual that preliminarily processes food with or without an enterprise registration certificate.

10. Small food trader means an individual, a group of individuals or a household that has been registered as a business household or does not have a business registration certificate, an enterprise registration certificate or an investment certificate as prescribed by law.

## Chapter II

### PROCEDURES FOR PRODUCT SELF-DECLARATION

#### **Article 4.** Product self-declaration

1. Food producers and food traders shall self-declare prepackaged processed foods, food additives, food processing aids, food containers and primary packages of foods (below collectively referred to as products) other than the products specified in Clause 2 of this Article, and Article 6, of this Decree.

2. Products and materials that are produced or imported only for export production or processing or internal production and are not sold on the domestic market are exempted from self-declaration.

#### **Article 5.** Product self-declaration dossiers and procedures

1. A product self-declaration dossier must comprise:

a/ The product self-declaration, made according to Form No. 01 in Appendix I to this Decree;

b/ The original or a certified copy of the food safety testing result sheet issued no more than 12 months up to the date of submission of the dossier, made by a designated testing laboratory or a testing laboratory accredited to comply with ISO 17025, showing safety indicators prescribed by the Ministry of Health according to risk management principles in conformity with international regulations or safety indicators up to relevant regulations or standards declared by the dossier submitter if relevant regulations of the Ministry of Health are not available.

2. Product self-declaration shall be made according to the following procedures:

a/ A food producer or trader shall publish its self-declaration in the mass media or on its website or publicly post it at its head office and submit 1 (one) self-declaration by post or directly to the competent state management agency designated by the People's Committee of the province or centrally run city (below referred to as provincial-level People's Committee);

b/ Right after making the self-declaration, the food producer or trader may produce and/or trade in the product and take full responsibility for the safety of such product;

c/ The competent state management agency shall receive the self-declaration for preservation and post the name of the food producer or trader and name of the product stated in the self-declaration on its website.

If the food producer or trader has 2 (two) or more factories that produce the same product, it/he/she may submit the self-declaration dossier to the state management agency of only one of the localities where is located one of these factories. Subsequent self-declaration dossiers shall be submitted to the selected agency only.

3. Documents in a self-declaration dossier shall be written in Vietnamese; for documents in a foreign language, their notarized Vietnamese translations are required. These documents must remain valid at the time of self-declaration.

4. In case there is any change in a product's name, origin or ingredients, a food producer or trader shall submit another self-declaration. For other changes, a food producer or trader shall submit a written notice of such change to a competent state management agency

and may produce and/or trade in the product after sending the notice.

### Chapter III

#### PROCEDURES FOR REGISTRATION OF PRODUCT DECLARATIONS

##### **Article 6.** Registration of product declarations

Food producers or traders shall register declarations for the following products:

1. Dietary supplements, medical foods, and foods for special dietary uses.
2. Dietary products for children up to 36 months old.
3. Mixed food additives with new uses, food additives that are outside the list of food additives permitted for use or are not used for intended users prescribed by the Ministry of Health.

##### **Article 7.** Dossiers for registration of product declarations

1. A dossier for registration of the declaration of imported products must comprise:

a/ The product declaration, made according to Form No. 02 in Appendix I to this Decree;

b/ The consularly legalized certificate of free sale, certificate of exportation or health certificate issued by a competent agency of the country of origin/exporting country, which assures safety for users or permits free sale of the product in the market of the country of origin/exporting country;

c/ The original or a certified copy of the food safety testing result sheet issued no more than 12 months up to the date of submission of the dossier by a designated testing laboratory or a testing laboratory accredited to comply with ISO 17025, showing safety indicators prescribed by the Ministry of Health according to risk management principles in conformity with international regulations or safety indicators up to relevant regulations or standards declared by the food producer or trader if relevant regulations of the Ministry of Health are not available;

d/ Scientific evidence proving the declared effects of the product or ingredients (the original documents or copies certified by the dossier submitter). If scientific evidence on the effects of the ingredients of the product is used, the daily dose of the product must be greater than or

equal to 15% of the content of such ingredients mentioned in the documents;

dd/ The certificate of good manufacturing practice (GMP) or an equivalent certificate if the imports are dietary supplements, to be required as from July 1, 2019 (a copy certified by the food producer or trader).

2. A dossier for registration of the declaration of domestically made products must comprise:

a/ The product declaration, made according to Form No. 02 in Appendix I to this Decree;

b/ The original or a certified copy of the food safety testing result sheet issued no more than 12 months by the date of submission of the dossier by a designated testing laboratory or a testing laboratory accredited to comply with ISO 17025, showing safety indicators prescribed by the Ministry of Health according to risk management principles in conformity with international regulations or safety indicators up to relevant regulations or standards declared by the food producer or trader if relevant regulations of the Ministry of Health are not available;

c/ Scientific evidence proving the effects of the product or ingredients (the original documents or copies certified by the dossier submitter). If scientific evidence on the effects of the ingredients of the product is used, the daily dose of the product must be greater than or equal to 15% of the content of such ingredients mentioned in the documents;

d/ The certificate of food safety eligibility in case the food producer or trader is required to have this certificate (a copy certified by the food producer or trader);

dd/ The certificate of good manufacturing practice (GMP) if the domestically made products are dietary supplements, to be required as from July 1, 2019 (a copy certified by the food producer or trader).

3. The documents in a dossier for registration of the product declaration shall be written in Vietnamese; for documents in a foreign language, their notarized translations are required. Documents must remain valid at the time of submission of the dossier.

