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### Vietnam

### Post: Hanoi GVN Reformed Decree Guiding the Law on Food Safety

### **Report Categories:**

Sanitary/Phytosanitary/Food Safety Snack Foods Beverages Retail Foods Food Processing Ingredients Livestock and Products Poultry and Products Fishery Products Wine Fresh Fruit

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### **Report Highlights:**

This report provides a summary and unofficial translation of Decree 15/2018/ND-CP, dated February 2, 2018 of the Government of Vietnam (GVN), regulating the implementation of a number of articles on the Food Safety Law. Most significantly, this Decree sets new simplified registration procedures for prepackaged and processed foods, as well as establishes a new import inspection regime to replace

existing regulations. In addition, this Decree consolidates existing registration regulations for the export of food derived from terrestrial animals, aquatic animals, and plants to Vietnam. This Decree also reassigns the responsibilities for establishing maximum residue limits (MRLs) for agrochemicals, including veterinary drugs and pesticides, from the Ministry of Health to the Ministry of Agriculture and Rural Development. The Decree went into effect on February 2, 2018, replacing Decree 38/2012 (dated April 25, 2012) which had previously regulated the implementation of a number of articles in the Law on Food Safety (FSL). Post will issue an updated FAIRS Report at later date to reflect the new effects of Decree 15 on the export of food and agricultural products to Vietnam.

### **Summary:**

Decree 15/2018 renews the implementation a number of articles of the 2010 Food Safety Law and makes fundamental changes to the registration and inspection for both domestic and imported food and the assignment of food safety management among the Ministry of Health (MOH), the Ministry of Agricultural and Rural Development (MARD), and the Ministry of Industry and Trade (MOIT). This Decree completely replaces Decree 38/2012 regulating the implementation of a number of articles of the Food Safety Law and repeals Chapter II of Joint Circular No. 13/2014/TTLT-BYT-BNNPTNT-BCT dated April 09, 2014 of MOH, MARD, and MOIT regarding guidelines for assignments and coordination of state management of food safety.

Vietnam originally notified this Decree to the World Trade Organization (WTO) as a draft Decree amending and supplementing a number of articles of Decree 38/2012 regulating the implementation of a number of articles on the Food Safety Law (G/SPS/N/VNM/88 dated March 3, 2017). However, following industry comments, the Vietnamese Government (GVN) revised the final draft to completely replace Decree 38/2012. The GVN decided against re-notifying the new legislation to the WTO and, despite U.S. requests that Vietnam notify the WTO of supplementary information regarding the replacement of Decree 38/2012, the USG has not yet received an official GVN response at the time of this report.

The organizational structure of the Decree is as follows:

- Chapter I: Procedures for product self-declaration
- Chapter II: Procedures for registration procedures of product declaration
- Chapter III: Safety assurance for genetically engineered (GE) food
- Chapter IV: Issuance of Certificate on establishments satisfying food safety conditions
- Chapter V: State inspection for import-export food
- Chapter VI: Food labelling
- Chapter VII: Food advertising
- Chapter VIII: Conditions of food safety assurance in production of health supplements and dietary supplements
- Chapter IX: Conditions of food safety assurance in production, trade and use of food additives
- Chapter X: Traceability for food
- Chapter XI: Assignment of state management on food safety

### **Self-declaration procedure** (Article 4-5)

The GVN now applies a new simplified registration procedure for pre-packaged processed foods, food additives, and food processing aids in an attempt to replace the existing required conformity registration. Vietnam now authorizes food enterprises to produce, import, and sell these products immediately after the enterprise has posted the Product Self-Declaration documentation (Form 1 of Appendix I of this Decree) on either mass media, their company's website, or premises. As a result of this change, for imported prepacked foods, Vietnam no longer requires exporters to provide a certificate of analysis and certificate of HACCP (hazard analysis and critical control points), or their equivalents in order to register a product in advance of its first importation to Vietnam. Post will issue an updated FAIRS Report later to reflect the new effects of Decree 15 on the export of food and agricultural products to Vietnam.

Post also notes that due to Clause 2 Article 4 of this Decree, the GVN now allows products and raw materials imported for processing for export or for internal production and which are not for domestic sales to be exempt from self-declaration. On March 9, 2018, the Directorate of Customs instructed local customs authorities to allow this exemption based on the importer's declaration on the purposes of use for imported shipments. However, importers must be fully responsible for the use of imported shipments in accordance with their declaration.

### Registration procedure of product declaration (Article 6-7)

This procedure applies to the following products:

- Health supplements, medical foods, food for special dietary uses.
- Dietary products for children up to 36 months.

- Mixed food additives with new usages, food additives that are not on the list of permitted food additives, or food additives not intended for use for the food categories as prescribed by MOH.

Importers are required to submit an application for product declaration to the Vietnam Food Administration (VFA) or provincial competent authorities via the online public service system, via post, or directly. Within 07 working days (for unregistered food additives, medical foods, food for special dietary uses, and dietary products for children up to 36 months) or 21 working days (for health supplements) from the day on which the competent authorities receive adequate documents, the authorities shall verify the application and issue a Certificate of Registered Product Declaration. An application for product declaration consists of:

- Certificate of Free Sale, Certificate of Exportation, or Health Certificate issued by the competent authority of the country of origin/exporting country, which has a safety assurance statement for users or permits free sale of the products in the country of origin/exporting country (the certificate must be consular legalized);

- Original copy or certified true copy of the testing results issued by recognized laboratories or ISO 17025 accredited laboratories within 12 months up to the date of document submission. The testing results must specify safety indicators prescribed by MOH according to risk management principles under international regulations or standards applied by the supplier if relevant MOH's regulations are not available.

- Documents about scientific evidence of the effects of the product or ingredients: original or authenticated copy.

- Authenticated copy of Certificate of Good Manufacturing Practice (GMP) or an equivalent certificate for health supplements will be required starting July 01, 2019.

### **State inspection for imported food** (Article 13-21)

Decree 15 establishes a broader range of foods exempt from of import inspections. Compared with the previous Decree 38/2012, additional products exempted from import inspection consist of<sup>1</sup>:

- Products having a Certificate of Registered Product Declaration.
- Products temporarily imported for re-export.
- Products, raw materials imported for production or processing of exports or internal production and are not for sale at the domestic market.
- Temporarily imported products for sale at duty-free shops.
- Imports serving emergency purposes under orders of the GVN or the Prime Minister.

The GVN also establishes a new import inspection regime to streamline and synchronize the inspection methods that the three Ministries (MOH, MARD, and MOIT) had applied inconsistently in the past. The new inspection regime includes three (3) inspection methods: *reduced inspection, tightened inspection, and normal inspection,* which will reduce the amount of required sampling, mainly through document examinations. Significantly, customs authorities are charged with implementing reduced inspections, while the inspection bodies under MOH, MARD and MOIT shall continue to oversee tightened and normal inspections.

### **Reduced** inspection

A reduced inspection denotes a document examination of up to 5 percent of the total shipments imported within one (01) year. Decree 15 allows this inspection to occur for a broader range of products in one of the following cases:

- Products that have been certified as having satisfied food safety requirements by the competent authority of the exporting country that has entered into a mutual recognition agreement regarding food safety inspections (to which Vietnam is also a signatory); and the inspection result given by the competent authority of the exporting country shows that these products satisfy Vietnam regulations;

- Products have results of three (03) consecutive normal inspections meeting import requirements within 12 months;

- Products are manufactured at establishments applying either GMP, HACCP, ISO 22000, IFS, BRC, FSSC 22000 or an equivalent system.

To register for a reduced inspection, importers are required to submit an application to local customs authorities that includes:

- Product self-declaration;

<sup>&</sup>lt;sup>1</sup> A full list of products exempted from import inspection specified at Article 13 of this Decree.

