THE GOVERNMENT -------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No. 15/2018/ND-CP	*Hanoi, February 02, 2018*

DECREE

ELABORATION OF SOME ARTICLES OF THE LAW OF FOOD SAFETY

Pursuant to the Law on Government organization dated June 19, 2015;

Pursuant to the Law on Food safety dated June 17, 2010;

At the request of the Minister of Health;

The Government promulgates a Decree to elaborate some Articles of the Law of Food safety.

Chapter I

GENERAL PROVISIONS

Article 1. Scope

This Decree elaborates some Articles of the Law of Food safety on:

1. Procedures for product self-declaration.

2. Procedures for registration of the product declaration.

3. Assurance of genetically modified GM foods.

4. Issuance of the certificate of food safety.

5. State inspection of safety of imported and exported foods.

6. Food labeling.

7. Food advertisements.

8. Food safety requirements in production of dietary supplements.

9. Food safety requirements in production, sale and use of food additives.

10. Tracing food origins.

11. Food safety authorities.

Article 2. Regulated entities

This Decree applies to Vietnamese and foreign organizations and individuals that produce or sell foods in Vietnam; organizations and individuals whose operation involve food safety in Vietnam.

Article 3. Definitions

For the purpose of this Decree, the following terms are construed as follows:

1. 1) “dietary supplement” means a product used as a supplement to the daily diet to improve user’s health and immunity. Dietary supplement may contain one or more of the following substances:

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

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

c) Sources of the substances mentioned in Point a and Point b above.

Dietary supplements may be in the form of soft gels, pellets, tablets, granules, powder, liquid and other dosage form divided into smaller doses.

2. "medical food" or "food for special medical purposes" means a food that can be consumed orally or tube feeding, prescribed to regulate the patient's diet, the use of which has to be supervised by a health worker.

3. "food for special dietary uses" means food for people on a diet, elderly people and other users defined by Codex Alimentarius, processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological conditions and/or specific disease and disorder of the user. The composition of this kind of food differs significantly from that of ordinary foods of comparable nature, if such ordinary foods exist.

4. "scientific evidence" means scientific documents and information from researches accepted by competent authorities or published in Vietnamese or foreign academic journals or articles about traditional medicine in academic prints.

5. "goods owner" means the organization or individual responsible for the goods specified in the declaration or self declaration of products, or the organization or individual authorized to import or export food products.

6. "exports and imports" are food products of the same category, names, labels, producers and packaging materials.

7. "shipment" means the entire food products of an export or import shipment (in the same bill of lading). A shipment may comprise a single or multiple commodities.

8. "micro food manufacturer" means a household or individual that obtains food ingredients by means of farming, breeding, fishing or collecting with or without a certificate of enterprise registration.

9. "micro food processor" means a household or individual that processes food with or without a certificate of enterprise registration.

10. "micro food business" means an individual, a group of individual or a household that has registered as a business household and does not have the certificate of business registration, certificate of enterprise registration and investment registration certificate.

Chapter II

PROCEDURES FOR PRODUCT SELF-DECLARATION

Article 4. Product self-declaration

1. Food manufacturers and food sellers (hereinafter referred to as "suppliers") shall prepare self-declaration of pre-packaged processed foods, food additives, food processing aids, food containers, primary packages of foods (hereinafter referred to as "products") other than the commodities specified in Clause 2 of this Article and Article 6 of this Article.

2. Products, raw materials that are manufactured or imported for production or processing of exports or internal production and are not sold domestically are exempt from self-declaration.

Article 5. Self-declaration procedures and documents

1. Self-declaration documents include:

a) The self-declaration form (Form No. 01 in Appendix I hereof);

b) Original copy or certified true copy of the food safety data sheet issued within 12 months before the self-declaration is made by an designated laboratory or a laboratory complying with ISO 17025; the data sheet must specify safety indicators prescribed by the Ministry of Health according to risk management principles under international regulations (or standards applied by the supplier if relevant regulations of the Ministry of Health are not available).

2. Self-declaration procedures:

a) The self-declaration shall be posted through mass media or the producer's website or premises; 01 copy of the self-declaration shall be submitted, directly or by post, to regulatory authority designated by the People's Committee of the province (hereinafter referred to as "receiving authority");

b) Right after the self-declaration is submitted, the supplier is entitled to manufacture and sell the product and assume full responsibility for the safety of such product;

c) The receiving authority shall post the self-declaration and the product names therein on its website.

If the supplier has more than one factory that produces the same product, self-declaration documents shall be submitted to the regulatory authority of one of the provinces of the supplier's choice. Once selected, self-declaration documents shall be submitted to the same authority.

3. Self-declaration documents must be written in Vietnamese language; documents in other languages must be translated into Vietnamese language and notarized. The documents must be unexpired when the self-declaration is submitted.

4. In case of change to the product name, origin or ingredients, the supplier shall submit another self-declaration. In case of other changes, the supplier shall submit a written notification to the receiving authority and is entitled to carry on the production or sale of the product afterwards.