#### **Article 8.** Procedures for registration of product declarations

1. A food producer or trader shall submit a dossier for registration of the product declaration via the online public service system, by post or directly to the following agency:

a/ The Ministry of Health, for declarations of dietary supplements, mixed food additives with new uses, and food additives that are outside the list of food additives permitted for use as prescribed by the Minister of Health;

b/ A competent state management agency designated by the provincial-level People's Committee, for medical foods, food for special dietary uses and dietary products for children up to 36 months old;

c/ In case a producer produces many types of products falling within the competence of both the Ministry of Health and a competent state management agency designated by the provincial-level People's Committee, it/he/she may submit a dossier to either of them.

If the food producer has 2 (two) or more factories that produce the same product, it/he/she may submit the declaration dossier to the state management agency of only one of the localities where is located one of these factories (except the products to be registered with the Ministry of Health). Subsequent dossiers for registration shall be submitted to the selected agency only.

2. Within 7 (seven) working days after receiving a complete dossier for registration of the declaration of mixed food additives with new uses, food additives that are outside the list of food additives permitted for use or are not used for intended users as prescribed by the Minister of Health, medical foods, foods for special dietary uses, and dietary products for children up to 36 months old, or 21 working days for dietary supplements, the dossier-receiving agency specified in Clause 1 of this Article shall appraise the dossier and issue a receipt of the registration of the product declaration, made according to Form No. 03 in Appendix I to this Decree.

The time limit for dossier appraisal shall be counted from the time of submission of the dossier in the online public service system or the incoming mail stamp of the dossier-receiving agency (for dossiers submitted by post or directly).

3. If the dossier-receiving agency rejects the product declaration dossier or requests its modification and supplementation, it shall issue a written request stating the reason and legal basis for such request. The dossier-receiving agency may request modification and supplementation only once.

Within 7 (seven) working days after receiving the modified and supplemented dossier, the dossier-receiving agency shall appraise it and issue a written reply. If the dossier submitter fails to modify and

supplement the dossier after 90 working days from the date it/he/she receives a written request, the dossier will become invalid.

4. In case there is any change in a product's name, origin or ingredients, the food producer or trader shall submit another declaration. For other changes, the food producer or trader shall submit a written notice of such change to the dossier-receiving agency specified in Clause 1 of this Article and may produce and/or trade in the product right after sending the notice.

5. The agency that receives a dossier for registration of a product declaration shall publicly post on its website and update in the food safety database the names and products of food producers or traders whose product declarations have been registered.

6. Food producers and traders shall pay a fee for appraisal of dossiers for registration of product declarations in accordance with the law on charges and fees.

#### Chapter IV

#### ASSURANCE OF SAFETY OF GENETICALLY MODIFIED FOODS

**Article 9.** Assurance of safety of foods with ingredients derived from genetically modified organisms and products thereof

The conditions, order and procedures for grant and revocation of certificates of eligibility of genetically modified organisms for use as foods and the list of genetically modified organisms granted such certificates must comply with the Government's Decree No. 69/2010/ND-CP of June 21, 2010, on biosafety for genetically modified organisms and genetic specimens and products thereof, and Decree No. 108/2011/ND-CP of November 30, 2011, amending a number of articles of Decree No. 69/2010/ND-CP.

**Article 10.** Labeling of goods containing genetically modified organisms and products thereof used as foods

1. Producers and traders of foods containing genetically modified organisms and products thereof at least one of which exceeds 5% of the total ingredients shall, in addition to complying with the law on goods labeling, display information about the genetically modified organisms on the goods label, except the cases specified in Clause 2 of this Article.

2. Labeling of goods containing genetically modified organisms and products thereof used as foods shall be exempted in the following cases:

a/ Prepackaged genetically modified foods containing genetically modified ingredients in which no modified gene or product thereof is found;

b/ Fresh genetically modified foods and unpackaged processed genetically modified foods sold directly to consumers;

c/ Genetically modified foods used in cases of emergency to cope with natural disasters or epidemics.

## Chapter V

### GRANT OF CERTIFICATES OF FOOD SAFETY ELIGIBILITY

#### **Article 11.** Grant of certificates of food safety eligibility

1. Food production or trading establishments must have a certificate of food safety eligibility when operating, except those specified in Clause 1, Article 12 of this Decree.

2. The conditions for grant of a certificate of food safety eligibility are prescribed in Clause 1, Article 34 of the Law on Food Safety. Particularly, establishments producing dietary supplements must satisfy the requirements specified in Article 28 of this Decree.

**Article 12.** Establishments not required to possess a certificate of food safety eligibility

1. A certificate of food safety eligibility is not required for establishments that:

a/ Produce foods on a small scale;

b/ Produce or trade in foods without a fixed place;

c/ Process foods on a small scale;

d/ Trade in foods on a small scale;

dd/ Trade in prepackaged foods;

e/ Produce and trade in food packages and containers;

g/ Are restaurants within hotels;

h/ Are collective kitchens without food trading registration;

i/ Are street food vendors;

k/ Have one of the following certificates: GMP, HACCP, ISO 22000, IFS, BRC, FSSC 22000 or an equivalent certificate, which remains valid.

2. The establishments specified in Clause 1 of this Article must satisfy corresponding food safety requirements.

## Chapter VI

### STATE INSPECTION OF SAFETY OF IMPORTED AND EXPORTED FOODS

**Article 13.** Imported foods exempted from state inspection of food safety (unless there is a food safety warning)

1. Products that have a receipt of the registration of the product declaration.

2. Foods in hand luggage of people on entry, foods sent before or after the entry of people to serve their daily-life needs or trips; gifts and presents within import duty-free allowances in accordance with the laws on taxes.

3. Imports serving personal needs of people eligible for diplomatic privileges and immunities.

4. Products in transit or border-gate transfer, transshipped, temporarily imported for re-export or stored in bonded warehouses.

5. Products for use as testing or research samples in a quantity suitable to the testing or research purpose, as certified by the related organization or individual.