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

- For products derived from aquatic animals and terrestrial animals, except for processed or prepackaged products: an original copy of the certificate of fulfilment of food safety requirements issued by competent authorities of exporting countries.

The customs authority shall randomly choose up to 5 percent of total imported shipments eligible for reduced inspection within one (01) year for the document examination. The customs authority must provide an explanation and legal basis if they require additional documents.

However, as the time of this report, Post notes that customs authorities have yet to implement the new inspection methods due to a lack of information about eligible products and importers, as well as a lack of guidance on random selection methods of up to 5 percent of the total imported shipments. As a result, the Directorate of Customs has requested all three Ministries – MOH, MARD, and MOIT to develop and provide their databases on the products and importers subject to this inspection.

### Tightened inspection

A tightened inspection is a combination of a documents examination and sampling for testing. This inspection shall apply for imported products in one of the following cases:

- Products have a result during a previous inspection of not meeting import requirements;
- Products fail to meet requirements when inspected or examined during circulation in the Vietnam market (if any);
- Products subject to warnings issued by MOH, MARD, or MOIT or by the competent authorities of foreign countries or by their manufacturers.

Within seven (07) working days from the receipt of an application, the inspection authority shall perform a document examination, sample for testing safety criteria, and issue a notice of a satisfactory or unsatisfactory inspection result. The inspection authority must provide an explanation and legal basis if they require additional documents.

### Normal inspection

This method requires only a document examination and applies to products not subject to reduced or tightened inspections.

Before the shipment arrives at the border checkpoint, the owner of the goods is required to submit an application directly to the inspection authority or via the National Single-window Information Portal. This application consists of:

- Registration form;
- A copy of the product self-declaration;
- A copy of the packing list;

- An original copy of the certificate of fulfilment of food safety requirements issued by the competent authorities of exporting countries for food derived from terrestrial animals and aquatic animals. However, this certificate is not applicable for fish caught and processed by foreign vessels, then sold directly to Vietnam.<sup>2</sup>

Within three (03) working days from the receipt of the application, the inspection authority shall perform a document examination and issue a notice of a satisfactory or unsatisfactory inspection result. The goods owner shall submit the notice of a satisfactory inspection result to the customs authority for customs clearance.

# **Registration for export of food derived from aquatic animals, terrestrial animals and plants** (Article 22)

Vietnam maintains the lists of countries and exporters previously approved for the export of food derived from aquatic animals, terrestrial animals, and plants<sup>3</sup>. However, Decree 15 consolidates and supersedes import requirements for food derived from aquatic animals, terrestrial animals, and plants previously regulated under MARD's regulatory circulars.

To be eligible to export to Vietnam, foreign countries are required to register for the list of countries and territories approved for export to Vietnam. In addition, exporters of food derived from aquatic animals and terrestrial animals, except for processed and prepackaged products, are required to register on the list of facilities approved by Vietnam competent authorities<sup>4</sup>.

Article 22 of Decree 15 details registration procedures for export to Vietnam. Accordingly, exporting countries are required to submit an application to MARD consisting of: i) Information on their management system (laws, standards, food safety control system) and their capacity for food safety control; ii) A list of exporters wishing to export food derived from terrestrial animals or aquatic animals to Vietnam; and, iii) Information about exporters' fulfilment of food safety requirements.

<sup>&</sup>lt;sup>2</sup> Post notes that the MARD's Department of Animal Health (DAH) currently performs both quarantine and food safety inspections for food derived from terrestrial and aquatic animals per MARD's Circular 25/2016 and Circular 26/2016. As of March 30, 2018, DAH continues to maintain these existing inspection procedures and proposes MARD amend these above-mentioned Circulars in order to synchronize their procedures with Decree 15. Post will issue an updated FAIRS Report at later date to reflect the new effects of Decree 15 on food and agricultural product exports to Vietnam.

<sup>&</sup>lt;sup>3</sup> As of March 2018, the United States has been approved for the export of food derived from aquatic animals, terrestrial animals and plants to Vietnam.

<sup>&</sup>lt;sup>4</sup> The list of facilities approved for export to Vietnam is published at the Department of Animal Health's website:

<sup>-</sup> For animal products: <u>http://cucthuy.gov.vn/Pages/danh-sach-cac-doanh-nghiep-cua-22-nuoc-du-dieu-kien-xuat-khau-thuc-pham-co-nguon-goc-dong-vat-tren-can-vao-viet-nam.aspx</u>

<sup>-</sup> For fishery products: http://cucthuy.gov.vn/Pages/danh-sach-thuy-san.aspx

Based on the verification results of registration dossiers, MARD shall perform an audit of the food safety control system of the exporting country (if necessary). MARD is required to publish results within thirty (30) working days from the end of the audit.

For additional registrations to the list of facilities approved for the export of food derived from terrestrial animals or aquatic animals to Vietnam, competent authorities of exporting countries are required to submit an application to MARD for a document examination or on-site inspection.

### Safety assurance for genetically engineered (GE) food (Article 9-10)

Decree 15 maintains procedures for the issuance and revocation of certificates for GE organisms to be used for food and the list of GE organisms granted such certificates as specified by the Government's Decree No. 69/2010/ND-CP and Decree No. 108/2011/ND-CP.

In addition, Decree 15 maintains requirements for the labelling of information about the GE organisms for foods containing at least one GE ingredient in the content of the product that exceeds 5 percent of the total ingredients. Decree 15 also allows labeling exemptions for GE food in the following cases:

- Pre-packaged food containing GE ingredients without detection of the modified genes or products of the modified genes in the food;

- Fresh GE foods, unpackaged processed GE foods sold directly to consumers;
- GE foods used in emergencies, such as natural disasters or epidemics.

### Food labelling (Article 24-25)

Decree 15 maintains current food labeling requirements and allows labeling exemptions for goods in transit, temporarily imported goods; goods in bonded warehouses; test samples; goods for display at an exhibition or fair; raw materials imported for processing of exports or internal production and not being for sale in the domestic market.

For imported products, the name and address of the manufacturer and name and address of the organization or individual that submits the product declaration or registers the product self-declaration must be displayed on labels.

### Food advertisement (Article 26-27)

Decree 15 narrows the list of food products subject to registration of advertisement of contents. Due to this Decree, the registration of the advertisement of contents is only required for the following products:

- Health supplements, medical foods, food for special dietary uses.

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

### Assignment of state management responsibilities on food safety (Article 37-39)

Decree 15 clarifies the principles for assignment of food safety management, and details responsibilities for each Ministry – MOH, MARD, and MOIT. MOH will continue to preside over the development and organization for implementation of national strategies and overall planning for food safety. MOH shall also report on the management of food safety to the GVN based on supervisions and reports from other Ministries and local authorities.

The lists of food products, groups of food products and goods under the management of each Ministry - MOH, MARD, and MOIT are specified in Appendix II-IV of this Decree. Accordingly, each Ministry shall be responsible for the following products:

- MOH: bottled waters, mineral water, functional foods, food additives, flavors, and food processing aids;

- MARD: cereal, meat, poultry, seafood, fruits and vegetables, eggs, raw milk, honey, GE food, spice, sugar, tea, coffee, cocoa, pepper, cashew, and other agricultural products;

- MOIT: flour, starch, dairy products, vegetable oils, confectionary, beer, alcohol and alcoholic drinks, soft drinks.

Post notes that Decree 15 has reassigned the responsibilities for the development of maximum safety limits (MRLs) in food from MOH to MARD and MOIT. Accordingly, MARD and MOIT shall establish MRLs for the relevant products under their management and will send their proposals to MOH for promulgation. However, MOH will continue to establish national technical regulations for food additives, flavors, and food processing aids. At this time, MOH/VFA is also expected to continue its responsibility of notifying any new or modified MRLs to international organizations, however Post will continue to monitor this process.

In addition, the GVN requests all three ministries, MOH, MARD, and MOIT to review and revoke any regulations under their management that conflict with Decree 15.