Chapter III

PROCEDURES FOR REGISTRATION OF THE PRODUCT DECLARATION

Article 6. Registration of the product declaration

Food suppliers must register the declarations of the following products:

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

2. Dietary products for children up to 36 months.

3. Mixed food additives with new uses, food additives that are not on the list of permitted food additives compiled by the Ministry of Health (hereinafter referred to as "unregistered food additives").

Article 7. Application for registration of the product declaration

1. An application for regulations of the declaration of imported products consists of:

a) The declaration form (Form No. 02 in Appendix I hereof);

b) The Certificate of Free Sale, Certificate of Exportation or Health Certificate issued by a competent authority of the country of origin/exporting country, which assures safety of users or permit free sale of the products in the country of origin/exporting country (the certificate must be consularly legalized);

c) Original copy or certified true copy of the food safety data sheet issued within 12 months before the self-declaration is made by an designated laboratory or a laboratory complying with ISO 17025; the data sheet must specify safety indicators prescribed by the Ministry of

Health according to risk management principles under international regulations (or standards applied by the supplier if relevant regulations of the Ministry of Health are not available)

d) Documents about scientific evidence of the effects of the product or ingredients (original or authenticated copy). If scientific evidence of effects of the ingredients is used, the daily dose must be greater or equal to 15% of the content of such ingredients mentioned in the document;

dd) The certificate of Good Manufacturing Practice (GMP) or an equivalent certificate if the imports are dietary supplements, applicable from July 01, 2019 (a copy authenticated by the supplier).

2. An application for regulations of the declaration of domestic products consists of:

a) The declaration form (Form No. 02 in Appendix I hereof);

b) Original copy or certified true copy of the food safety data sheet issued within 12 months before the self-declaration is made by an designated laboratory or a laboratory complying with ISO 17025; the data sheet must specify safety indicators prescribed by the Ministry of Health according to risk management principles under international regulations (or standards applied by the supplier if relevant regulations of the Ministry of Health are not available);

c) Scientific evidence of the effects of the product or ingredients (original or authenticated copy). If scientific evidence of effects of the ingredients is used, the daily dose must be greater or equal to 15% of the content of such ingredients mentioned in the document;

d) The certificate of food safety if one is required (a copy authenticated by the supplier);

dd) The certificate of Good Manufacturing Practice (GMP) if the domestic products are dietary supplements, applicable from July 01, 2019 (a copy authenticated by the supplier).

3. The documents must be written in Vietnamese language; documents in other languages must be translated into Vietnamese language and notarized. The documents must be unexpired when the application is submitted.

Article 8. Procedures for registration of the product declaration

1. The supplier shall submit the application for registration of the product declaration, whether online, by post or directly, to the following receiving authorities:

a) The Ministry of Health for declarations of dietary supplements and unregistered food additives;

b) A competent authority designated by the People's Committee of the province for medical foods, food for special dietary uses and dietary products for children up to 36 months;

c) In the cases where the declaration includes of the products mentioned in both Point a and Point b of this Clause, the application may be submitted to either receiving authority.

If the supplier has more than one factory that produces the same product, the declaration may be registered to the regulatory authority of one of the provinces of the supplier's choice (except for products that have to be registered to the Ministry of Health). Once selected, the next applications for registration shall be submitted to the same authority.

2. Within 07 working days (for unregistered food additives, medical foods, food for special dietary uses, dietary products for children up to 36 months) or 21 working days (for dietary supplements) from the day on which adequate documents are received, the receiving authority specified in Clause 1 of this Article shall verify the application and issue a certificate of registered product declaration (Form No. 03 in Appendix I hereof).

The time limit for document verification begins on the date of receipt according to the online public service system (if the application is submitted online) or date stamp of the receiving authority (if the application is submitted by post or directly).

3. If the application needs to be supplemented, the receiving authority shall provide explanation in writing and specify the legal basis. The receiving authority may request the applicant to supplement the application 01 time.

Within 07 working days from the day on which the supplemented application is received, the receiving authority shall verify it and make a written response. If the applicant fails to supplement the application within 90 working days from the day on which a written request is made, the application will be invalidated.

4. In case of change to the product name, origin or ingredients, another application shall be submitted. In case of other changes, the applicant shall submit a written notification to the receiving authority mentioned in Clause 1 of this Article and is entitled to carry on the production or sale of the product afterwards.

5. The receiving authority shall post on its website and update on the food safety database the names and products of suppliers whose product declarations have been registered.

6. Food suppliers shall pay fees for document verifications in accordance with regulations of law on fees and charges.

Chapter IV

ASSURANCE OF SAFETY OF GENETICALLY MODIFIED FOODS

Article 9. Assurance of safety of food derived from genetically modified organisms (GMO) and GMO products

Conditions and procedures for issuance and revocation of the certificate of edible GMO and the list of GMOs granted such certificate are specified in the Government's Decree No. 69/2010/ND-CP and Decree No. 108/2011/ND-CP.