6. Products for display at exhibitions or fairs.

7. Products and materials that are produced or imported for export production or processing only or internal production and are not sold in the domestic market.

8. Products temporarily imported for sale at duty-free shops.

9. Goods imported for emergency purposes under instructions of the Government or Prime Minister.

**Article 14.** Requirements for products derived from terrestrial animals, aquatic animals and plants imported for use as foods

1. Products derived from terrestrial animals, aquatic animals and plants imported for use as foods, except those that have been processed or prepackaged or exported by Vietnamese organizations or individuals then returned and those in the cases specified in Article 13 of this Decree, must satisfy the following requirements:

a/ They originate from a country or territory that has a food safety control system complying with Vietnam's regulations and is included by a competent Vietnamese agency in the list of countries and territories having registered to export foods derived from terrestrial animals, plants and aquatic animals to Vietnam;

b/ Products derived from terrestrial animals or aquatic animals imported for use as foods are produced by production or trading establishments that are recognized by a competent Vietnamese agency to satisfy all food safety requirements prescribed by Vietnam;

c/ Each imported lot of products derived from terrestrial animals or aquatic animals has a certificate of compliance with food safety regulations issued by a competent agency of the exporting country (except aquatic animals caught and processed by foreign fishing vessels and sold directly to Vietnam).

2. Procedures for registration of countries and territories and production and trading establishments referred to in Clause 1 of this Article in the list of those permitted to export the above-said products to Vietnam are prescribed in Article 22 of this Decree.

3. The Ministry of Agriculture and Rural Development shall provide customs offices with the list of countries and territories and organizations and individuals permitted to export the above-said products to Vietnam.

**Article 15.** Agencies performing state inspection of imported foods

1. Agencies performing state inspection of imported foods are those assigned or designated by the Ministry of Health, the Ministry of Agriculture and Rural Development or the Ministry of Industry and Trade.

In case an imported lot comprises different types of foods falling under the management of more than one ministry, the Ministry of Agriculture and Rural Development shall assign or designate an agency to perform state inspection of such lot.

2. A state inspection agency has the following powers and responsibilities:

a/ To decide to switch from normal inspection to reduced inspection and to apply normal inspection after 3 (three) tightened inspections show satisfactory results;

b/ To carry out food inspections according to the methods and procedures specified in this Decree;

c/ To take and keep samples in accordance with law;

d/ To collect testing and inspection charges and fees in accordance with the law on charges and fees;

dd/ To ensure professional standards, accuracy, honesty and objectivity of the inspection and certification of food safety of imported lots and goods;

e/ To comply with organizational and professional instructions, inspections and guidance of the Ministry of Health, the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade;

g/ To receive and settle complaints of goods owners. To refund all testing and inspection charges and pay compensation if causing any damage to goods owners in accordance with law;

h/ To preserve inspection documents in accordance with law and produce them at the request of competent agencies;

i/ To send biannual reports to the related line ministry, made according to Form No. 06 in Appendix I to this Decree, and extraordinary reports when there is a warning issued by the Ministry of Health, the Ministry of Agriculture and Rural Development or the Ministry of Industry and Trade of Vietnam or a competent foreign authority or the producer, or reports on disposal of imported foods that fail to comply with requirements.

#### **Article 16.** Inspection methods

Safety inspection of imported foods shall be conducted according to one of the following methods:

1. Reduced inspection, whereby document inspection shall be conducted of up to 5% of the total number of lots imported within 1 year randomly chosen by the customs office.

2. Normal inspection, whereby only document inspection shall be conducted of imported lots.

3. Tightened inspection, whereby both document inspection and sample taking shall be conducted.

#### **Article 17.** Application of inspection methods

1. Reduced inspection shall be applied to imported lots and goods falling into one of the following cases:

a/ They have a certificate of food safety eligibility issued by a competent agency or organization of a country that has concluded a mutual recognition agreement regarding food safety inspection to which Vietnam is a contracting party; and have an inspection result issued by a

competent agency of the exporting country which is compliant with Vietnam's law;

b/ The results of their 3 (three) consecutive normal inspections conducted within 12 months are satisfactory;

c/ They are produced by establishments that apply either GMP, HACCP, ISO 22000, IFS, BRC, FSSC 22000 or an equivalent system.

2. Normal inspection shall be applied to all goods of imported lots, except the cases specified in Clauses 1 and 3 of this Article.

3. Tightened inspection shall be applied to imported goods and lots falling into one of the following cases:

a/ The result of their previous inspection is not satisfactory;

b/ They fail to meet requirements during inspections (if any);

c/ A warning is issued by the Ministry of Health, the Ministry of Agriculture and Rural Development, the Ministry of Industry and Trade, a provincial-level People's Committee or a competent authority of a foreign country or the producer.

4. Tightened inspection shall be switched to normal inspection in:

a/ The cases specified at Points a and b, Clause 3 of this Article, if the results of 3 (three) consecutive tightened inspections are satisfactory;

b/ The case specified at Point c, Clause 3 of this Article, the Ministry of Health, the Ministry of Agriculture and Rural Development or the Ministry of Industry and Trade of Vietnam issues a notice of cessation of tightened inspection.

#### **Article 18.** Dossier for registration of inspection

1. A dossier for registration of reduced inspection must comprise:

a/ The product self-declaration;

b/ Three notices of satisfactory results of three consecutive normal inspections, or a certified copy or consularly legalized original of the GMP, HACCP, ISO 22000, IFS, BRC or FSSC 22000 certificate or an equivalent certificate that remains valid at the time of submission of the dossier;

c/ For products derived from aquatic animals or terrestrial animals, except processed or prepackaged ones, the original of the certificate of compliance with food safety requirements issued by a competent authority of the exporting country.