### **Comments:**

Post has gathered some early reactions from governmental agencies and interested industry sources on Decree 15/2018. Most significantly, MOH/VFA, in cooperation with the Vietnam Commercial Chamber (VCCI) and funding from the American Chamber of Commerce in Vietnam (ACCJ), and other food associations, held two conferences in Hanoi and Ho Chi Minh City in March 2018 for dissemination of Decree 15 for local industries. During these meetings, VFA introduced new contents of the Decree and provided Q&A sessions on its implementation, with special focus on the new procedures for self-declaration and product declaration. The GVN also emphasized that food industries shall now assume full responsibility for the safety of products as Decree 15 has streamlined and consolidated many existing regulations. MOH/VFA also confirmed they are currently drafting a revised Decree on administrative and civil penalties for food safety violations. As such, violations of Decree

15/2018 might be subject to tougher penalties once the GVN issues its new Decree on administrative and civil penalties.

At the time of this report, MARD requested its Department of Legal Affairs to review existing regulations in order to amend, supplement, or revoke any regulations in conflict with Decree 15. MARD also assigned the National Agro-Forestry and Quality Assurance Department (NAFIQAD) to be the agency responsible for establishing a list of criteria and safety limits for products under MARD's jurisdiction. Regarding import inspections, MARD requested the Department of Animal Health (DAH) and the Department of Plant Protection (PPD) to announce their new inspection procedures for imported food under MARD's jurisdiction by April 2018. Post will update any new developments regarding the registration for export of food derived from terrestrial and aquatic animals to Vietnam. In addition, Post continues to work with MARD/DAH to specify the list of processed and pre-packaged products subject to exemption of registration prior to export to Vietnam as stipulated in Decree 15.

Furthermore, local importers confirmed that they have started applying Decree 15's self-declaration procedures for processed and prepackaged food such as: milk powder, confectionary, seasonings, syrups, margarine and butter, food additives, etc. After publishing the product's self-declaration, these enterprises are entitled to import and sell these products and apply for reduced inspection with local customs authorities.

Post plans to follow up with the ACCJ and others stakeholders to monitor the impact of this Decree and will work closely with Vietnam competent authorities to ensure that its implementation does not negatively impact the trade of food and agricultural products from the United States. Should U.S. exporters have any questions, please email: <u>aghanoi@fas.usda.gov</u>.

The full text of the Decree is available at: <u>https://thuvienphapluat.vn/van-ban/The-thao-Y-te/Nghi-dinh-15-2018-ND-CP-huong-dan-Luat-an-toan-thuc-pham-341254.aspx</u>

Below is an unofficial translation of Decree 15/2018/ND-CP.

### THE GOVERNMENT SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

No. 15/2018/ND-CP

Hanoi, February 02, 2018

#### DECREE

### REGULATING THE IMPLEMENTATION OF A NUMBER OF ARTICLES OF THE LAW ON 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 regulate the implementation of a number of articles of the Law on Food Safety.

#### **Chapter I**

#### **GENERAL PROVISIONS**

#### Article 1. Scope

This Decree regulates the implementation of a number of articles of the Law on Food Safety on:

- 1. Procedures for product self-declaration.
- 2. Procedures for registration of the product declaration.
- 3. Assurance of genetically engineered foods.
- 4. Issuance of the certificate of establishment meeting adequate conditions for food safety.
- 5. State inspection of safety of imported and exported foods.
- 6. Food labelling.
- 7. Food advertisements.
- 8. Food safety requirements in production of health supplements.

9. Food safety requirements in production, trade 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 (hereafter referred as organizations and individuals).

### **Article 3. Definitions**

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

1. "Health supplement" or "Dietary supplement" means products used as a supplement to the daily diet to maintain, improve, strengthen user's health and immunity. Health 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 natural sources, including animals, minerals, plants in the form of extracts, isolates, concentrates or metabolites;

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

Health 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 dossiers 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 producer" 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 does preliminary food processing 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. Organizations and individuals (hereafter referred as "suppliers") that produce and sale food, shall conduct the self-declaration for 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 Decree.

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

### Article 5. Self-declaration procedures and dossiers

1. Dossiers for product self-declaration include:

a) The product self-declaration (Form 1 in Appendix I hereof);

b) Original copy or a certified true copy of the food safety testing results issued by recognized laboratories or ISO 17025 accredited laboratories within 12 months up to the date of document submission. The testing results must specify safety indicators prescribed by the Ministry of Health (MOH) according to risk management principles under international regulations or standards applied by suppliers if relevant MOH's regulations are not available.

2. Self-declaration must be carried out as follows:

a) The self-declaration shall be published on mass media or on the supplier's website or posted at supplier's premises; one (1) 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) Immediately after publishing the self-declaration, suppliers are entitled to manufacture and sell the product and assume full responsibility for the safety of such product;

c) The receiving authority shall receive the self-declaration for archiving and announce 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 dossiers shall be submitted to the regulatory authority of one of the provinces of the supplier's choice. Once selected, the follow-up 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 re-submit selfdeclaration. 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. Health supplements, medical foods, food for special dietary uses.

2. Dietary products for children up to 36 months.

3. Mixed food additives with new usages, food additives that are not on the list of permitted food additives or food additives that are not used for the food categories as prescribed by MOH. (hereinafter referred to as "unregistered food additives").

### Article 7. Application of the product declaration

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

a) Declaration form (Form 2 in Appendix I hereof);

b) Certificate of Free Sale, Certificate of Exportation or Health Certificate issued by a competent authority of the country of origin/exporting country, which has a safety assurance statement for users or permits free sale of the products in the country of origin/exporting country (the certificate must be consular legalized);

c) Original copy or certified true copy of the testing results issued by recognized laboratories or ISO 17025 accredited laboratories within 12 months up to the date of document submission. The testing results must specify safety indicators prescribed by MOH according to risk management principles under international regulations or standards applied by the supplier if relevant MOH's regulations 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 percent of the content of such ingredients mentioned in the document;

dd) Certificate of Good Manufacturing Practice (GMP) or an equivalent certificate in cases where imports are health supplements that will be required starting July 01, 2019 (a copy authenticated by the supplier).

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

a) The declaration form (Form 2 in Appendix I hereof);

b) Original copy or certified true copy of the food safety testing results issued by recognized laboratories or ISO 17025 accredited laboratories within 12 months up to the date of document submission. The testing results must specify safety indicators prescribed by MOH according to risk management principles under international regulations or standards applied by the supplier if relevant MOH's regulations 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 percent of the content of such ingredients mentioned in the document;

d) The certificate of suppliers meeting adequate conditions 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 health supplements, applicable from July 01, 2019 (a copy authenticated by the supplier).

3. The documents must be written in the Vietnamese language; documents in other languages must be translated into Vietnamese 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 an application for product declaration via the online public service system, by post, or directly, to the following receiving authorities:

a) MOH for declarations of health 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 shall 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 MOH). Once selected, the follow-up 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 health 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 3 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 is permitted to request additional documents only one time.

Within seven (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 ninety (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 on fees and charges.

### Chapter IV

### ASSURANCE OF SAFETY OF GENETICALLY ENGINEERED FOODS

### Article 9. Assurance of safety of food derived from genetically engineered (GE) organisms and GE products

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

# Article 10. Labelling of goods containing genetically engineered organisms and GE products used as foods

1. Manufacturers and sellers of foods containing at least one GE ingredients of the content exceeding 5 percent of total ingredients, in addition to compliance with common regulations of law on goods labelling, the goods label must contain information about the genetically engineered organisms, except for the cases specified in Clause 2 of this Article.

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

a) Pre-packaged GE food containing GE ingredients without detection of the modified genes or products of the modified genes in the food;

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

c) GE foods used in emergencies such as natural disasters or epidemics.

