GOVERNMENT	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness
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Draft 8
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DECREE
Amending and supplementing several articles of Decree No. 15/2018/ND-CP dated February 02, 2018, of the Government detailing the implementation some articles of the Law on Food Safety

Pursuant to the Law on Organization of the Government dated February 18, 2025;

Pursuant to the Law on Organization of Local Governments dated February 19, 2025;

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

As per request of the Minister of Health;

The Government promulgates the Decree amending and supplementing several articles of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018, detailing the implementation of several articles of the Law on Food Safety.

Article 1. Amending and supplementing several articles of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 detailing the implementation of several articles of the Law on Food Safety

1. Clauses 12, 13 and 14 are added into Article 1 as follows:

"12. Conditions for food products exported to be redirected for domestic consumption.

13. Testing of food products in service of state management.

14. Post-marketing inspection of food safety."

2. Clauses 3, 4 and 8 are amended and supplemented and Clauses 11, 12, 13, 14 15 and 16 are added to Article 3 as follows:

a) Amend Clauses 3, 4 and 8 as follows:

"3. *Food for Special Dietary Uses* for dieters, the elderly, pregnant women and other special subjects as prescribed by the Committee on International Food

Standards (CODEX) are foods that are specially formulated or blended to meet the specific dietary requirements of the or according to the medical condition and specific disorders of the user. The composition of this food must be markedly different from the composition of ordinary foods of the same nature, if any.

4. *Scientific evidence* means scientific information, scientific data and scientific documents that support the claims on intended use and effect on health of a product or its components from scientific research works published in national journals, internationally, prestigious journals ISI (Institute of Scientific Information), SCOPUS; or documents on traditional medicine, medicinal plants, herbal medicine, medical, pharmaceutical and food literature published in scientific publications.

8. *Small-scale initial production establishments* are the establishments engaging in cultivation, livestock farming, harvesting, fishing, and exploitation on a household basis, individual households and not being granted enterprise registration certificates or investment certificates as prescribed by law."

b) Clauses 11, 12, 13, 14, 15 and 16 are added to Article 3 as follows:

"11. *Food product owner* means an organization or individual that owns the formula, production process, standard or trademark of a food product or is certified by a competent authority of the country of origin or exporting country.

12. *Organizations and individuals responsible for placing food products on the market* are manufacturers or owners of food products or organizations or individuals authorized by manufacturers or owners of food products to be applicant of Product self-declaration or Product Declaration.

13. Stringent Regulatory Authorities (SRA) are drug regulatory agencies classified by the World Health Organization (WHO) on the SRA list, including:

- ICH members before October 23, 2015, including: the United States Food and Drug Administration (US-FDA), the European Union Medicines Administration, the United Kingdom Medicines and Medical Products Administration (MHRA), the Japan Medicines and Medical Devices Administration (PMDA).

- Observer members of the ICH prior to 23 October 2015 include: the European Free Trade Association (EFTA) Drug Regulatory Authority with representatives of Swissmedic and Health Canada.

- Members who have association and mutual recognition agreements with ICH Members before 23 October 2015 include Australia, Iceland, Liechtenstein and Norway.

14. Quality *management system of testing establishments (hereinafter referred to as quality management system)* includes a system of management and technical documents and dossiers related to testing activities such as personnel, equipments, facilitties, testing methods to ensure quality, accuracy and transparency of the test results.

15. *Inter-laboratory comparison* means the organization, implementation and evaluation of testing methods on the same subject or on similar subjects by two or more testing establishments under predetermined conditions.

16. *Proficiency test* means the evaluation of the performance of the participants according to the established criteria through inter-agency comparison."

3. Article 4 is amended and supplemented as follows**:**

"**Article 4. Product Self-Declaration**

1. Organizations and individuals responsible for placing products on the market (applicant) shall perform the self-declaration for pre-packaged processed foods; food additives; food processing aids; food containers in direct contact with food; primary packaging materials; micronutrients (hereinafter collectively referred to as products), except for those prescribed 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 internal production and are not sold domestically; imported products in service of aid are exempt from the self-declaration."