2. A dossier for registration of normal inspection or tightened inspection must comprise:

a/ The written registration for inspection of imported foods, made according to Form No. 04 in Appendix I to this Decree;

b/ The product self-declaration;

c/ Three original notices of satisfactory results of three consecutive tightened inspections, for imported lots or goods eligible for switch from tightened inspection to normal inspection;

d/ A copy of the packing list;

dd/ For the products mentioned in Article 14 of this Decree, the original of the certificate of compliance with food safety requirements issued by a competent authority of the exporting country, except aquatic animals caught and processed by foreign fishing vessels and directly sold to Vietnam.

### **Article 19.** Procedures for inspection of imported foods

#### 1. Procedures for reduced inspection:

a/ When carrying out customs procedures, the goods owner shall submit a dossier made according to Clause 1, Article 18 of this Decree;

b/ The customs office shall randomly choose up to 5% of the total lots imported within 1 (one) year for dossier inspection under regulations.

Within 3 (three) working days after receiving the dossier, the customs office shall inspect it and permit customs clearance for the goods. If requesting supplementation of the dossier, it shall clearly state the reason and legal basis for its request.

#### 2. Procedures for normal inspection:

a/ Before or when the goods arrive at the border gate, the goods owner shall submit a dossier of registration for inspection made according to Clause 2, Article 18 of this Decree to the related state inspection agency or the Vietnam National Single Window's sub-system of the Ministry of Health, the Ministry of Agriculture and Rural Development or the Ministry of Industry and Trade (if applied);

b/ Within 3 (three) working days after receiving the dossier, the state inspection agency shall examine it and issue a notice of whether the inspection result is satisfactory, made according to Form No. 05 in Appendix I to this Decree. If requesting supplementation of the dossier, it shall clearly state the reason and legal basis for its request;

c/ The goods owner shall submit the notice of satisfactory inspection result to the customs office for customs clearance.

#### 3. Procedures for tightened inspection:

a/ The same as Point a, Clause 2 of this Article;

b/ Within 7 (seven) working days after receiving the dossier, the state inspection agency shall examine it and take samples and test them according to food safety indicators as required and issue a notice of whether the inspection result is satisfactory, made according to Form No. 05 in Appendix I to this Decree. If requesting supplementation of the dossier, it shall clearly state the reason and legal basis for its request;

c/ The goods owner shall submit the notice of satisfactory inspection result to the customs office for customs clearance.

4. If the inspection result is not satisfactory in the case specified at Point b, Clause 2, or Point b, Clause 3, of this Article, the state inspection agency shall take appropriate measures prescribed in Clause 3, Article 55 of the Law on Food Safety and send a report on disposal of foods that fail to satisfy import requirements to the related line ministry.

**Article 20.** Disposal of foods that fail to satisfy import requirements

1. After completely disposing of foods that fail to satisfy import requirements under a decision of the state inspection agency, the goods owner shall submit one of the following documents to the state inspection agency and the agency that received the product declaration dossier:

a/ Re-export documents in case of re-export;

b/ The destruction record certified by a competent agency;

c/ The transfer contract between the goods owner and the buyer or transferee of the goods. The buyer or transferee of the goods may not use them as foods.

2. If wishing to import the products into Vietnam after completely remediating the products' flaws or their label errors, the goods owner shall register for inspection according to Article 19 of this Decree.

If the imported lots or goods remain unsatisfactory after the remediation, either of the handling measures specified at Points c and d, Clause 3, Article 55 of the Law on Food Safety shall be applied.

**Article 21.** Rights and obligations of goods owners

A goods owner has the following rights and obligations:

1. To request reduced inspection for imported lots and goods falling into one of the cases specified in Clause 1, Article 17 of this Decree.

2. To request the state inspection agency to reconsider the inspection result or request the product declaration-receiving agency to

select a designated testing laboratory to conduct a re-inspection. If the result of the re-inspection is the same as the result of the initial inspection, the goods owner shall pay the re-inspection cost; if the result of the re-inspection shows that the imported goods are satisfactory, the goods owner will be reimbursed with the paid re-inspection cost.

3. To propose the application of the measures specified in Clause 3, Article 55 of the Law on Food Safety to the lot or goods that fail(s) to comply with import requirements.

4. To keep intact the imported lot or goods for the state inspection agency to take samples.

5. To comply with the competent state inspection agency's decision on disposal of the lot or goods that fail(s) to comply with import requirements.

**Article 22.** Procedures for registration of countries and territories and food production and trading establishments in the list of those permitted to export foods to Vietnam, and state inspection of food safety in exporting countries

1. A competent state management agency of Vietnam shall prepare an inspection plan, inform it to a competent agency of the exporting country and coordinate with the latter in inspecting the food safety control system of the exporting country and the food production and trading establishments exporting foods to Vietnam according to the following procedures:

a/ The competent authority of the exporting country shall send 1 (one) set of registration dossier to the Ministry of Agriculture and Rural Development, which contains information about the management system of the exporting country or territory (laws, standards and food safety management organizations) and the food safety control capacity of such authority, made according to Form No. 08 in Appendix I to this Decree; a list of establishments producing and trading in products derived from terrestrial animals and aquatic animals registering to export these products to Vietnam, made according to Form No. 07 in Appendix I, and information about their food safety conditions, made according to Form No. 09 in Appendix I to this Decree;

b/ Within 30 working days after receiving a complete dossier for registration of the list of production and trading establishments prescribed at Point a of this Clause from the competent authority of the exporting country, the competent agency of the related line ministry shall verify the dossier, inform the competent authority of the exporting

country of the verification result and the inspection plan, if inspection of the exporting country is necessary;

c/ An inspection in the exporting country will focus on the legal system on food safety management and control; capacity of the food safety control authority of the exporting country; and food safety conditions of production and trading establishments registering to export foods to Vietnam.