### **Chapter V**

### ISSUANCE OF THE CERTIFICATE OF ESTABLISHMENT MEETING FOOD SAFETY CONDITIONS

### Article 11. Issuance of the certificate of establishment meeting adequate conditions on food safety

1. [Domestic] Food manufacturers and sellers must obtain the certificate of establishment meeting adequate conditions on food safety, except for those specified in Clause 1 Article 12 of this Decree.

2. Requirements for issuance of the certificate of establishment meeting adequate conditions on food safety are specified in Clause 1 Article 34 of the Law on Food Safety. Manufacturers of health supplements shall apply the requirements specified in Article 28 of this Decree.

### Article 12. Exemption from the certificate of establishment meeting adequate conditions on food safety

1. The following establishments are not required to obtain the certificate:

a) Micro food manufacturers;

b) Food manufacturers and sellers that have no fixed locations;

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 food services not registered as a food business;

i) Street food vendors;

k) Any food business that has one of the following certificates: Good manufacturing practice (GMP), Hazards analysis and critical control points (HACCP), Food safety management system standard ISO 22000, International Food Standards (IFS), BRC food safety standard, Food safety system certification (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 are exempted (unless there is a food safety warning)

1. The product has a 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 or the travel purpose; gifts within duty-free allowances.

3. Imports for personal use of people eligible for diplomatic immunities.

4. Products in transit, temporarily imported for re-export or in bonded warehouses.

5. Samples for testing or research whose quantities are suitable for the testing or research purposes and confirmed by the owners.

6. Products used for displayed at exhibitions or fairs.

7. Products, raw materials imported for production or processing of exports or internal production and are not for domestic sale.

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. Food products derived from terrestrial animals, aquatic animals and plants, excluding processed, prepackaged foods and foods exported by a Vietnamese organization or individual but then returned and [foods subject to] the cases specified in Article 13 of this Decree must satisfy the following requirements:

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

b) Food derived from terrestrial animals and aquatic animals must be manufactured by facilities approved by Vietnamese authorities that the facilities satisfy food safety requirements prescribed in Vietnam's regulations;

c) Each shipment of food derived from terrestrial animals and aquatic animals has a certificate of satisfying food safety requirements issued by the competent authority of the exporting country (except for fish caught and processed by foreign vessels, then sold directly to Vietnam).

2. Procedures for exporting countries, territories and facilities mentioned in Clause 1 of this Article to be registered on the lists of countries and exporters approved for export to Vietnam are specified in Article 22 of this Decree.

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

### Article 15. Inspection authorities for imported food

1. Inspection authorities for imported food are the agencies under or designed by MOH, MARD and the Ministry of Industry and Trade (MOIT) (hereinafter referred to as "inspection authorities").

In the cases where the content of a shipment is under the management of more than one ministry, inspection authorities shall be the agencies under or designed by MARD.

2. Inspecting authorities have the following entitlements and obligations:

a) Decide to switch over from normal inspection to reduced inspection and switch back to normal inspection after the results of three (3) tightened inspections are 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 laws and regulations;

d) Collect testing and inspection fees in accordance with laws and regulations;

dd) Ensure professional qualifications, accuracy, truthfulness and objectivity when inspecting and certifying food safety for imported shipments and items;

e) Comply with instructions, verification and guidance from MOH, MARD and MOIT;

g) Receive and settle complaints of goods owners. If causing any damages to the goods' owners, state inspection authorities have to pay all the inspection and testing fees for the goods' owner and pay compensation for any damage to the goods owners in accordance with laws and regulations;

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

i) Submit biannual reports to relevant supervisory ministries in compliance with Form 6 in Appendix I hereof; or submit ad hoc reports due to warnings of MOH, MARD and MOIT, or of competent authorities of the exporting countries, or of producers; or reports on disposal of disqualified imported foods [to relevant supervisory ministries].

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

Food safety inspection for imported food shall be implemented in compliance with one of the following methods:

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

2. Normal inspection: document examination only.

3. Tightened inspection: document examination in combination with sampling.

### Article 17. Application of the inspection methods

1. Reduced inspection shall apply for shipments, commodities in one of the following cases:

a) Products are certified as satisfying of food safety requirements 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 shows that these products satisfy Vietnam regulations;

b) Products have results of 03 consecutive normal inspections meeting import requirements within 12 months;

c) Products are manufactured at establishments applying either GMP, HACCP, ISO 22000, IFS, BRC, FSSC 22000 or an equivalent system.

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

3. Tightened inspection shall apply for shipments, commodities in one of the following cases:

a) Shipments or commodities have a result during previous inspection of not meeting import requirements;

b) Shipment or commodities fail to meet requirements when inspected or examined during circulation the Vietnam market (if any);

c) Warnings are issued by MOH, MARD, MOIT, the provincial People's Committee or by competent authorities of foreign countries or by their manufacturers.

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

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

b) MOH, MARD or MOIT 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) Product self-declaration;

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

c) An original copy of the certificate of fulfilment of food safety requirements issued by competent authorities of exporting countries for products derived from aquatic animals and terrestrial animals, except for processed or pre-packaged products.

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

a) A registration for inspection (Form 4 in Appendix I hereof);

b) Product self-declaration;

c) Original copies of three (03) notices of satisfactory results of consecutive tightened inspections for shipments, commodities subject to switching over from tightened inspection to normal inspection.

d) A copy of the packing list;

dd) An original copy of the certificate of fulfilment of food safety requirements issued by competent authorities of exporting countries for the products mentioned in Article 14 of this Decree, except for fish caught and processed by foreign vessels, then sold directly to Vietnam.

### **Article 19. Inspection procedures**

1. Procedures for reduced inspection:

a) When applying customs procedures, the goods owner shall submit an application to [the customs authority] in accordance with Clause 1 Article 18 of this Decree;

b) The customs authority shall randomly choose up to 5 percent of the total imported shipments eligible for reduced inspection within one (01) year for document examination.

Within three (03) working days from the receipt of the application, the customs authority shall process document examination 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, the goods owner shall submit the application according to Clause 2 Article 18 of this Decree to the inspection authority or the National Single-window Information Portal of MOH, MARD, MOIT (if applied);

b) Within three (03) working days from the receipt of the application, the inspection authority shall process it and issue a notice of satisfactory or unsatisfactory inspection result (Form 5 of Appendix I hereof). If the application has to be supplemented, an 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) Submission of application is as stipulated at Point a Clause 2 of this Article;

b) Within seven (07) working days from the receipt of the application, the inspection authority shall process document examination, take samples for testing safety indicators and issue a notice of satisfactory or unsatisfactory inspection result (Form 5 of Appendix I hereof). If the application has to be supplemented, an 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 as stipulated at Point b Clause 2, Point b Clause 3 of this Article, the inspection authority shall apply appropriate measures in accordance with Clause 3 Article 55 of the Law on Food Safety and submit a report on disposal of unconformable foods to the supervisory Ministry.

### Article 20. Disposal of nonconforming foods

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

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 nonconforming products. The buyer or recipient of the nonconforming 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 re-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 on Food Safety shall be applied.

### Article 21. Rights and obligations of the goods owner

The goods owner has the following rights and obligations:

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

2. Request the inspection authority to reconsider the inspection result or request the receiving authority to select a designated laboratory to carry out a re-inspection test. 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 on Food Safety if the inspection result is unsatisfactory.

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

5. Implement the decision on disposal of non-conforming foods issued by the inspection authority.

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

1. Vietnam competent authorities shall develop inspection plan, inform and cooperate with competent authorities of exporting countries to inspect food safety control systems of exporting countries and exporters as follows:

a) The competent authority of the exporting country shall send an application to MARD, including information about its management system (laws, standards, food safety control system) and its capacity for food safety control according to Form 8 in Appendix I hereof; a list of exporters wishing to export food derived from terrestrial animals or aquatic animals to Vietnam (Form 7 in Appendix I) and information about their fulfilment of food safety requirements (Form 9 in Appendix I).

b) Within thirty (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; fulfilment of food safety requirements by the registered exporters.