Article 10. Labeling of goods containing GMO and GMO products used as foods

1. Manufacturers and sellers of foods the content of GM ingredients in which exceeds 5% of total ingredients, in addition to compliance with common regulations of law on goods labeling, the goods label must contain information about the GMOs, except for the cases specified in Clause 2 of this Article.

2. Labeling of GM foods is exempted in the following cases:

a) The prepackaged GM food contains GM ingredients without discovery of the modified gene or products of the modified gene in the food;

b) Fresh GM foods, unpackaged processed GM foods sold directly to consumers;

c) GM foods serving recovery from a natural disaster or epidemic.

Chapter V

ISSUANCE OF THE CERTIFICATE OF FOOD SAFETY

Article 11. Issuance of the certificate of food safety

1. Every food manufacturer and seller must obtain the certificate of food safety, except for those specified in Clause 1 Article 12 of this Decree.

2. Requirements for issuance of the certificate of food safety are specified in Clause 1 Article 34 of the Law of Food safety. Manufacturers of dietary supplements shall apply the requirements specified in Article 28 of this Decree.

Article 12. Exemption from the certificate of food safety

1. The following entities are not required to obtain the certificate of food safety:

a) Micro food manufacturers;

b) Mobile food manufacturers and sellers;

c) Micro food processors;

d) Micro food sellers;

dd) Sellers of prepackaged foods;

e) Manufacturers and sellers of instruments and materials for wrapping and storing food;

g) Restaurants within hotels;

h) Industrial kitchens not registered as a food business;

i) Street food vendors;

k) Any food business that has one of the following certificates: GMP, HACCP, ISO 22000, IFS, BRC, FSSC 22000 or an equivalent certificate.

2. The entities mentioned 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. Cases in which state inspection of food safety is exempted unless there if a food safety warning

1. The product has the certificate of registered product declaration.

2. Foods in hand luggage of inbound passengers that are sent before or after the passengers arrive to serve the passengers' personal needs; gifts within duty-free allowances.

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

4. Products in transit, temporarily imported or in bonded warehouses.

5. Test samples whose quantities are suitable for the testing purposes and confirmed by the owners.

6. Products used for displayed at exhibitions or fairs.

7. Products, raw materials that are manufactured or imported for production or processing of exports or internal production and are not sold domestically.

8. Temporarily imported products for sale at duty-free shops.

9. Imports serving emergency purposes under orders of the Government or the Prime Minister.

Article 14. Requirements applied to imported products derived from terrestrial animals, aquatic animals and plants

1. Products derived from terrestrial animals, aquatic animals and plants that are processed or prepackaged and exported by a Vietnamese organization or individual but then returned in the cases specified in Article 13 of this Decree must satisfy the following requirements:

a) Their country of origin is a country or territory that has a food safety control system satisfying Vietnam's regulations and included in the list of registered countries and territories that export foods derived from animals, plans and aquatic animals to Vietnam;

b) Terrestrial animals and aquatic animals used as foods must be manufactured by facilities that satisfy food safety requirements as certified by Vietnamese authorities;

c) Each shipment has a certificate of food safety issued by a competent authority of the exporting country (except for fish caught and processed by foreign vessels and sold to Vietnam's market).

2. Procedures for registration of the exporting countries and territories (hereinafter referred to as "exporting countries") mentioned in Clause 1 of this Article are specified in Article 22 of this Decree.

3. The Ministry of Agriculture and Rural Development shall provide the customs authorities with the list of exporting countries and exporters allowed to export the aforementioned products to Vietnam (hereinafter referred to as "list of permitted exporting countries and exporters").

Article 15. Inspecting authorities

1. The Ministry of Agriculture and Rural Development, the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade shall appoint authorities responsible for inspection of food safety of imported foods (hereinafter referred to as "inspecting authorities").

In the cases where the content of a shipment is under the management of more than one Ministry, the Ministry of Agriculture and Rural Development shall be the inspecting authority.

2. Inspecting authorities have the following entitlements and obligations:

a) Decide to switch over from regular inspection to reduced inspection and switch back to normal inspection after the results of 03 tightened inspections is satisfactory.

b) Carry out food inspection in accordance with the methods and procedures specified in this Decree;

c) Taking and storing samples in accordance with law;

c) Collect testing and inspection fees in accordance with law;

dd) Ensure accuracy and objectivity of the inspections;

e) Comply with instructions from the Ministry of Health, the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade;

g) Settle complaints of goods owners. Pay the inspection and testing fees and compensation for any damage to the goods owners;

h) Retain inspection documents and present them at the request of competent authorities;

i) Submit biannual reports to the supervisory Ministry (form 06 in Appendix I hereof) and ad hoc reports to the Ministry of Health, the Ministry of Agriculture and Rural Development, the Ministry of Industry and Trade or a competent authority of the manufacturer's home country, or reports on disposal of disqualified foods.

Article 16. Inspection methods

1. Reduced inspection: document inspection of up to 5% of the shipments within 01 year randomly chosen by the customs authority.