4. Points b, c, Clause 1; Point b, Clause 2; Clause 3 of Article 5 are amended and supplemented as follows:

a) Points b and c, Clause 1 are amended as follows:

"b) Product CoA (certificate of Analysis). At the time of self-declaration, CoA is issued within 12 months by an accredited laboratory in conformity with ISO/IEC 17025 and shall include quality criteria and safety criteria (a copy affixed with the organization/ individual seal, or certified electronic copy).

c) A power of attorney issued by the manufacturer or the owner of the food product for the applicant of the product self-declaration contains all of the information specified in Article 8a of this Decree (in case of authorization) (a copy affixed with the organization/ individual seal; or certified electronic copies)."

b) Point b Clause 2 is amended as follows:

"b) Within 21 days from the date to receive the self-declaration dossier, if having no written opinion, the competent authority shall post the self-declaration dossier on the website or online public service system and the organization, individuals are entitled for production and trade of the product.

In case the imported food product has been licensed for circulation by the competent authority of the country which the drug administration agency is on the list of SRA (Stringent Regulatory Authorities), the organization or individual is entitle for trading the product immediately after submission of self-declaration; The competent authority shall post the self-declaration dossier on the website or online public service system within 10 days from the receipt of the self-declaration.

Applicant is fully responsible for the legality of the self-declaration dossier and the quality and safety of self-declared products."

c) Clause 3 is amended as follows:

"3. Documents in the Product Self-Declaration dossier must be presented in Vietnamese.

a) If the documents are in English, the applicant (organization or individual) shall translate them into Vietnamese and be responsible for the accuracy of the translated contents.

b) For documents in foreign languages other than English, they must be translated into Vietnamese and authenticated with the translator's signature. Otherwise, the applicant must submit the translation into English and have the translator's signature certified in the country of origin or export; applicant translates documents into Vietnamese and take responsibility for the accuracy of the translated contents.

c) If the product label is expressed in many different languages but not in English, only the language of the country of origin or the exporting country shall be translated.

The document must be valid at the time of Self-Declaration."

5. Article 6 is amended, supplemented as follows:

"**Article 6. Product Declaration**

1. Organizations and individuals responsible for placing products on the market (applicant) shall register Product Declaration for the following products:

a) Health Supplement, medical nutritional foods, foods used for special diets, supplemented foods.

b) Nutritional products for children up to 36 months of age.

2. Food products specified in Clause 1 of this Article imported for aid purposes are exempt from the Product Declaration.

3. Documents in Product Declaration dossier must be presented in Vietnamese.

a) If the document is in English, applicant shall translate it into Vietnamese and take responsibility for the accuracy of the translated contents.

b) For documents in foreign languages other than English, they must be translated into Vietnamese and authenticated with the translator's signature. Otherwise, the applicant shall submit the translation into English and have the translator's signature certified in the country of origin or export; applicant shall translate the documents into Vietnamese and take responsibility for the accuracy of the translated contents.

c) If the product label is expressed in many different languages but not in English, only the language of the country of origin or the exporting country shall be translated.

The document must be valid at the submission time of Product Declaration.

4. Organizations and individuals responsible for placing products on the market shall be fully responsible for the legality of the declaration dossier and food quality and safety for the declaraed products and only put the products into production and trading when they have been granted the Certificate of Product Declaration."

6. Article 7 is amended and supplemented as follows:

"**Article 7. Registration dossier of Product Declaration for imported food products**

1. Registration dossier of a Product Declaration for imported food products comprises:

a) The Product Declaration is specified in Form No.02, Appendix I issued in conjuction with this Decree.

b) Certificate of Free Sale or Certificate of Exportation or Health Certificate or other relevant certificates for exported food issued by a competent authority of the country of origin or exporting country as prescribed in Clause 3 of this Article (consular legalization or electronic copy enclosed with the results of self-search from

the website or English database of the issuing authority or competent authority and stamped with the applicant's seal).