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

a) If an on-site inspection in the exporting country is not necessary, MARD shall announce the list of countries and territories eligible for the export to Vietnam. For products derived from terrestrial animals and aquatic animals, a list of eligible exporters must be published in attachment;

b) If an on-site inspection in the exporting country is necessary, MARD shall publish the inspection result within thirty (30) working days from the end of the inspection.

If the inspection result is not satisfactory, MARD shall issue a notice and provide a specific explanation.

c) In cases where [exporting countries] request to add new establishments to the List of establishments eligible for export of animal products and seafood to Vietnam, the competent authorities of the exporting countries shall send registration dossiers including a list of [new] establishments and establishment information in accordance with Form 7 and Form 8 as mentioned in Point a Clause 1 of this Article to MARD for document inspection or on-site inspection at exporting countries, [MARD shall] consider and decide adding [new establishments] to the List.

### Article 23. State inspection of foods for export

1. MOH, MARD and MOIT shall regulate the power to carry out state inspection of food safety for export under their management in accordance with Article 62, Article 63, and Article 64 of the Law on Food Safety at the request of the importing country.

2. MARD 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 "Sån phẩm dinh dưỡng (cho đối tượng cụ thể)" ("Products for specific users") to differ with conventional food.

2. For imported products, name of organizations or individuals liable for the products must be shown on the label including: name and address of the manufacturers and name and address of the organization or individual that submits the declaration or registers the self-declaration of products.

### Article 25. Exemptions of a number of mandatory labelling contents

1. The secondary label is not required for goods in hand luggage for 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 being for sale in the domestic market.

2. In addition to seasonings and herbs, small packages whose surface area is smaller than  $10 \text{ cm}^2$  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 packaging materials in direct contact with food.

### **Chapter VIII**

### FOOD ADVERTISEMENTS

### Article 26. Foods for which advertisement contents must be registered

1. Health 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 Registered Product Declaration.

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 health 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 drug and is not intended to replace any drug"), 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 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 (a copy certified by the applicant);

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

dd) The usages 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 Product Declaration;

b) Within ten (10) working days from the receipt of the satisfactory application, the receiving authority shall process it and issue Form 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 via post) or the date of receipt on the online public service system.

If the advertisement's content is not concurrent or the application has to be supplemented, the receiving authority shall provide an explanation in writing and specify the legal basis. The receiving authority may request the applicant to supplement the application one (01) time.

Within ten (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 applicant fails to supplement the application within ninety (90) working days from the day on which a written request is made, the application will be invalidated;

c) The receiving authority shall announce 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 HEALTH SUPPLEMENTS

### Article 28. Food safety requirements in production of health supplements

1. Manufacturers of health 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 on Food Safety and the following regulations:

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

b) Have an appropriate number of employees whose qualifications are suitable for their positions and trained in GMP, food safety and relevant knowledge. The head of the production department and the 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 three (3) years' working experience in relevant fields;

c) The factory, equipment, and auxiliary utilities are installed suitably for their purposes of use, following a one-way rule, are easy to clean, and to be able to prevent dust, pollution and other detrimental elements to product quality; and must be cleaned on a daily basis;

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

dd) All tasks must be performed in accordance with prescribed procedures and instructions. Carry out inspections and supervision during the manufacture process to avoid confusion, pollution and cross-contamination. Record the result immediately after performing each step in the production process or carrying out the final step;

e) Establish a quality control department to ensure that the products are manufactured under appropriate conditions, procedures and required standards; necessary tests must be carried out; use of raw materials and sale of products shall not be approved before evaluating product quality; 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 health supplement established by a competent authority.

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

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

3. From July 01, 2019, manufacturers of health 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 health supplements

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

- a) The application Form 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 health 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 carry out a site inspection and issue the inspection record according to Form 13 in Appendix I hereof.

The inspectorate shall consist of at least five (5) persons, two (2) of whom must be experienced in GMP, and one (1) person must be specialized in testing.

c) In cases where the inspection result is satisfactory, the receiving authority shall issue the certificate of GMP for health supplements (Form 14 in Appendix I hereof) within thirty (30) days from the receipt of the application;

d) In cases where the inspection results is unsatisfactory, the inspectorate shall clearly state the contents not satisfying the requirements in the inspection records for the establishments to overcome them. After taking corrective actions, the applicant shall send a notice to the inspectorate. Within seven (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 health supplements. If the establishment fails to complete corrective actions as requested within three (03) months from the end of the inspection or a notice of corrective actions is not sent to the inspectorate, the application shall be rejected.

3. A certificate of GMP for health supplements is valid for three (03) years from its date of issuance. At least six (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 health 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 comply with the following food safety requirements:

1. Comply with general food safety requirements specified in specified in Clause 1 Article 19, Clause 1 Article 20 and Clause 1 Article 21 of the Law on Food Safety.

2. Only mix food additives on the list of approved 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. Food additives included in the list of approved food additives compiled by the Ministry of Health are subject to [product] self-declaration.

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

### Article 32. Mixed food additives with new effects

1. Mixed food additives with new effects must register for product declarations at the Ministry of Health.

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

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

### Article 33. Use of food additives

Organizations, individuals that manufacture or sell food additives must be responsible for:

1. The use of only food additives on the list of approved 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 MOH in accordance with Article 7 and Article 8 of this Decree.

2. Use food additives within the maximum 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 on 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. Principles for determination of responsibility for state management of food safety

1. Conformity with the Law on 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 among 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, MOIT 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 supervisory authority to follow administrative procedures.

### Article 37. Responsibilities of MOH

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

2. Submit periodic and ad hoc reports on management of food safety to the Government based on 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 on Food Safety and the products in Appendix II hereof; promulgate technical regulations or establish 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 establishments satisfying food safety conditions regarding health supplements and unregistered food additives; Certificate of GMP for health supplements; Certificate of advertisement contents for health 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 cases of discrepancies in results given by various laboratories.

7. Appoint regulatory authorities responsible for import inspection of products under its management.

### Article 38. Responsibilities of MARD

1. Promulgate technical regulations on products under its management according to Article 63 of the Law on 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, harvesting, fishing and 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 establishments satisfying food safety conditions 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 import inspection of products under its management.

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

### Article 39. Responsibilities of MOIT

1. Promulgate technical regulations on products under its management according to Article 64 of the Law on 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 MOH 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 establishment satisfying food safety conditions to manufacturers and sellers of the products under its management.

7. Carry out inspection to prevent counterfeit foods and trade fraud regarding all types 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; organize the 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 provincial food safety committees.

4. Organize dissemination and education of food safety law and regulations 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 fulfilment of food safety requirements by micro food manufacturers and sellers, street vendors, food and drink businesses and markets in their provinces.

7. Develop and promulgate regulations on food safety for 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. Organize receipt of product self-declaration and grant certificate of establishment satisfying food safety conditions.

### Article 41. Cooperation in food safety assurance

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

2. MOH shall develop a food safety education program; MARD, MOIT, and other ministries shall cooperate with MOH in running the program.

3. MOH, MARD, and MOIT shall plan and carry out inspections of products under their management in cooperation with other ministries.

4. In cases of food poisoning, MOH is responsible for organizing emergency treatment. Other Ministries shall provide adequate documents and information about the origin of the food suspected of poisoning within their management scopes; cooperate with MOH in investigating and tracing the origin and disposal of the poisoning food.

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

### Chapter XIII

### **IMPLEMENTATION**

### Article 42. Transitional provision

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 on Food Safety; and repeals Chapter II of Joint Circular No. 13/2014/TTLT-BYT-BNNPTNT-BCT dated April 09, 2014 of MOH, MARD and MOIT regarding guidelines for assignments and coordination of state management of food safety.