2. Normal inspection: document inspection only.

3. Tightened inspection: both document inspection and sampling.

Article 17. Application of the inspection methods

1. Reduced inspection will be carried out if:

a) There is a certificate of food safety issued by the competent authority of a country that has entered a mutual recognition agreement regarding food safety inspection to which Vietnam is also a signatory; the inspection result given by the competent authority of the exporting country is satisfactory;

b) The results of 03 consecutive normal inspections within 12 months are satisfactory;

c) The manufacturer applies either GMP, HACCP, ISO 22000, IFS, BRC, FSSC 22000 or an equivalent system.

2. Normal inspection applies to all commodities of the shipment, except for the cases specified in Clause 1 and Clause 3 of this Article.

3. Tightened inspection will be carried out if:

a) The result of the previous inspection is not satisfactory;

b) A shipment or commodity fails to meet requirements during the 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, the People's Committee of the province or a competent authority of a foreign country or the manufacturer's home country.

4. The tightened inspection will be changed into normal inspection in the following cases:

a) The results of 03 consecutive tightened inspection are satisfactory in the cases specified in Point a and Point b Clause 3 of this Article;

b) The Ministry of Health, the Ministry of Agriculture and Rural Development or the Ministry of Industry and Trade of Vietnam issues a request for suspension of tightened inspection in the cases specified in Point c Clause 3 of this Article.

Article 18. Application for inspection

1. An application for reduced inspection consists of the following documents:

a) The product self-declaration;

b) 03 notices of satisfactory results of consecutive normal inspections, or certified true copies or consularly legalized copies of either GMP, HACCP, ISO 22000, IFS, BRC, FSSC 22000 certificate of an equivalent certificate that is unexpired when submitted;

c) For products derived from aquatic animals and terrestrial animals, except for processed or prepackaged products, the original copy of the certificate of fulfillment of food safety requirements issued by a competent authority of the exporting country.

2. An application for normal inspection and tightened inspection consists of the following documents:

a) The registration form No. 04 in Appendix I hereof;

b) The product self-declaration;

c) Original copies of 03 notices of satisfactory results of consecutive tightened inspections (to switch over 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 copy of the certificate of fulfillment of food safety requirements issued by a competent authority of the exporting country, except for fish caught and processed by foreign vessels and sold to Vietnam's market.

Article 19. Inspection procedures

1. Procedures for reduced inspection:

While following customs procedures, the goods owner shall submit an application according to Clause 1 Article 18 of this Decree;

b) The customs authority shall carry out document inspection of up to 5% of the shipments eligible for reduced inspection within 01 year.

Within 03 working days from the receipt of the application, the customs authority shall process it and consider granting customs clearance. If the application has to be supplemented, explanation and legal basis must be provided.

2. Procedures for normal inspection:

a) Before the shipment arrives at the border checkpoint, he goods owner shall submit the application according to Clause 2 Article 18 of this Decree to the inspecting authority or National Single-window Information Portal of the Ministry of Health, the Ministry of Agriculture and Rural Development or the Ministry of Industry and Trade (if applied);

b) Within 03 working days from the receipt of the application, the customs authority shall process it and issue a notice of whether the inspection result is satisfactory (form No. 05 of Appendix I hereof). If the application has to be supplemented, explanation and legal basis must be provided;

c) The goods owner shall submit the notice of satisfactory inspection result to the customs authority to be granted customs clearance.

3. Procedures for tightened inspection:

a) The same as Point a Clause 2 of this Article;

b) b) Within 07 working days from the receipt of the application, the customs authority shall process it and issue a notice of whether the inspection result is satisfactory (form No. 05 of Appendix I hereof). If the application has to be supplemented, explanation and legal basis must be provided;

c) The goods owner shall submit the notice of satisfactory inspection result to the customs authority to be granted customs clearance.

4. If the inspection result is not satisfactory, the inspecting authority shall take appropriate measures in accordance with Clause 3 Article 55 of the Law of Food safety and submit a report on disposal of unconformable foods to the supervisory Ministry.

Article 20. Disposal of unconformable foods

1. After unconformable foods are disposed of under the decision issued by the inspecting authority, the goods owner shall submit the following documents to the inspecting authority and the receiving authority:

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

b) The destruction record certified by a competent authority;

c) The repurposing contract between the goods owner and the buyer or recipient of the unconformable products. The buyer or recipient of the unconformable products must not use them as foods.

2. If the goods owner wishes to import the products to Vietnam after rectifying the violations or label, the goods owner shall follow apply for inspection in accordance with Article 19 of this Decree.

If the inspection result is still unsatisfactory after rectification, one of the measures specified in Point c and Point d Clause 3 Article 55 of the Law of Food safety shall be implemented.

Article 21. rights and obligations of the goods owner

1. Request reduced inspection in the cases specified in Clause 1 Article 17 of this Decree.

2. Request the inspecting authority to reconsider the inspection result or request the receiving authority to select a designated laboratory to carry out a re-inspection. If the result of the re-inspection matches the initial result, the goods owner shall pay the re-inspection cost; if the result of re-inspection is satisfactory, the goods owner will be reimbursed for the re-inspection cost.