2. Processing of inspection results and notification of the list of countries and territories and the list of production and trading establishments permitted to export foods to Vietnam must comply with the following provisions:

a/ If a site inspection in an exporting country is unnecessary, the Ministry of Agriculture and Rural Development shall publish the inspection result and names of countries and territories permitted to export foods to Vietnam. Particularly for products derived from terrestrial animals and aquatic animals, it shall also publish the list of production and trading establishments permitted to export such products to Vietnam;

b/ If an inspection in an exporting country is necessary, within 30 working days after completing such inspection, the Ministry of Agriculture and Rural Development shall process and publish the inspection result.

If the inspection result shows that the prescribed requirements are not fully satisfied, the Ministry of Agriculture and Rural Development shall issue a notice stating reasons for ineligibility to export foods to Vietnam;

c/ In case of requesting addition to the list of production and trading establishments wishing to export products derived from terrestrial animals and aquatic animals to Vietnam, the competent authority of the exporting country shall send a dossier containing a list and information about these establishments, made according to Forms No. 07 and No. 08 mentioned at Point a, Clause 1 of this Article, to the Ministry of Agriculture and Rural Development for verification of the dossier or site inspection in the exporting country before considering and deciding on the addition.

### **Article 23.** State inspection of exported foods

1. The Minister of Health, the Minister of Agriculture and Rural Development and the Minister of Industry and Trade shall prescribe the competence to conduct state inspection of safety of exported foods under

their respective management prescribed in Articles 62, 63 and 64 of the Law on Food Safety at the request of the importing countries.

2. The Ministry of Agriculture and Rural Development shall inspect exported food lots containing different types of foods under the management of two or more ministries.

## Chapter VII

### FOOD LABELING

#### **Article 24.** Mandatory labeling contents

1. Producers and traders of products in Vietnam shall comply with the law on goods labeling and the following provisions:

a/ The label of medical food must contain the phrase “*Thực phẩm dinh dưỡng y học*” (medical food) and “*Sử dụng cho người bệnh với sự giám sát của nhân viên y tế*” (Used for patients under supervision);

b/ The label of food for special dietary uses must contain the phrase “*Sản phẩm dinh dưỡng (cho đối tượng cụ thể)*” (Dietary product (for specific target users) on its main front to distinguish it from normal food.

2. Particularly, the label of an imported product must contain the name and address of the producer, and the name and address the organization or individual that makes self-declaration or registers the product declaration.

**Article 25.** Cases in which some mandatory labeling contents may be omitted

1. No secondary label is required for products in hand luggage of people on entry for their personal use, or gifts or presents within the import duty-free limits; imports of people eligible for diplomatic privileges and immunities; products in transit or border-gate transfer, transshipped products, products temporarily imported for re-export and products stored in bonded warehouses; products for use as testing samples or for research; products for display at exhibitions or fairs; products and materials produced or imported only for export production or processing or internal production and not for sale on the domestic market.

2. In addition to seasonings and herbs, small packages whose surface area is smaller than 10 cm<sup>2</sup> are not required to show ingredients, expiry date, and preservation and use instructions if there is a secondary label or an outer package containing such information.

3. The date of production is not required to be shown on food containers and primary packages.

## Chapter VIII

### FOOD ADVERTISEMENT

**Article 26.** Foods for which advertisement contents shall be registered

1. Dietary supplements, medical foods, and foods for special dietary uses.

2. Dietary products for children up to 36 months old not banned from advertising as prescribed in Article 7 of the Law on Advertising.

**Article 27.** Registration of food advertisement contents

The registration of food advertisement contents must comply with the law on advertising and the following provisions:

1. Before advertising, the owner of the advertised product shall register the advertisement contents with the agency that issued the receipt of the registration of the product declaration under current regulations.

2. The advertisement contents must match the effects of the product stated in the product declaration. It is prohibited to use images, equipment, uniforms, names and documents of health facilities, medical physicians, pharmacists, health workers, patients' letters of thanks and articles written by medical physicians, pharmacists or health workers to advertise foods.

3. Regarding dietary supplements:

a/ It is required to have the recommendation "*Thực phẩm này không phải là thuốc và không có tác dụng thay thế thuốc chữa bệnh*" (This product is not a medicine and cannot replace medical treatment), which shall be written clearly and printed in a color contrasting with the background color;

b/ The recommendation provided at Point a above shall be read aloud in radio or television advertisements;

c/ The recommendation provided at Point a above is not required to be read aloud if the duration of a radio or television advertisement is shorter than 15 seconds, but shall be shown during the advertisement.

4. A dossier for registration of certification of advertisement contents must comprise:

a/ A registration paper, made according to Form No. 10 in Appendix I to this Decree;

b/ The receipt of the registration of the product declaration and the product declaration certified by a competent agency (a copy certified by the registrant);

c/ A product label specimen (certified by the registrant);

d/ An audio or video disc that contains the advertisement script and contents, for radio or television advertisements,; or the advertisement layout (certified by the registrant), for advertisements in other media;

d/ Scientific documents proving the uses or effects of the product other than those written in the product declaration (copies certified by the registrant);

Documents in the dossier must be in Vietnamese; for documents in a foreign language, their notarized Vietnamese translations are required.

#### 5. Procedures for grant of certificates of advertisement contents:

a/ The owner of the advertised product shall submit a dossier of registration for certification of advertisement content to the agency that issued the receipt of the registration of the product declaration;

b/ Within 10 working days after receiving a valid dossier, the dossier-receiving agency shall examine it and issue a reply, made according to Form No. 11 in Appendix I to this Decree. This time limit shall be counted from the date of the incoming mail stamp appended by the dossier-receiving agency (if the dossier is sent by post) or the date of receipt of a complete dossier in the online public service system.