### 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./.

### **Recipients:**

- Secretariat of the Party Central Committee;
- Prime Minister, Deputy Prime Ministers;
- Ministries, ministerial-level agencies, Government agencies;
- People's Councils and People's Committees of provinces and centrally-run cities;
- Central Office and Commissions of the Party;
- Office of the General Secretary;
- Office of the State President;
- Ethnic Council and Committees of the National Assembly;
- The National Assembly's office;
- Supreme People's Court;
- Supreme People's Procuracy;
- State Audit;
- Committee of the National Financial Supervision;
- Bank of Social Policy;
- Vietnam Development Bank;
- The Central Committee of the Vietnam Fatherland Front;
- Central offices of the unions;
- Governmental Office: Minister-Chairman, Deputy Chairmen, PM Assistant, Director General of web portal, Departments, Subordinate units, Official Gazette;
- Keep as archives: Office, KGVX.

#### ON BEHALF OF THE GOVERNMENT PRIME MINISTER

Signed Nguyen Xuan Phuc

### Appendix I

(promulgated in conjunction with Decree 15/2018/ND-CP dated February 2, 2018)

Form 1	Product Self-Declaration
Form 2	Product Declaration
Form 3	Certificate of Registered Product Declaration
Form 4	Application for Food Safety Inspection of Imported Food
Form 5	Notice of Satisfactory Results/Unsatisfactory Results
Form 6	Report on Inspection of Imported Food
Form 7	List of food producers/traders registering for the export to Vietnam
Form 8	Information on the management system and food safety control capacity of competent authorities of exporting countries
Form 9	Brief information on food safety conditions of food producers/traders
Form 10	Application for Certification of Advertisement Contents
Form 11	Certificate of Advertisement Contents
Form 12	Application for Certification of Good Manufacturing Practices (GMP) for Health Supplement
Form 13	Minutes of Audit (for Certification of GMP)
Form 14	Certificate of GMP for Health Supplement

#### Form 1

### SOCIALIST REPUBLIC OF VIETNAM

Independence - Freedom - Happiness

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#### **PRODUCT SELF-DECLARATION**

No.:..../Name of organization, individual /Year of Declaration

#### I. Information of organization, individual:

lame of organization, individual:	
ddress:	
hone:Fax	-
mail:	•
Code of business:	
Sumber of Certificate of establishment satisfying food safety conditions:	
Date/Location of issuance:	ject to
ertification as stipulated)	-

### **II. Product information**

- 1. Product name:....
- 4. Packaging: .....
- 5. Name and address of manufacturer: .....

**III.Sample of label:** (enclosed with product's label sample or intended product's label)

### **IV. Requirements of food safety**

Organizations, individuals manufacture and sale safe food in compliance with:

- National technical regulations: .....; or
- Ministry's Circular:....; or
- Provincial technical regulations:.....; or
- National standard (*if there is no national technical regulation, ministry's circular, or provincial technical regulation*):..... or;
- Codex standard, regional standard, foreign standard (*if there is no national technical regulation, ministry's circular, provincial technical regulation or national standard*)
- Manufacturer's specifications (*if there is no documents as mention above*)

We commit to fulfil laws and regulations on food safety and are fully responsible for legitimation of self-declaration documents./.

......date.....month.....year..... Representative of organization, individual (sign and stamp)
#### SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom – Happiness

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#### **PRODUCT DECLARATION**

No.:..../

#### I. Information of organization, individual:

ame of organization, individual:
ddress:
hone:Fax
mail:
ode of business:
lumber of Certificate of establishment satisfying food safety conditions:
Pate/Location of issuance:
ertification as stipulated)

#### **II. Product information**

1. l	Product name:
2. 1	Ingredients:
	Key quality indicator(s) for product's usage (for health supplement):
4. ]	Expiration date:
	Packaging:
6. I	Name and address of manufacturer:

**III.** Sample of label: (enclosed with product's label sample or intended product's label)

#### IV. Requirements of food safety

Organizations, individuals manufacture and sale safe food in compliance with:

- National technical regulations: .....; or
- Ministry's Circular:....; or
- Provincial technical regulations:.....; or
- National standard (*if there is no national technical regulation, ministry's circular, or provincial technical regulation*):.....or;
- Codex standard, regional standard, foreign standard (*if there is no national technical regulation, ministry's circular, provincial technical regulation or national standard*)
- Manufacturer's specifications (*if there is no documents as mention above*)

We commit to fulfill laws and regulations on food safety and are fully responsible for legitimation of declaration documents. We shall manufacture or sale products only after receiving Certificate of Registered Product Declaration./.

......date.....month.....year..... Representative of organization, individual (sign and stamp)

Name of Receiving Authority

-----

SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

.....date....month.....year.....

#### CERTIFICATE OF REGISTERED PRODUCT DECLARATION No.:..../Year/DKSP

......(Name of Receiving Authority).....certify to receive a Product Declaration of:......(name of organization, individual), address:....., phone:....., Fax:....., Email:......, for product:...... manufactured by .....(name, address of manufacturer and origin country) in compliance with technical regulations//standards...(number, code, name)......

The enterprise shall be fully responsible for the conformity of product.

**Representative of Receiving Authority** 

(sign and stamp)

Name of Goods Owner

-----

SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom – Happiness

## REGISTRATION FOR FOOD SAFETY INSPECTION OF IMPORTED FOOD No: .../20.../DKNK

1.	Name, address and telephone of goods owner:
2.	Name, address and telephone of traders liable for goods
	quality
3.	Name, address and telephone of exporter:
4.	Date of import ( <i>intended</i> ):
5.	Exporting port:
	Importing/Entry port:
	Date of inspection:
	Location for inspection:
	Name of inspection agency (intended):

10. Goods in details:

No.	Name of goods	Product Category (due to Vietnam technical regulations, CODEX or manufacturer's specifications)	Name and address of manufacturer	Inspection method	Number of Certification of Inspection Method *
(1)	(2)	(3)	(4)	(5)	(6)

\* Number of Certification of Inspection Method is the number of the competent authority's notice announcing an inspection method applied for the goods.

.......date.......datemonthyearGoods ownerFood Safety InspectionSOCIALIST REPUBLIC OF(Sign and stamp)AgencyVIETNAM(Sign and stamp)(Sign and stamp)Independence – Freedom –<br/>Happiness

------

Name of Inspection Authority

#### SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

#### NOTICE ON SATISFYING RESULTS/ UNSATISFYING RESULTS FOR IMPORTED FOOD No.:.../20.../TBNK

1. Name, address and telephone of goods owner: .....

2. Name, address and telephone of traders liable for goods quality.....

- 3. Name, address and telephone of exporter: .....
- 4. Number of Customs Declaration
- 5. Exporting port: .....
- 6. Importing/Entry port:....
- 7. Date of inspection:
- 8. Location for inspection: .....
- 9. Goods in details:

No	Nam e of goods	Product categor y	Name and address of manufacture r	Inspectio n method	Results (qualified or disqualified )	Explanatio n of disqualified goods	Treatment measures for disqualifie d goods
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

#### **Recipients:**

- Goods owner;

- Customs authority.