3. Propose the measures specified in Clause 3 Article 55 of the Law of Food safety if the inspection result is unsatisfactory.

4. Maintain the status quo of the shipment to facilitate sampling by the inspecting authority.

5. Implement the decision on disposal of unconformable foods issued by a competent authority.

Article 22. Procedures for registration of the exporting countries and exporters; state inspection of food safety in the exporting country

1. A competent authority of Vietnam shall develop an inspection plan, inform and cooperate with the competent authority of the exporting country in inspecting the food safety control system of the exporting country and the exporter as follows:

a) The competent authority of the exporting country shall send 01 application to the Ministry of Agriculture and Rural Development, including information about its management system (laws, standards, food safety control system) and its capacity for food safety control according to form No. 08 in Appendix I hereof; a list of registered exports (form No. 07 in Appendix I) and information about their fulfillment of food safety requirements (form No. 09 in Appendix I).

b) within 30 working days from the day on which adequate documents are received according to Point a of this Clause, the competent authorities of the exporting country and the supervisory Ministry shall verify them, 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) The inspection in the exporting country deals with: regulations of law on food safety management and control; capacity of food safety authorities of the exporting country; fulfillment of food safety requirements by the registered exporters.

2. Processing of inspection result and publishing of the list of permitted exporting countries and exporters:

a) if a site inspection in the exporting country is not necessary, the Ministry of Agriculture and Rural Development shall publish the inspection result and list of eligible exporting. For products derived from terrestrial animals and aquatic animals, a list of permissible exporters shall also be published;

b) If a site inspection in the exporting country is necessary, the Ministry of Agriculture and Rural Development shall publish the inspection result within 30 working days from the end of the inspection.

If the inspection result is not satisfactory, the Ministry of Agriculture and Rural Development shall issue a notice and provide specific explanation.

c) For addition of eligible exporters of products derived from terrestrial animals and aquatic animals, the competent authority of the exporting country shall submit an application for document inspection or site inspection which contains a list and information about the exporters according to form No. 07 and form No. 08 mentioned in Point a Clause 1 of this Article to the Ministry of Agriculture and Rural Development. The inspection result is the basis for addition of eligible exporters.

Article 23. State inspection of foods for export

1. The Minister of Health, the Minister of Agriculture and Rural development, the Minister of Industry and Trade shall specify the power to carry out state inspection of safety of foods for export under their management in accordance with Article 62 through 64 of the Law of Food safety at the request of the importing country.

2. The Ministry of Agriculture and Rural Development shall specify responsibility to inspect shipments of foods under the management of more than one Ministry.

Chapter VII

FOOD LABELING

Article 24. Compulsory labeling contents

1. Manufacturers and sellers of foods in Vietnam, in addition to common regulations of law on goods labeling, shall comply with the following regulations:

a) The label of medical food shall 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 under supervision of health workers");

b) The front label of food for special dietary uses shall contain the phrase "Sản phẩm dinh dưỡng (cho đối tượng cụ thể)".

2. The label of imported products must specify: name and address of the importer, the organization or individual that submits the declaration or registers the self-declaration of products.

Article 25. Exceptions

1. The secondary label is not required for goods in hand luggage serving personal use or meant as gifts within the duty-free allowance; imports of entities eligible for diplomatic immunity; goods in transit, temporarily imported goods; goods in bonded warehouses; test samples; goods for display at an exhibition or fair; raw materials imported for production or processing of exports or internal use and not sold domestically.

2. In addition to seasoning and herbs, small packages whose surface area is smaller than 10 cm^2 does not have to specify ingredients, expiration date, storage conditions and instruction for use if there is a secondary label or secondary package which contains such information.

3. The date of manufacturing is not required on food containers and primary packages.

Chapter VIII

FOOD ADVERTISEMENTS

Article 26. Foods for which advertisement contents must be registered

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

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

Article 27. Registration of advertisement contents

The registration of food advertisement contents shall comply with advertising laws and the following regulations:

1. Before advertising, the owner of the advertised product shall register the advertisement content to the authority that issued the certificate of product registration.

2. The advertisement content must be consistent with the effects of the product specified in the product declaration. Do not use images, equipment, uniforms, documents of health facilities, physicians, pharmacists, health workers, patients' appreciation letter, articles written by health facilities, physicians or pharmacists to advertise foods.

3. Regarding dietary supplements:

a) It is required to have the text "Thực phẩm này không phải là thuốc và không có tác dụng thay thế thuốc chữa bệnh" (equivalent to "this product is not intended to diagnose, treat, cure or prevent any disease"), which must be written clearly and has a contrasting color with the background;

b) The text in Point a above must be read aloud in case of audio and video advertisements;

c) The text mentioned in Point a above is not required if the duration of an audio or video advertisement is shorter than 15 seconds, but must be displayed during the advertisement.