These certificates must contain at least the following information: Name of the competent authority granting the certificate; Date of issue; product name; Type or group of products; Name and address of the manufacturing site; Full name and signature of the issuer; have contents that ensure safety for users or are suitable for users or are sold freely in the market of the manufacturing or exporting country;

c) CoA including quality and safety criteria. At the submission time, CoA is issued within 12 months (copy affixed with the applicant's seal and the original copy to be presented for comparison when submitting or receiving the result of administrative procedures; or a certified electronic copy) by:

- Laboratory accredited in accordance with ISO/IEC 17025; or

- The testing laboratory of the manufacturing facility that meets the Good Manufacturing Practice (GMP) requirements and can test the products of the manufacturing facility itself;

d) Scientific evidence supporting the contents related to the intended use and dosage or documents evaluated and published by domestic and foreign competent authorities proving the intended use and effect of the product or of the ingredients constituting the declared intended use (a copy affixed with applicant's seal).

When using scientific evidence on the use of ingredients of the product to make uses of the product, the daily dose of the product must be higher than or equal to 15% of the amount of use of such ingredient stated in the document.

dd) The power of attorney, issued the manufacturer or the owner of the food product for registration of the Product Declaration, contains all the information specified in Article 8a of this Decree (in case of authorization to register the product declaration) (a copy affixed with applicant's seal and the original copy will be provided for comparison when submitting or receiving results of administrative procedures; or certified electronic copies).

2. Registration dossier of Product Declaration for Health Supplement:

a) Documents specified in Clause 1 of this Article.

b) Certificate of food safety eligibility meeting Good Manufacturing Practice (GMP) requirements or equivalent certification (a copy affixed with the applicant's seal or an electronic copy enclosed with the result of self-search from the website or

English database of the issuing authority or competent authority and affixed with applicant’s seal).

c) Sample of Product label and instruction for use (if any).

d) Report on product research and development.

dd) Documents on quality and safety standards

e) Documents on the production process.

g) Report on the results of the study on product stability.

i) Other documents related to product technical assessment; Additional test results requested by competent authority (if requested); other technical justification (if any).

Detailed instructions for the above documents and the dossier of product declaration of Health Supplement are specified in Form No. 15; Appendix I issued in conjunction with this Decree.

3. Registration dossier of Product Declaration for medical nutritional foods, foods used for special diets, supplemented food, and nutritional products for children up to 36 months of age:

a) Documents specified in Clause 1 of this Article.

b) Certificate of Food Safety Eligibility meeting Good Manufacturing Practice (GMP) requirementsthat meets Good Manufacturing Practices (GMP) or Hazard Analysis and Critical Control Points (HACCP) System or ISO 22000 Food Safety Management System or International Food Standard (IFS) or Global Standard for Food Safety (BRC) or Food Safety System Certification (FSSC 22000) or equivalent certification (a copy affixed with applicant’s seal or an electronic copy enclosed with the result of self-search from the website or English database of the issuing authority or competent authority and affixed with the applicant’s seal of the organization, individuals);

c) Sample of Product label and instruction for use (if any);

d) Report on product research and development.

dd) Documents on quality and safety standards.

e) Documents on the production process.

g) Report on the results of the study on product stability.

h) Other technical justification (if any).

Detailed instructions for the above documents and the dossier of Product Declaration of medicinal nutritional foods, foods used for special diets, supplemented food and nutritional products for children up to 36 months are specified in Form No. 16, Appendix I issued in conjunction with this Decree.

7. Article 7a is added after Article 7 as follows:

"Article 7a. Dossier of Product Declaration for domestically produced food products

1. Registration dossier of Product Declaration for domestically manufactured food product comprises:

a) Product Declaration is specified in Form No. 02, Appendix I issued in conjuction with this Decree.

b) CoA includes quality and safety criteria. At the submission time, CoA is issued within 12 months (a copy affixed with applicant’s seal and the original copy to be presented for comparison when submitting or receiving the result of administrative procedures; or a certified electronic copy) by:

- Laboratory accredited in accordance with ISO/IEC 17025; or

- The testing laboratory of the manufacturing facility that meets the Good Manufacturing Practice (GMP) requirements and can test the products of the manufacturing facility itself.

c) Scientific evidence supporting the contents related to the intended use and dosage or documents evaluated and published by domestic and foreign competent authorities proving the intended use and effect of the product or of the ingredients constituting the declared intended use (a copy affixed with applicant’s seal).