If rejecting the advertisement content or requesting modification and supplementation of the advertisement content, the dossier-receiving agency shall issue a notice clearly stating the reason and legal basis for its request. The dossier-receiving agency may request modification and supplementation only once.

Within 10 working days after receiving the modified and supplemented dossier, the dossier-receiving agency shall appraise it and issue a written reply. If the dossier is not modified and supplemented after 90 working days from the date a written request is made, it will become invalid;

c/ The dossier-receiving agency shall post on its website and update in the food safety database the names and products of organizations and individuals that have been granted the certificates of advertisement contents;

d/ The registrants shall pay a fee for dossier appraisal to the dossier-receiving agency.

6. The owner of the advertised product and the advertiser may only advertise the product that has a certificate of advertisement contents according to the certified content.

## Chapter IX

### FOOD SAFETY CONDITIONS FOR PRODUCTION OF DIETARY SUPPLEMENTS

**Article 28.** Food safety requirements for production of dietary supplements

1. Producers of dietary supplements must satisfy the general food safety conditions specified in Clause 1, Article 19; Clause 1, Article 20, and Clause 1, Article 21, of the Law on Food Safety and shall comply with the following provisions:

a/ Establishing and maintaining a quality control system to control the production and distribution process in order to ensure that all of its products satisfy the declared quality standards and are safe to consumers until their expiry date;

b/ Having sufficient employees who possess professional qualifications suitable to their working positions and have been trained in GMP, food safety and relevant professional knowledge. The heads of the production unit and quality control unit must be full-time employees and work independently from each other. The professional manager of the establishment must possess a bachelor's or higher degree in medicine, pharmacy, nutrition, food safety or food technology and at least three years' working experience in a relevant field;

c/ Having workshops, equipment and auxiliary utilities designed, constructed and installed in conformity with their use purposes and the one-way principle, easy to clean, able to prevent and minimize risks of misuse and prevent dust, pollution and other elements adversely affecting the product quality; and cleaned every day;

d/ Making and fully preserving adequate records and documents about the production, quality control and distribution process to serve the tracing of every product batch, and documents about all other activities carried out at the establishment;

dd/ Performing all production operations according to procedures and instructions. Applying inspection and supervision measures during the production process to prevent and avoid risks of misuse, pollution

and cross-contamination. Recording results immediately after every production operation or stage is performed or completed;

e/ Having a quality control unit to ensure that products are produced under suitable conditions and processes and up to established standards; necessary tests are performed; materials are not used and products are not sold before they are checked to meet quality requirements; and product stability is monitored;

g/ In case of testing or production under a contract, the contractor must have adequate workshops, equipment and employees satisfying the requirements of the principal, and observe regulations of competent management agencies on conditions for testing or production of dietary supplements;

h/ Establishing processes for complaint settlement, product recall and self-inspection; applying these processes and recording and fully preserving documents about these activities.

2. The Ministry of Health shall guide the application of GMP to dietary supplements for establishments producing dietary supplements.

3. From July 1, 2019, establishments producing dietary supplements shall apply GMP under the guidance of the Ministry of Health.

**Article 29.** Dossiers, procedures and competence for grant and re-grant of certificates of food safety eligibility according to GMP requirements for production of dietary supplements

1. A dossier of application for a certificate of food safety eligibility according to GMP requirements for production of dietary supplements must comprise:

a/ An application, made according to Form No. 12 in Appendix I to this Decree;

b/ A plan of the production area and production lines (certified by the applicant);

c/ A list of main equipment used at the establishment (certified by the applicant).

2. Procedures for grant of certificates of food safety eligibility according to GMP requirements for production of dietary supplements

a/ The applicant shall prepare a dossier prescribed in Clause 1 of this Article and submit it via the online public service system, by post or directly to the Ministry of Health;

b/ Within 15 working days after receiving a complete and valid dossier, the dossier-receiving agency shall form an appraisal team to

carry out site inspection at the applicant's establishment and make an appraisal record according to Form No. 13 in Appendix I to this Decree.

The appraisal team shall be composed of at least 5 people, at least 2 of whom are experienced in GMP, and 1 is specialized in testing.

c/ If the appraisal result is satisfactory, within 30 days after receiving a complete and valid dossier, the dossier-receiving agency shall issue a certificate of food safety eligibility according to GMP requirements for production of dietary supplements, made according to Form No. 14 in Appendix I to this Decree;

d/ If the appraisal result is unsatisfactory, the appraisal team shall clearly record the unsatisfactory contents in the appraisal record and request the applicant to remedy them. After the remediation, the applicant shall send a written notice to the appraisal team. Within 7 (seven) working days after receiving such notice, the appraisal team shall consider and propose the Ministry of Health to grant a certificate. If the applicant fails to finish the remediation after 3 (three) months from the date of completing the appraisal as requested and to send a notice of the remediation to the appraisal team, its dossier will be invalidated.

3. A certificate of food safety eligibility according to GMP requirements for production of dietary supplements is valid for 3 (three) years from the date of grant. At least 6 months before the expiration of the certificate, the certificate holder shall submit a dossier of request for re-grant of a certificate. Dossiers and procedures for re-grant are the same as those specified in Clauses 1 and 2 of this Article.

4. Applicants for a certificate of food safety eligibility according to GMP requirements for production of dietary supplements shall pay a charge for dossier appraisal to the dossier-receiving agency.

## Chapter X

### FOOD SAFETY CONDITIONS IN THE PRODUCTION, TRADING AND USE OF FOOD ADDITIVES

#### **Article 30.** Food safety conditions for food additives

Establishments producing and trading in food additives must satisfy the following food safety conditions:

1. General food safety conditions prescribed in Clause 1, Article 19; Clause 1, Article 20, and Clause 1, Article 21, of the Law on Food Safety.