#### LIST OF FOOD PRODUCTION AND BUSINESS ESTABLISHMENTS REGISTERED TO EXPORT TO VIETNAM

No.	Name of establishment	Code	Address	Products registered to export to Vietnam	Note

...date...month...year... Competent authority on food safety of exporting countries (sign and stamp)

#### INFORMATION ON FOOD SAFETY MANAGEMENT SYSTEM AND CONTROL CAPACITY OF COMPETENT AUTHORITIES OF EXPORTING COUNTRIES

1. Organizational system and control system	em:
2. Officer in-charge (number of staff, qual	lifications, training courses):
3. Legal documents, standards, food safe	ty control and certification procedures:
4. <b>Inspection and surveillance systems for</b> <i>producers/traders</i> ):	r residues, pathogens, (applied for food
5. Food safety inspection and surveilland	ce program:
	datemonthyear
C	ompetent authority on food safety of exporting countries
	(sign and stamp)

#### BRIEF INFORMATION ON FOOD SAFETY CONDITIONS OF FOOD PRODUCTION AND BUSINESS ESTABLISHMENTS

#### -----

1.	Name of establishment:
2.	Address:
3.	Products:
4.	Description of production processes:
5.	Quality management system applied:

...date...month...year... Certifying of competent authority on food safety of the exporting country (sign and stamp)

Form 10

Name of Applie	cant SOCIALIST REPUBLIC OF VIETNAM
	Independence – Freedom – Happiness
RE	datemonthyear GISTRATION FOR CERTIFICATION OF ADVERTISEMENT CONTENTS
	То:
1.	Name of applicant:
2.	Address:
Telej	bhone:Fax:
Requ	ests to register for advertisement contents as follows:

No.	Name of	Number of the Certificate of	Date of Registration for
	products	Product Declaration	Product Declaration

The advertisement shall be posted on:

The dossier consists of the following documents.....

We commit that the dossier and information mentioned above are true and shall advertise the products in compliance with the Certificate of advertisement contents.

Applicant

(sign and stamp)

Name of Receiving Authority

#### SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom – Happiness

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...date...month...year....

#### CERTIFICATE OF ADVERTISEMENT CONTENTS

Name of organization or individual: Address: Phone: Fax.

No.	Name of products	Number of the Certificate of Product Declaration

The advertisement shall be posted on:

.....

With the contents (in attachment) complied with current regulations.

Organization or individual is responsible for advertising the products in compliance with the approved contents.

Authority

(sign and stamp)

#### SOCIALIST REPUBLIC OF VIETNAM

Independence-Freedom-Happiness

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#### APPLICATION FOR THE CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR HEALTH SUPPLEMENT

-----

То: .....

Name of organization or individual:
Address:
Business code:
Name, address of manufacturing facilities:
We apply for the certificate of good manufacture practice

......date.....month.....year..... Goods owner (Sign and stamp) Name of Competent Authority

-----

### SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

### AUDIT RESULT OF GOOD MANUFACTURING PRACTICES (GMP) FOR HEALTH SUPPLEMENT

Due to the Decision No.....date...month...year...of ...[the competent authority]

Today, date...month...year..., auditors include:

1.	Head of the auditing group (name, title, agency):
2.	Head assistant (name, title, agency):
	Member (name, title, agency):
	To audit the good manufacturing practices applied at the facility:
	Representative of manufacturer:

#### **GENERAL INFORMATION**

- 1. Information about the applicant:..... Business code:....
- Legal representative:
- 2. Information about the audit:
- The time of audit:
- The latest audit:
- Form of audit: reviewing reports, auditing on-site or examining documents for evaluation of the level of compliance with GMP principles and regulations stipulated in Decision...../QD-BYT dated.....

- Scope of audit: based on the manufacturer's application

#### AUDIT RESULT

I.	On-site evaluation
1.	Facilities and equipment:
	Sanitary conditions and control:
3.	Information on food ingredients, food additives, food processing aids:
4.	
	Analysis and quality control for food ingredients, semi-final and finished products:
	· · · · · · · · · · · · · · · · · · ·
6.	Documentation:
7.	Other contents as prescribed in GMP guidance:
II	. Findings:

# III. Conclusion:

.....

.....

#### IV. Comments of the representative of manufacturer:

This minute is accepted by all parties and is made in three (3) copies, each party shall keep one copy.

Auditor

(Sign and stamp)

- 1. Head of group:
- 2. Assistant:
- 3. Member:

Representative of manufacturer (Sign and stamp) SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

Name of Competent Authority

SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

No.....

#### **CERTIFICATE OF GOOD MANUFACTURING PRACTICES**

### NAME OF MANUFACTURER: ADDRESS:

Satisfies the Good Manufacturing Practices (GMP) for Health Supplement for the following products:

.....

This certificate is valid for three (3) years from the date of signing.

.....date.....month....year.... Representative of Authority (sign and stamp)

### Appendix II

# LIST OF FOOD PRODUCTS, GROUPS OF FOOD PRODUCTS, AND GOODS UNDER THE MANAGEMENT OF THE MINISTRY OF HEALTH

(promulgated in conjunction with Decree 15/2018/ND-CP dated February 2, 2018)

No.	Name of product/group of products	Notes
1	Bottled water, mineral water, consumable ice (ready-to-use ice and ice used for food processing)	Except for ice used for preservation, processing of products under the management of the Ministry of Agriculture and Rural Development
2	Functional foods	
3	Micronutrients to be added to foods	
4	Food additives, flavorings, food processing aids	
5	Food containers and packaging materials in direct contact with food	Except for those under the management of the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade that are manufactured by the same facility for internal use only
6	Other products not enumerated in the list of the Ministry of Industry and Trade and the Ministry of Agriculture and Rural Development	

#### Appendix III

# LIST OF FOOD PRODUCTS, GROUPS OF FOOD PRODUCTS, AND GOODS UNDER THE MANAGEMENT OF THE MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

(promulgated in conjunction with Decree 15/2018/ND-CP dated February 2, 2018)

No.	Name of product/group of products	Notes
I	Cereal	
1	Cereal	
2	Preprocessed, processed cereal (husked, cut, hulled, in pieces, germinated, heated, etc.)	Except for flour, starch, and products thereof.
II	Meat and products thereof	
1	Fresh meat, cooled meat, frozen meat (as a whole or cut, sliced, ground, rolled, etc.)	
2	Edible by-products of livestock (offal, bones, legs, necks, wings, fat, blood, etc.)	
3	Products derived from meat and edible by-products of livestock and poultry (dried, smoked, canned, heated, cured with salt, collagen, gelatin, etc.)	Except for functional foods under the management of the Ministry of Health
4	Blended products that contain meat (rolls, sausages, salami, sausage, ham, pâté, breaded meats, meat treated with oil, soup, juice, extracts, etc.)	Except for products in the form of cakes under the management of the Ministry of Industry and Trade.
III	Aquatic animals and products thereof (including amphibious species)	
1	Live, fresh, chilled, frozen fish (whole fish, preprocessed, fillets, ground, rolled, sliced, laminated, etc.)	
2	Edible by-products of fish (skin, fins, bubbles, fat, livers, eggs etc.)	
3	Products of fish and edible by-products of fish (fermented, salted, heated, smoked, dried, brined, breaded, treated with oil, extracts, juices, gelatin, collagen, etc. including chemicals, additives, and	Except for functional foods under the management of the Ministry of Health

	processing aids)	
4	Fat and oil derived from fish, refined or not refined, used as food	Except for functional foods and medicinal products derived from fish under the management of the Ministry of Health
5	Fish products blended with flour, starch, bread, processed milk, vegetable oil (including pawn- crackers, fish-crackers, squid-crackers, etc.)	Except for products in the form of cakes under the management of the Ministry of Industry and Trade.
6	Seaweed, algae, and products thereof, used as food	Except for functional foods derived from seaweed and algae under the management of the Ministry of Health
IV	Vegetables, tubers, fruits, and products thereof	
1	Fresh and pretreated vegetables, tubers, fruits (cut, hulled, threshed, segmented, ground, etc.)	Except for vegetables, tubers, fruits, and seeds used for sowing
2	Processed vegetables, tubers, fruits (fermented, dried, heated, powdered, canned, breaded, pickled, treated with oil, sugar, extracts, juices, etc.)	Except for products in the form of confectionery, dried fruits, and soft drinks under the management of the Ministry of Industry and Trade
V	Eggs and products thereof	
1	Eggs of terrestrial and amphibious animals	
2	Preprocessed or processed eggs of terrestrial and amphibious animals (peeled, molded, frozen, fine ground, heated, salted, cured with herbs, etc.)	
3	Mixed foods that have eggs, powdered eggs	Except for confectionery that contains eggs, powdered eggs under the management of the Ministry of Industry and Trade.
VI	Raw milk	
VII	Honey and products thereof	
1	Pure, condensed, diluted honey	
2	Beeswax, pollen, royal jelly with or without honey.	