4. An application for certification of advertisement contents consists of the following documents:

a) The application form (Form No. 10 in Appendix I hereof);

b) The certificate of registered product declaration and the product declaration certified by a competent authority (a copy certified by the applicant);

c) A sample label (certified by the applicant);

d) For audio or video advertisement, a disc that contains the advertisement script; For other types of advertisement, a maquette (certified by the applicant);

d) The uses or effects other than those written in the product declaration must be proven by scientific documents (copies certified by the applicant);

The documents must be written in Vietnamese language; documents in other languages must be translated into Vietnamese language and notarized.

5. Procedures for issuance of the certificate of advertisement contents:

a) The owner of the advertised product shall submit the application for the certificate of advertisement content to the authority that issued the certificate of registered product declaration;

b) Within 10 working days from the receipt of the satisfactory application, the receiving authority shall process it and issue form No. 11 in Appendix I hereof. The aforementioned time limit is determined according to the date stamp of the receiving authority (if the application is sent by post) or the date of receipt on the online public service system.

If advertisement content is not concurred with or the application has to be supplemented, the receiving authority shall provide explanation in writing and specify the legal basis. The receiving authority may request the applicant to supplement the application 01 time.

Within 10 working days from the day on which the supplemented application is received, the receiving authority shall process it and make a written response. If the application fails to supplement the application within 90 working days from the day on which a written request is made, the application will be invalidated;

c) The receiving authority shall post on its website and update on the food safety database the products that have the certificate of advertisement contents and names of their suppliers;

d) The applicant shall pay the fee for application processing to the receiving authority.

6. The owner of the advertised product and the advertiser may only advertise the product after having obtained the certificate of advertisement contents and must adhere to the content of the certificate.

Chapter IX

FOOD SAFETY CONDITIONS IN PRODUCTION OF DIETARY SUPPLEMENTS

Article 28. Food safety requirements in production of dietary supplements

1. Manufacturers of dietary supplements shall satisfy general food safety conditions specified in Clause 1 Article 19, Clause 1 Article 20 and Clause 1 Article 21 of the Law of Food safety and the following regulations:

a) Establish and maintain a quality control system which control the manufacture and distribution in order to ensure that all products satisfy the applied standards and are safe until their expiration;

b) Hire employees whose qualifications are suitable for their positions and are trained in GMP, food safety and relevant knowledge. The head of the production department and quality control department must be full-time employees and work independently from one another. The chief supervisor of the facility must have at least a bachelor’s degree in medicine, pharmacy, nutrition, food safety or food processing technology and 3 years' working experience in a relevant field;

c) The factory, equipment and auxiliary utilities are installed suitable for their purposes, following one-way rules, easy to clean, not confusing, able to prevent dust, pollution and other elements detrimental to product quality. They must be cleaned on a daily basis;

d) Retain documents about the manufacture process, quality control and distribution in a manner that the history of every batch can be accessed, and documents about other activities at the facility;

dd) All tasks must be performed in accordance with procedures and instructions. Carry out inspections and supervision during the manufacture process to avoid confusion, pollution and cross-contamination. Record the result immediately after a process is done;

e) Establish a quality control department to ensure that the products are manufactured under conformable conditions and processes; necessary tests are run; use of raw materials and sale of products are not approved before the quality is satisfactory; product stability must be monitored;

g) In case of testing or production under a contract, the contractor shall have adequate equipment and personnel to satisfy requirements of the hirer, satisfy requirements for testing or production of dietary supplement established by a competent authority.

h) There are procedures for complaint settlement, product recall, self-inspection; documents about these tasks must be retained in full.

2. The Ministry of Health shall provide instructions on application of GMP requirements to dietary supplements.

3. From July 01, 2019, manufacturers of dietary supplements shall satisfy GMP requirements in accordance with instructions from the Ministry of Health.

Article 29. Procedures for issuance and reissuance of the certificate of GMP for dietary supplements

1. An application for the certificate of GMP for dietary supplements consists of the following documents:

a) The application form No. 12 in Appendix I hereof;

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

c) A list of primary equipment at the facility.

2. Procedures for issuance of the certificate of GMP for dietary supplements

a) An application specified in Clause 1 of this Article shall be submitted to the Ministry of Health directly, by post or through the online public service system;

b) Within 15 working days from the receipt of the satisfactory application, the receiving authority shall establish an inspectorate, which will to carry out a site inspection and issue the inspection record according to form No. 13 in Appendix I hereof.

The inspectorate shall consist of at least 5 people, 2 of whom are experienced in GMP, and 1 person is specialized in testing.

c) If the inspection result is satisfactory, the receiving authority shall issue the certificate of GMP for dietary supplements (Form No. 14 in Appendix I hereof) within 30 days from the receipt of the application;

d) If the inspection result is not satisfactory, explanation shall be provided in the inspection record. After rectification, the applicant shall send a notice to the inspectorate. Within 07 working days from the receipt of such notice, the inspectorate shall consider and request the Ministry of Health to issue the certificate of GMP for dietary supplements. If rectification is not done within 03 months from the end of the inspection or a notice of rectification is not sent to the inspectorate, the application shall be rejected.