2. Only food additives on the list of additives permitted for use in foods issued by the Ministry of Health may be mixed, given that the

mixture does not cause any harm to human health. In case of creating a new product with new uses, they shall prove such uses, intended users and maximum dose.

3. Food additives shall be divided and packaged at an establishment that satisfies the food safety conditions, and labeled under the current regulations.

**Article 31.** Provisions on single-ingredient food additives

1. Food additives on the list of additives permitted for use in foods issued by the Ministry of Health are subject to self-declaration.

2. Procedures for self-declaration of single-ingredient food additives are the same as those prescribed in Article 5 of this Decree.

**Article 32.** Provisions on mixed food additives with new uses

1. Product declarations shall be made for mixed food additives with new uses and registered with the Ministry of Health.

2. The quantity of every ingredient in a mixed food additive with new uses shall be listed.

3. Procedures for registration of product declarations of mixed food additives with new uses are the same as those prescribed in Articles 7 and 8 of this Decree.

**Article 33.** Provisions on use of food additives

Food additive producers and traders shall:

1. Use only food additives on the list of additives permitted for use in foods issued by the Ministry of Health. For food additives not on such list or not used for intended users prescribed by the Ministry of Health, food additive producers and traders shall register product declarations with the Ministry of Health under Articles 7 and 8 of this Decree.

2. Use food additives within permissible limits, for appropriate types of foods; use only food additives that have clear origins and are unexpired; and satisfy all administration and technical requirements applied to food additives.

## Chapter XI

### TRACING OF FOOD ORIGIN

**Article 34.** Tracing of origin of unsafe food products

When detecting that a food product being produced or traded is unsafe or at the request of a competent state agency, food producers or

traders shall trace its origin in accordance with Clauses 1 and 2, Article 54 of the Law on Food Safety.

**Article 35.** Tracing of origin of unsafe food products

1. Food producers and traders shall preserve information about producers or suppliers of products and customers who have bought products under contracts, keep books or apply other methods to serve origin tracing. Information serving origin tracing includes:

a/ Names and categories of the products bought and sold;

b/ Dates, quantities, weights and batch numbers (if any) of the products bought and sold.

2. The Minister of Health, Minister of Agriculture and Rural Development and Minister of Industry and Trade shall promulgate specific regulations on tracing of origins of products under their respective management.

Chapter XII

ASSIGNMENT OF RESPONSIBILITIES FOR STATE  
MANAGEMENT OF FOOD SAFETY

**Article 36.** Principles of assignment of responsibilities for state management of food safety

1. Conformity with the Law on Food Safety and relevant legal documents.

2. Uniform state management of food safety.

3. Management throughout the course of food production and trading.

4. Close coordination among ministries and sectors.

5. Single-window management whereby a product and a production or trading establishment is placed under the management of a single state management agency.

6. Scientificity, comprehensiveness and feasibility.

7. Assignment of state management responsibilities for food safety between the central administration and local administrations at different levels.

8. For an establishment producing different types of food products under the management of 2 or more line agencies, the agency that manages the product with the largest quantity shall manage the establishment.

9. For an establishment that does not produce but trades in different types of food products under the management of 2 or more line agencies, the industry and trade agency shall manage the establishment, except wholesale markets and auction markets of farm produce.

10. For an establishment that both produces and trades in different types of food products under the management of 2 or more line agencies, its owner may select one of them to carry out food safety-related administrative procedures.

**Article 37.** The Ministry of Health's state management responsibility for food safety

1. To implement regulations on general state management responsibilities for food safety defined in Clause 1, Article 62 of the Law on Food Safety.

2. To report periodically and upon request on food safety management work on the basis of supervisions and reports from other line ministries and provincial-level People's Committees.

3. To promulgate national technical regulations on products under its assigned management prescribed in Article 62 of the Law on Food Safety and the groups of products prescribed in Appendix II to this Decree; to promulgate national technical regulations or set safety limits for groups of products at the request of other line ministries.

4. To perform food safety management throughout the production, processing, storage, transportation, export, import and trading of the products specified in Appendix II to this Decree and of establishments producing and trading in these products.

5. To receive and manage dossiers of application, grant receipts of registrations of product declarations, certificates of food safety eligibility for dietary supplements, mixed food additives with new uses, food additives outside the list of additives permitted for use or not intended for use in foods as prescribed by the Ministry of Health; certificates of food safety eligibility according to GMP requirements for dietary supplements; certificates of advertisement contents for dietary supplements; certificates of free sale for products under its assigned management; and health certificates.

6. To designate laboratories to test foods for state management purposes and verifying laboratories under its assigned management; to designate laboratories to perform tests serving arbitration and giving final conclusions in case of different testing results given by food testing laboratories inside and outside the health sector.

7. To designate agencies to perform state inspection of food safety of imported products under its assigned management.

**Article 38.** The Ministry of Agriculture and Rural Development's state management responsibility for food safety

1. To promulgate national technical regulations applicable to products under its assigned management prescribed in Article 63 of the Law on Food Safety and the groups of products prescribed in Appendix III to this Decree.

2. To set safety limits for the groups of products prescribed in Appendix III to this Decree and send them to the Ministry of Health for promulgation.

3. To perform and assign food safety management tasks throughout the initial production of agricultural, forest and aquatic products and salt, including farming, breeding, collection, fishing and harvest, and salt production.

4. To perform and assign food safety management tasks throughout the production, collection, slaughter, preliminary processing, processing, storage, transportation, export, import and trading of the food products prescribed in Appendix III to this Decree and with regard to establishments producing and trading in these products.