When using scientific evidence on the use of ingredients of a product to make the product use, the daily dose of the product must be higher than or equal to 15% of the amount of use of such ingredient stated in the document.

2. Registration dossier of Product Declaration for Health Supplement:

a) Documents specified in Clause 1 of this Article.

b) Sample of Product label and instruction for use (if any).

c) Report on product research and development.

d) Documents on quality and safety standards.

d) Documents on the production process.

dd) Report on the results of the study on product stability.

e) Information on primary packaging materials.

h) Other documents related to the technical assessment of the product, additional test results requested by competent authority (if requested) and other technical justification (if any)

Detailed instructions for the above documents and dossier of Product Declaration of Health Supplement are specified in Form No. 15, Appendix I issued in conjunction with this Decree.

3. Registration dossier of Product Declaration for medical nutritional foods, foods used for special diets, supplemented food, and nutritional products for children up to 36 months:

a) Documents specified in Clause 1 of this Article;

b) Certificate of food safety eligibility that meets Good Manufacturing Practices (GMP) or Hazard Analysis and Critical Control Points (HACCP) System or ISO 22000 Food Safety Management System or International Food Standard (IFS) or Global Standard for Food Safety (BRC) or Food Safety System Certification (FSSC 22000) or equivalent certification (a copy affixed with applicant’s seal);

c) Sample of Product label and instruction for use (if any).

d) Report on product research and development.

dd) Documents on quality and safety standards

e) Documents on the production process.

g) Report on the results of the study on product stability.

h) Other technical explanations (if any).

Details of guidance on the above documents and dossier of Product Declaration of medicinal nutritious food products, foods used for special diets, suppleneted food and nutritional products for children up to 36 months of age are specified in Form No. 17, Appendix I issued in conjunction with this Decree."

8. Clauses 1, 2 and 3 of Article 8 are amended and supplemented as follows:

"1. Organization and individual producing and trading food (applicant) shall submit registration dossiers of Product Declarations via the online public service system or postal services or directly to the competent authority as prescribed below:

a) Submit to the Ministry of Health for Health Supplement.

b) Submit to competent state management agencies designated by provincial-level People's Committees for medical nutritional foods, foods used for special diets, supplemented food and nutritional products for children up to 36 months of age.

c) If applicant has 02 (two) or more manufacturing facilities producing the same product, applicant shall only carry out procedures of Product Declaration at one state management agency in the locality where manufacturing facility is located, chosen by applicant (except for Product Declaration at the Ministry of Health). Once the state management agency has been selected for Product Declaration, the subsequent submissions must be done at the selected agency.

2. Within 90 days from the date of receiving a complete registration dossier of Product Declaration, the competent authority specified in Clause 1 of this Article shall appraise the dossier and issue a Receipt of Product Declaration according to Form No. 03, Appendix I issued in conjuction with this Decree.

c) During the appraisal period, competent authority shall set up specialized subcommittees to appraise and issue the Receipt of Product Declaration for products prescribed in Clauses 2, 3 and 4, of Article 7 and Clauses 2, 3 and 4 of Article 7a of this Decree. In case of necessity, the competent authority shall set up an advisory council to issue the Receipt of Product Declaration and shall not directly participate in the appraisal of the Product Declaration dossier.

3. In case of disagreement with registration dossier of Product Declaration or a request for amendment or supplementation, the competent authority must provide an official document stating clearly the reason and legal grounds as well as the professional basis of the request.

Within 60 days from the date of receiving the written request for amendment and supplementation from the competent authority, the applicant shall complete and submit the dossier of amendment and supplementation. Applicants are only allowed to amend and supplement 01 time. Past the time limit for amendment and supplementation, the registration dossier of Product Declaration is no longer valid. Competent authority is only allowed to request amendments and supplementation once for each registration dossier of Product Declaration or amendment and supplementation submitted by applicant.