3. A certificate of GMP for dietary supplements is valid for 03 years from its date of issuance. At least 06 months before expiration of the certificate, the certificate holder shall submit an application for its reissuance. Documents and procedures for reissuance are the same as those specified in Clause 1 and Clause 2 of this Article.

4. Applicants for the certificate of GMP for dietary supplements shall pay fees for document processing to the receiving authority.

Chapter X

FOOD SAFETY REQUIREMENTS APPLIED TO FOOD ADDITIVES

Article 30. Food safety requirements applied to food additives

Manufacturers and sellers of food additives shall satisfy the following food safety requirements:

1. Satisfy general food safety requirements specified in specified in Clause 1 Article 19, Clause 1 Article 20 and Clause 1 Article 21 of the Law of Food safety.

2. Only mix food additives on the list of permitted food additives complied by the Ministry of Health, provided the mixture does not cause any harm to human health. In the cases where a new product with new effects is created, such effects, intended users and dose must be proven.

3. Packaging of food additives shall be carried out at a facility that satisfies food safety requirements. Food additives must be labeled in accordance with applicable law.

Article 31. Single-ingredient food additives

1. Foods on in the list of permitted food additives compiled by the Ministry of Health shall be self-declared.

2. Procedures for declaration of single-ingredient food additives are specified in Article 5 of this Decree.

Article 32. Mixed food additives with new uses

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

2. Content of every ingredient in a mixed food additive with new uses must be specified.

3. Procedures for registration of product declaration of mixed food additives with new uses are specified in Article 7 and Article 8 of this Decree.

Article 33. Use of food additives

1. Only use the food additives on the list of permitted food additives compiled by the Ministry of Health. Product declarations of food additives that are not on the list of permitted food additives compiled by the Ministry of Health shall be submitted to the Ministry of Health in accordance with Article 7 and Article 8 of this Decree.

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

Chapter XI

TRACING FOOD ORIGINS

Article 34. Tracing origins of unsafe foods

The manufacturer or seller, upon discovery that a food being manufactured or sold is not safe or at the request of a competent authority, shall trace its origin in accordance with Clause 1 and Clause 2 Article 54 of the Law of Food safety.

Article 35. Tracing origins of unsafe foods

1. Food manufacturers and sellers shall retain information about manufacturers or suppliers of products and buyers (if any) in the form of contracts, logbooks or other methods to serve origin tracing. Information serving origin tracing includes:

a) Names and categories of the products sold;

d) Dates, quantities, batch numbers of the products sold.

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

Chapter XII

STATE MANAGEMENT OF FOOD SAFETY

Article 36. Rules for determination of responsibility for state management of food safety

1. Conformity with the Law of Food safety and relevant legislative documents.

2. Uniform state management of food safety.

3. Ensure continuous management of food production and sale.

4. Close cooperation between ministries.

5. Ensure that a product, a manufacturer or a seller is under the management of a single authority.

6. Ensure scientificness, adequacy and feasibility.

7. Distribution of responsibility for state management of food safety between central and local authorities.

8. Regarding a manufacturer whose products are under the management of more than one authority, the authority that is responsible for the largest quantity of the products shall be the supervisory authority.

9. Regarding a seller whose products are under the management of more than one authority, the Ministry of Industry and Trade shall be the supervisory authority, except for wholesale farm produce markets

10. A facility that both manufactures and sells products that are under the management of more than one authority, is entitled to select its supervise authority to follow administrative procedures.

Article 37. Responsibility of the Ministry of Health

1. Implement regulations on state management of food safety in Clause 1 Article 62 of the Law of Food safety.

2. Submit periodic and ad hoc reports on management of food safety on be basis of supervisions and reports from other Ministries and the People's Committees of provinces.

3. Promulgate technical regulations on products under its management according to Article 62 of the Law of Food safety and the products in Appendix II hereof; promulgate technical regulations or impose safety limits on various groups of products at the request of other Ministries.

4. Perform food safety management throughout the production, processing, storage, transport, export, import, sale of the products specified in Appendix II hereof.

5. Receive and manage applications, issue the certificate of registered product declaration, certificate of food safety regarding dietary supplements and unregistered food additives; Certificate of GMP for dietary supplements; Certificate of advertisement contents for dietary supplements;: Certificate of free sale for products under its management, health certificate.

6. Appoint food testing laboratories and verifying laboratories under its management; appoint laboratories that run tests serving of arbitration and giving final conclusions in case of discrepancies in results given by various laboratories.

7. Appoint regulatory authorities responsible for food safety of products under its management.

Article 38. Responsibility of state capital

1. Promulgate technical regulations on products under its management according to Article 63 of the Law of Food safety and the products in Appendix III hereof.

2. Establish safety limits applied to the products in Appendix III hereof and send them to the Ministry of Health for promulgation.

3. Monitor and assign food safety management tasks regarding the processes of farming, breeding, collecting, fishing, salt production.