3	Products that contain honey, beeswax, pollen, royal jelly.	Except for confectionery, and beverages that contain honey under the management of the Ministry of Industry and Trade.
		Except for functional foods and medicinal products under the management of the Ministry of Health.
VIII	Genetically engineered foods	
IX	Salt	
1	Sea salt, rock salt	
2	Refined salt, processed salt, salt mixed with other ingredients	
X	Spices	
1	Single spices, mixed spices, spices derived of animals, plants (flavorings extracted form meat, bones, in powder form, extracts, mustard, etc.)	Except for seasonings in the same package with starch products (instant noodle, instant porridge, etc.) under the management of the Ministry of Industry and Trade.
2	Sauces and preparations for sauces	
3	Sauces	
4	Fruits that belong to Capsicum or Pimenta genus, fresh, dried, ground, or crushed	
XI	Sugar	
1	Cane sugar or beet sugar and sucrose, chemically pure, solid.	
2	Other sugars (including lactose, mantose, glucose, and fructose, chemically pure, solid; sugar syrup without flavorings or colorings; artificial honey mixed or not mixed with natural honey; caramel)	
3	Molasses derived from extracting or refining sugar	
XII	Теа	

-		1 7
1	Fresh tea, processed tea with or without flavorings	Except for prepared products in the form of soft drinks; confectionery that contains tea under the management of the Ministry of Industry and Trade.
2	Other tea products derived from plants	Except for prepared products in the form of soft drinks under the management of the Ministry of Industry and Trade.
XIII	Coffee	
1	Fresh, dried coffee beans, substances extracted and condensed from coffee	
2	Coffee, roasted or not roasted, decaffeinated or not decaffeinated; coffee fruit and pulp; substitutes for coffee that contain certain proportion of coffee; powdered coffee with or without sugar, milk, cream for instant use; processed products that contain coffee	Except for prepared products in the form of soft drinks; confectionery that contains coffee under the management of the Ministry of Industry and Trade.
XIV	Сосоа	
1	Fresh, dried cocoa beans, broken or not broken, fresh or roasted; cocoa peel, cocoa pod husk, cocoa pulp, and other cocoa by-products; cocoa paste, defatted or not defatted; cocoa butter, cocoa fat and oil; cocoa powder without sugar or other sweeteners	
2	Products from powder of cocoa that are roasted, not roasted, solid, liquid, flour, for instant use or without sugar, milk, cream; other products that contain cocoa.	Except for soft drinks; confectionery that contains cocoa under the management of the Ministry of Industry and Trade.
XV	Pepper	
1	Dried, fresh, ground, crushed pepper (Piper genus)	
2	Fruits that belong to Capsicum or Pimenta, fresh, dried, ground, or crushed	
XVI	Cashew	
1	Cashew nuts	

2	Products of cashew nuts	Except for confectionery that contains cashew nuts under the management of the Ministry of Industry and Trade.
XVII	Other agricultural products	
1	Seeds (sunflower seeds, pumpkin seeds, watermelon seeds, etc.), processed or unprocessed	
2	Products derived from plant used as food, raw, preprocessed, or processed (bamboo shoots, black fungus, mushrooms; soy products, except for oil; edible bark, roots, leaves, stems, flowers of some plants, etc.)	Except for those used as herbal ingredients or functional foods under the management of the Ministry of Health
3	Edible bird's nests and products thereof	Except for those used as herbal ingredients or functional foods under the management of the Ministry of Health
4	Products derived from inspects, used as food (grasshoppers, crickets, caterpillars, etc.)	
XVIII	Instruments and materials for packaging and containing food during manufacture, processing, sale of foods under the management of the Ministry of Agriculture and Rural Development	
XIX	Ice for preservation and processing of products under the management of the Ministry of Agriculture and Rural Development.	

#### Appendix IV

#### LIST OF FOOD PRODUCTS, GROUPS OF FOOD PRODUCTS, AND GOODS UNDER THE MANAGEMENT OF THE MINISTRY OF INDUSTRY AND TRADE

(promulgated in conjunction with Decree 15/2018/ND-CP dated February 2, 2018)

No.	Name of product/group of products	Notes
I	Beer	
1	Draught beer	
2	Bottled beer	
3	Canned beer	
п	Alcohol and alcoholic drinks	Not including medicinal alcohol under the management of the Ministry of Health.
1	Wine	
1.1	Non-carbonated wine	
1.2	Carbonated wine	
2	Fruit wine	
3	Liqueur	
4	Strong wine	
5	White wine, vodka	
6	Other alcoholic drinks	
ш	Soft drinks	Not including mineral water and pure water under the management of the Ministry of Health
1	Canned beverages, including fruit and vegetable juices.	
2	Soft drinks that need diluting before drinking	
3	Instant soft drinks	Not including mineral water and pure water under the management of the

		Ministry of Health
IV	Processed milk	Not including micronutrient-enriched products and functional foods under the management of the Ministry of Health
1	Liquid milk (including liquid milk that contain flavorings or other food additives)	
1.1	Pasteurized products	
1.2	Products sterilized by ultra-high-temperature (UHT) processing or other high-temperature methods.	
2	Fermented milk	
2.1	Liquid	
2.2	Solid	
3	Powdered milk	
4	Condensed milk	
4.1	Sweetened	
4.2	Not sweetened	
5	Cream	
5.1	Pasteurized	
5.2	Sterilized by ultra-high temperature processing (UHT) technology	
6	Soy milk	
7	Other dairy products	
7.1	Butter	
7.2	Cheese	
7.3	Other products from processed milk	
V	Vegetable oil	Not including micronutrient-enriched products and functional foods under

		the management of the Ministry of Health
1	Sesame oil	
2	Bran oil	
3	Soya-bean oil	
4	Peanut oil	
5	Olive oil	
6	Palm oil	
7	Sunflower seed oil	
8	Rum oil	
9	Cottonseed oil	
10	Coconut oil	
11	Palm seed oil or babasu oil	
12	Rapeseed oil or mustard oil	
13	Flax oil	
14	Castor oil	
15	Other oils	
VI	Flour, starch	Not including micronutrient-enriched products and functional foods under the management of the Ministry of Health
1	Wheat flour of meslin flour	
2	Milled cereal	
3	Potato flour	
4	Malt: roasted or not roasted	
5	Starch: wheat, corn, potato, others	

6	Inulin	
7	Wheat gluten	
8	Products from dough, raw of cooked: spaghetti, macaroni, noodle, instant noodle, flat noodle, gnochi, ravioli, cannelloni, instant porridge, vermicelli, etc.	
9	Products from tapioca and substitutes made of starch, in pieces, grains, fine powder, and the likes	
VII	Confectionery	Not including micronutrient-enriched products and functional foods under the management of the Ministry of Health
1	Sweet, salted, or tasteless cookies	
2	Biscuits, baked bread, and the likes	
3	Dough bread	
4	Toast	
5	Birthday cakes	
6	Hard and soft candies with sugar and no cocoa	
7	Chewing gums, coated or not coated with sugar	
8	Chocolate	
9	Jam, fruit jelly, powder and paste from fruits or nuts, during cooking process, containing sugar, other sweeteners, or wine.	
10	Fruits, nuts, and other edible parts of plants, treated or otherwise preserved, containing with sugar, other sweeteners, or wine.	
11	Other confectionary products	
VIII	Instruments and materials for packaging and containing food during manufacture, processing, sale of foods under the management of the Ministry of Industry and Trade	