The registration dossier will no longer be valid if after 60 days from the receipt of the official document requesting amendment and supplementation, the applicant does not amend or supplement or amend or supplement more than 01 time."

9. Articles 8a, 8b and 8c are added after Article 8 as follows:

"**Article 8a. Regulations on Power of Attorney (PoA)**

1. The language of PoA shall be in Vietnamese, English or bilingual Vietnamese and English.

2. Authorization to be the applicant for Product Self-Declaration or Product Declaration must adhere to relevant legal provisions on authorization and include the following information:

a) Name and address of the manufacturer; in case the authorizing party is the owner of the food product, it is necessary to clearly state the name, address of the owner of the food product and the name, address of the manufacturing site:

b) Name and address of the authorized applicant.

c) Scope of authorization (being applicant of Product Self-Declaration or Product Declaration and jointly responsible for all matters related to the product).

d) Name of product.

3. The authorizer shall notify the competent authority of any change in the authorization contents by official letter.

Article 8b. Revoke of the Receipt of Product Declaration registration dossier and removal of product information posted on the website of the competent authority receiving the Product Declaration dossier

1. The competent authority shall withdraw the Receipt of Product Declaration registration and remove the product information posted on its website in one of the following cases:

a) One of the documents revoked by a foreign competent authority, and the revoked document is the one submitted for Product Self-Declaration or for the competent authority to issue the Receipt of Product Declaration registration in Vietnam.

b) Product Declaration registration dossiers based on forged and dishonest documents.

c) Product trademarks concluded to be infringing intellectual property rights by competent authority.

d) Product is found not manufactured or imported within 03 consecutive years from Product Self-Declaration or from the issuance of the Receipt of Product Declaration.

dd) The Receipt of Product Declaration registration is voluntarily recalled by the Applicant.

e) The Receipt of Product Declaration registration is issued by the uncorrect competent authority.

g) Changing the location of the organization or individual responsible for placing the product on the market without notifying the competent authority who receives the Product Self-Declaration/ Product Declaration registration.

h) Notice or conclusion of the investigation agency that the product is counterfeit or contains prohibited substances. In this case, all Receipts of Product Declaration of the manufacturer and the Applicant (organization or individual responsible for placing the product on the market) are recalled and the product information posted on the website of the competent authority is totally removed.

i) After 06 months from the effective date of this Decree, failing to supplement the power of attorney as prescribed in Article 8a and the test result sheet as prescribed at Point b, Clause 1, Article 5 of this Decree.

2. Authorization to issue decisions on revoking the Receipt of Product Declaration and removal of product information posted on the website of the competent authority:

a) VFA (Vietnam Food Administration) - Ministry of Health shall issue a decision to revoke the Receipt of Product Declaration and remove product information posted on the website of the competent authority for the products of which Receipt of Product Declaration is granted by VFA.

b) The competent authorities appointed by the provincial People's Committees shall issue decisions to revoke the Receipt of Product Declaration registration issued by their own units; request to withdraw the Product Self-Declaration dossier and remove product information posted on the website of the competent authorities receiving the Product Declaration registration dossier.

Article 8c. **Temporarily suspension to receive and process registration dossiers of Product Declaration**

Competent authority shall temporarily suspend the receipt and processing of Product Declarations registration dossiers of organizations and individuals who violate the provisions of the law on food safety until a violation handling decision is made by the competent authority, and the organization or individual has complied with the handling decision.

After the temporary suspension, once the organization or individual has fully remedied the violations and makes a report, the competent authority will continue to receive and process the registration dossier of Product Declaration."

10. Clause 3 is added to Article 11 as follows:

"3. The issuance of the Certificate of food safety eligibility shall comply with the provisions of Points b, c, d, dd, e, Clause 3, Article 6 of the Government's Decree No. 67/2016/ND-CP dated July 01, 2016 regulating conditions for food production and trading under the management of the Ministry of Health as amended in Clause 3, Article 2 Decree No. 155/2018/ND-CP dated November 12, 2018 of the Government amending and supplementing a number of regulations related to business investment conditions under the state management of the Ministry of Health."