5. To grant certificates of free sale for products under its assigned management.

6. To organize and assign the grant of certificates of food safety eligibility to producers and traders of the products under its assigned management mentioned in Clauses 3 and 4 of this Article.

7. To perform the food safety management at wholesale markets and auction markets of farm produce.

8. To designate laboratories to perform food tests for state management purposes and verifying laboratories; to make final conclusions in case of different testing results given by various testing laboratories under its assigned management.

9. To designate agencies to perform the state inspection of food safety of imported products under its assigned management.

10. To publish the list of countries and territories and the list of production and trading establishments permitted to export food products under its assigned management to Vietnam.

**Article 39.** The Ministry of Industry and Trade's state management responsibility for food safety

1. To promulgate national technical regulations applicable to products under its assigned management defined in Article 64 of the Law on Food Safety and the groups of products specified in Appendix IV to this Decree.

2. To set safety limits for the groups of products specified in Appendix IV to this Decree and send them to the Ministry of Health for promulgation.

3. To perform and assign food safety management tasks throughout the production, processing, storage, transportation, export, import and trading of the products specified in Appendix IV to this Decree and with regard to establishments producing and trading in these products.

4. To perform food safety management at supermarkets, trade centers, convenience stores and establishments in the storage and distribution systems, and other types of business.

5. To grant certificates of free sale for products under its assigned management.

6. To organize and assign the grant of certificates of food safety eligibility to producers and traders of the products under its assigned management.

7. To carry out inspections to prevent and combat counterfeit foods and trade frauds on the market related to all types of foods, food additives, food processing aids, and food containers and packages.

8. To designate laboratories to perform food tests for state management purposes and verifying laboratories; to make final conclusions in case of different testing results given by various testing laboratories under its assigned management.

9. To designate agencies to perform the state inspection of food safety of imported products under its assigned management.

**Article 40.** Provincial-level People's Committees' state management responsibility for food safety

1. To perform the state management of food safety in their localities and take responsibility to the Government for food safety in their localities. Chairpersons of provincial-level People's Committees shall act as heads of provincial interdisciplinary steering committees for food safety; to take the initiative in organizing inspection and supervision forces to ensure food safety in their localities; to direct and regularly press for and supervise the enforcement of the law on food safety by subordinate state agencies; to handle officials and civil servants who lack the sense of responsibility for and loosen management of their assigned

management tasks; to organize the settlement of complaints and denunciations and handling of violations of the law on food safety in accordance with law; to take responsibility to the Government and law for violations of the law on food safety in their localities.

2. To organize the implementation of the food safety regulations of the Government, ministries and sectors in their localities.

3. To organize and direct the provincial-level interdisciplinary steering committees for food safety.

4. To organize the dissemination and observance of the food safety regulations in their localities.

5. To provide resources for specialized agencies to perform the state management of food safety.

6. To take responsibility for food safety management in their localities; to manage food safety conditions of small food production and trading establishments, street food vendors, and catering service providers, and manage food safety in markets in their localities and other entities under their assigned management.

7. To develop and promulgate local technical regulations on food safety applicable to specific local food products.

8. To receive and manage dossiers of application and grant receipts of registrations of product declarations and certificates of advertisement contents for medical foods, foods for special dietary uses, and dietary products for children up to 36 months old.

9. To receive product self-declarations and grant certificates of food safety eligibility as assigned.

#### **Article 41.** Coordination in food safety assurance

1. Line ministries shall, within the ambit of their state management tasks, coordinate with the Ministry of Health in carrying out uniform and effective state management of food safety.

2. The Ministry of Health shall assume the prime responsibility for developing a food safety information, education and communication program; the Ministry of Agriculture and Rural Development, Ministry of Industry and Trade and other ministries and sectors shall, within the ambit of their functions and tasks, coordinate with the Ministry of Health in implementing this program.

3. The Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade shall plan and carry out inspections of products under their assigned management; other ministries shall coordinate with the former in this activity.

4. When a case of food poisoning occurs, the Ministry of Health shall organize first aid and timely treatment for victims. Other line ministries shall provide adequate documents and information relating to the origin of the food suspected of poisoning under their assigned management; and coordinate with the Ministry of Health in investigating the cause and tracing the origin and disposing the poisoning food under their assigned management.

5. Upon detecting food products under the management of other ministries or sectors that violate regulations and are likely to cause serious effects on consumer health, the Ministry of Health shall assume the prime responsibility for, and coordinate with related line ministries in, carrying out inspection and giving conclusions.

### Chapter XIII

#### IMPLEMENTATION PROVISIONS

##### **Article 42.** Transitional provisions

1. Products that have receipts of declarations of regulation conformity and certificates of declaration of conformity with food safety regulations granted before the effective date of this Decree may be used until the expiry date of such receipts and certificates and their expiry date.

2. Line ministries shall, within the ambit of their tasks and powers, review and announce the annulment of the regulations that contravene this Decree.

##### **Article 43.** Effect

1. This Decree takes effect on February 2, 2018.

2. This Decree replaces the Government's Decree No. 38/2012/ND-CP of April 25, 2012, detailing a number of articles of the Law on Food Safety; annuls Chapter II of Joint Circular No. 13/2014/TTLT-BYT-BNNPTNT-BCT of April 9, 2014, of the Ministry of Health, the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade, guiding the assignment of and coordination in the state management of food safety.

##### **Article 44.** Implementation responsibility

Ministries, heads of ministerial-level agencies, heads of government-attached agencies, chairpersons of provincial-level People's Committees and related organizations and individuals shall implement this Decree.-

*On Behalf of the Government*  
Prime Minister  
NGUYEN XUAN PHUC

*\* The appendices to this Decree are not translated.*

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