4. Perform food safety management and assign food safety management tasks throughout the processes of production, collecting, preparation, processing, storage, transport, export, import, sale of the products specified in Appendix III hereof.

5. Organize the issuance of the certificate of free sale for products under its management.

6. Organize the issuance of the certificate of food safety to manufacturers and sellers of the products mentioned in Clause 3 and Clause 4 of this Article.

7. Perform food safety management at wholesale farm produce markets.

8. Appoint food testing laboratories and verifying laboratories; appoint laboratories responsible for giving final conclusions in case of discrepancies in results given by various laboratories under its management.

9. Appoint regulatory authorities responsible for food safety of products under its management.

10. Publish the list of permitted exporting countries and exporters under its management.

Article 39. Responsibility of the Ministry of Industry and Trade

1. Promulgate technical regulations on products under its management according to Article 64 of the Law of Food safety and the products in Appendix IV hereof.

2. Establish safety limits applied to the products in Appendix IV hereof and send them to the Ministry of Health for promulgation.

3. Perform food safety management and assign food safety management tasks throughout the processes of production, collecting, preparation, processing, storage, transport, export, import, sale of the products specified in Appendix IV hereof.

4. Perform food safety management at supermarket, shopping malls, convenience stores, facilities of the storage and distribution system, and other types of business.

5. Organize the issuance of certificate of free sale for products under its management.

6. Organize the issuance of the certificate of food safety to manufacturers and sellers of the products under its management.

7. Carry out inspection to prevent counterfeit foods and trade fraud regarding every type of foods, food additives, food processing aids, food containers and packages.

8. Appoint food testing laboratories and verifying laboratories; appoint laboratories responsible for giving final conclusions in case of discrepancies in results given by various laboratories under its management.

9. Appoint regulatory authorities responsible for food safety of products under its management.

Article 40. Responsibility of the People's Committees of provinces

1. Perform state management of food safety in their provinces and take responsibility to the GOVERNMENT for food safety in their provinces. Presidents of the People's Committees of provinces shall hold the position of chief of the provincial food safety committee, which carry out inspection and supervision of food safety in their provinces; inspect implementation of law on food safety by inferior authorities; take actions against officials who fail to perform their food safety management duties; organize settlement of complaints and denunciations; take actions against violations against regulations of law on food safety; take responsibility to the Government for violations against food safety in their provinces.

2. Organize implementation of regulations on food safety of the Government and Ministries in their provinces.

3. Operate the provincial food safety committees.

4. Organize dissemination and education of food safety law in their provinces.

5. Provide resources for specialized agencies to perform their food safety management tasks.

6. Take responsibility for food safety management in their provinces; inspect fulfillment of food safety requirements by micro food manufacturers and sellers, street vendors, food and drink businesses and markets.

7. Develop and promulgate regulations on food safety on local foods.

8. Receive and manage applications; issue the certificate of registered product declaration and certificate of advertisement contents for medical foods, food for special dietary uses, dietary products for children up to 36 months.

9. Receive product self-declaration and grant certificate of food safety.

Article 41. Cooperation in food safety assurance

1. Ministries, within the scope of their management, shall cooperate with the Ministry of Health in performing state management tasks to ensure uniform and effective state management of food safety.

2. The Ministry of Health shall develop a food safety education program; the Ministry of Agriculture and Rural Development, the Ministry of Industry and Trade and other ministries shall cooperate with the Ministry of Health in running the program.

3. The Ministry of Health, the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade shall plan and carry out inspections of products under their management in cooperation with other ministries.

4. In case of food poisoning, the Ministry of Health is responsible for organizing emergency treatment. Other Ministries shall provide adequate documents and information about the origin of the food suspected of poisoning; cooperate with the Ministry of Health in investigating and tracing the origin and disposal of the poisoning food.

5. Upon discovery of unconformable foods under management of other ministries, the Ministry of Health shall take charge and cooperate with relevant Ministries in carrying out inspection and giving conclusion.

Chapter XIII

IMPLEMENTATION

Article 42. Transition clauses

1. The certificates of declaration of conformity and certificates of declaration of conformity with food safety regulations that are granted before the effective date of this Decree are still valid until the expiration date of such certificates or the products.

2. Supervisory Ministries shall review and annul the regulations that contravene this Decree.

Article 43. Effect

1. This Decree comes into force from February 02, 2018.

2. This Decree replaces the Government's Decree No. 38/2012/ND-CP dated April 25, 2012 elaborating some articles of the Law of Food safety; Chapter II of Circular No. 13/2014/TTLT-BYT-BNNPTNT-BCT dated April 09, 2014 of the Ministry of Health, the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade.

Article 44. Responsibility for implementation

Ministries, Heads of ministerial-level agencies, Heads of Governmental agencies, President of the People’s Committees of provinces, relevant organizations and individuals are responsible for implementation of this Decree./.

ON BEHALF OF THE GOVERNMENT
THE PRIME MINISTER

Nguyen Xuan Phuc