11. Point dd, Clause 1, Article 12 is amended and supplemented as follows:

"dd) Trading in pre-packaged foods, food additives, food processing aids, micronutrients;"

12. Article 12a is added after Article 12 as follows:

"**Article 12a. Revocation of the Certificate of Food Safety Eligibility**

1. Authorization of revocation:

The agency issuing the Certificate of Food Safety Eligibility and the Certificate of Food Safety Eligibility meets the requirements of Good Manufacturing Practices (GMP) for Health Supplement (hereinafter referred to as the Certificate of Food Safety Eligibility) has the right to revoke the granted Certificate Food Safety Eligibility.

2. Cases of revocation:

The competent authority to receive the dossier shall revoke the Certificate of Food Safety Eligibility of the establishment in one of the following cases:

a) Failing to have a business registration certificate, enterprise certificate or business registration certificate, enterprise certificate failing to register appropriate food business lines.

b) Within 12 months, being administratively sanctioned 02 (two) times or more for violations of food safety conditions specified in Chapter IV of the Law on Food Safety and legal documents regulating food safety conditions.

c) As per the request of the inspection agency.

d) Using substances in the list of substances banned for use in food production and trading or on the list of substances banned for use in the production and trading of Health Supplement.

dd) Producing counterfeit foods, food additives and food processing aids.

e) Within 12 months, there are 2 (two) or more cases of food poisoning, or there are at least 1 (one) case of food poisoning resulting in death.

g) Application for Certificate of Food Safety Eligibility has fake documents, fake seals or fake signatures.

h) Using fake CoA (Certificate of Analysis) or falsifying test results in product quality control dossiers of the establishment.

i) The organization or individual fails to notify the competent authority of the suspension of production and business activities for a period of 12 months at the location where the Certificate of Food Safety Eligibility has been granted.

k) As per the request of organizations and individuals that own the granted Certificates of Food Safety Eligibility."

13. Article 13 is amended as follows:

"Article 13. Cases exempted from state inspection of food safety in importation (except for cases with warnings on food safety)

1. Products being gifts or gifts within the import duty-free norms in accordance with the tax law.

2. Imported products for personal use of subjects entitled to diplomatic privileges and immunities.

3. Products in transit, border transfer, transshipment, temporary import, re-export, bonded warehouses.

4. Product to be used as a test or as research sample in quantity suitable to the purpose of testing or research certified by an organization or individual.

5. Products used for display at fairs and exhibitions.

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

7. Goods imported in service of urgent requests under the direction of the Government or the Prime Minister.

8. Imported products and raw materials are only used for production and processing of exported goods, not consumed in the domestic market."

14. Clause 1 and Points a, e, i, k, Clause 2, Article 15 are amended and supplemented as follows:

a) Clause 1 is amended as follows:

"1. The state inspection agency in charge of food safety means an agency or organization assigned or appointed by the provincial People's Committee to carry out the state inspection of product quality and safety as prescribed in Clause 1, Article 39 of the Law on Food Safety. The state inspection agency in charge of food safety must meet the following conditions:

a) Having been granted a Certificate of registration of inspection activities as prescribed in the Government's Decree No. 107/2016/ND-CP dated July 01, 2016 regulating conditions for business of conformity assessment services, including food assessment.

b) It has been certified as an inspection organization in accordance with ISO/IEC 17020 standards.

c) There are at least 04 assessors (civil servants, public employees or employees who sign contracts with a 12-month or more than 12 months labor term or employees who sign indefinite-term contracts) who have university degrees suitable to the inspected products and goods and have at least 03 years of practical experience in product quality assessment.

d) There are complete quality control and food safety procedures that comply with the state inspection methods for imported food corresponding to the groups of food products”.

b) Point a, Clause 2 is amended as follows:

"a) Decision on the conversion to the normal inspection method after 03 (three) times of tightened inspection and meet the requirements of imported food; to provide the inspection results of the imported food by the normal inspection to the customs authority to decide on the application of the reduced inspection to the imported goods;"

c) Point e, Clause 2 is amended as follows:

"e) Under direction, inspection, and guidance on organization and professionalism from the provincial People's Committee, the Ministry of Health, the Ministry of Agriculture and Environment, and the Ministry of Industry and Trade;"

d) Point i, Clause 2 is amended as follows:

"i) Report to the provincial People's Committee every 06 months as prescribed in Form No. 06, Appendix I issued in conjunction with this Decree or perform special reports and ad-hoc reports as per request of the Ministry of Health, the Ministry of Agriculture and Environment, the Ministry of Industry and Trade and the provincial People's Committee; Immediately notify the provincial People's Committee when the imported goods has results not meet the requirements of quality and safety norms; report on the unsatisfactory handling result of the shipment;"

dd) Point k, Clause 2 is added as follows:

"k) Taking samples for inspection of product labeling contents and quality, safety criteria for imported products for aid purposes."

15. Article 16 is amended as follows:

"Article 16. Inspection Method

1. Reduced inspection means only checking dossiers.

The reduced inspection shall only be applied for a maximum period of 12 months from the date on which the imported goods are imported, and the inspection meets the importation requirements by the normal inspection for the third time (except for the case specified at Point a, Clause 1, Article 17 of this Decree).

2. The normal inspection is the examination of dossiers and taking representative samples to check the appearance, labeling, packaging status, and special storage conditions (if any).

During the inspection process, if there are signs of suspicious appearance criteria, packaging condition, or special storage conditions (if any), the inspecting agency shall base its decisions on the nature of the components, the quality history of the product, the import history of the owner, and the region of origin, as well as the quality management system applied to that product in order to select quality and food safety criteria from the groups of quality and food safety criteria in the records for testing.

3. The tightened inspection is one of the following cases:

a) For items that fail to meet the previous state inspection of imported food: Examine the dossier and take sufficient samples to test the food quality and safety criteria in the dossier.

b) For goods items that fail to meet the inspection (if any): Examine the dossier and take all samples to test the unsatisfactory targets according to the conclusions of the inspection teams; groups of food quality and safety indicators in the dossier.

c) For items with warnings (of competent authorities or organizations and individuals responsible for placing products on the market): Examine the dossier and take all samples for testing the warned indicators and groups of food quality and safety indicators in the dossier."

16. Articles 18 and 19 are amended as follows:

"Article 18. Application for inspection

1. Application dossier for reduced inspection includes:

a) The application for inspection of imported food as prescribed in Form No. 04, Appendix I issued in conjuction with this Decree.

b) Product Self-Declaration dossier for the products subject to self-declaration; Product Declaration registration dossier for the products subject to product declaration; Product Specification for products not subject to Product Self-Declaration and Product Declaration.

c) 03 Notices of testing results of confirming that food product meets import requirements consecutively by the normal inspection method (original or certified electronic copy);

d) In the case of products of aquatic origin and terrestrial animals, except for products that have been processed and pre-packaged, there must be a certificate of satisfaction of food safety regulations issued by a competent authority of the exporting country (a copy affixed with the seal of the organization, individuals; or certified electronic copy).

2. Application dossier for the normal inspection and the tightened inspection comprises:

a) Application for inspection of imported food as prescribed in Form No. 04, Appendix I issued in conjuction with this Decree.

b) Product Self-Declaration dossier for the products subject to self-declaration; Product Declaration registration dossier for the products subject to product declaration; Product Specification for products not subject to Product Self-Declaration and Product Declaration.

c) 03 Notices of testing results of confirming that food product meets import requirements consecutively by tightened inspection for the products that are converted from tightened inspection to normal inspection (a copy affixed with the certification seal of the organization or individual).

d) A copy of the packing list.

dd) In case of products specified in Article 14 of this Decree, there must be a certificate of satisfaction with food safety regulations issued by a competent authority of the exporting country (a copy affixed with the seal of the organization or individual; or certified electronic copies), except for fishery products caught and processed by foreign fishing vessels and sold directly to Vietnam.

Article 19. Inspection procedures of imported food

1. Procedures of reduced inspection:

a) Before or after the goods arrive at the border gate, the goods owner shall submit the application dossier for inspection as prescribed in Clause 1, Article 18 of this Decree to the customs office.

b) Within 03 working days from the date receiving application dossier, Customs shall review the dossier and issue a notice of food that meets or fails the import requirements according to Form No. 05, Appendix I issued in conjuction with this Decree. In case of requesting additional dossiers, the reasons and legal grounds of the request must be clearly stated.

c) Goods owners are entitled to customs clearance of goods when there is a notification of the results confirming that the food meets the import requirements of the Customs.

2. Procedures of normal inspection:

a) Before or after the goods arrive at the border gate, the goods owner shall submit the application dossier for inspection as prescribed in Clause 2, Article 18 of this Decree to the state inspection agency or the national single-window information portal.

b) Within 07 working days from the date receiving the dossier, the state inspection agency shall inspect as prescribed in Clause 2, Article 16 of this Decree and issue a notification confirming that the food product meets or fails the import requirements according to Form No. 05, Appendix I issued in conjuction with this Decree. In case of requesting additional dossiers, the reasons and legal grounds of the request must be clearly stated.

c) Goods owners shall submit notification confirming that the food product meets the import requirements to Customs offices for customs clearance.

3. Procedures of tightened inspection:

a) Before or after the goods arrive at the border gate, the goods owner shall submit the application dossier for inspection as prescribed in Clause 2, Article 18 of this Decree to the state inspection agency or the national single-window information portal.

b) Within 15 days from the date of receiving the dossier, the state inspection agency shall inspect as prescribed in Clause 3, Article 16 of this Decree and issue a notification of whether the food meets or fails the import requirements according to Form No. 05, Appendix I issued in conjuction with this Decree. In case of requesting additional dossiers, the reasons and legal grounds of the request must be clearly stated.

c) Goods owners shall submit notification confirming that the food product meets the import requirements to Customs offices for customs clearance.

4. In case of issuing a notification confirming that the food product does not meet the import requirements as prescribed at Point b, Clause 1, Point b, Clause 2, Point b, Clause 3 of this Article, the Customs office (reduced inspection) or the state inspection agency (normal inspection and tightened inspection) shall decide on handling measures prescribed in Clause 3, Article 55 of the Law on Food Safety and report on the results of handling the food products not meet the import requirements to the specialized management ministries."

17. Clause 6 of Article 21 is added as follows:

"6. Organizations and individuals receiving aid are responsible for requesting the state inspection agency for imported food safety to take samples, check the labelling contents and test food safety criteria.

Organizations and individuals receiving aid are only allowed to accept the shipment after obtaining a suitable conclusion regarding food safety standards and labeling content from the state inspection authority, and they must fully take responsibility for the storage and usage instructions of the products according to the recommendations of the manufacturer stated on the product label. The use of aid goods must be for the right purposes and intended beneficiaries.

18. Article 23a is added after Article 23 as follows:

"**Article 23a. Conditions for food products exported to be redirected for domestic consumption.**

Food products exported and repurposed for domestic consumption must go through customs procedures like those for imported food products, while also

complying with legal regulations on food safety as applicable to food products produced for domestic consumption.”

19. Clause 1 of Article 26 is amended as follows:

"1. Health Supplement, medical nutrition foods, foods used for special diets, supplemented food."

20. Clause 2, Point d, Clause 4 and Point b, Clause 5, Article 27 are amended and supplemented as follows:

a) Clause 2 is amended as follows:

"2. Advertising content must be consistent with the Intended Uses, warnings and recommendations mentioned in the Product Declaration registration dossier. Do not use images, equipment, costumes, names and names of medical units, medical facilities, doctors, pharmacists, medical staff, opinions of patients, words and articles of doctors, pharmacists and medical staff to advertise food products. It is strictly forbidden to advertise food products that cause misunderstanding or exaggerate the use of foods such as medicines or disease treatments. Conveyors of advertising products, who are influencers must clearly disclose the sponsorship relationship when advertising functional foods, foods for special diets, nutritional products for children under 36 months of age that are not subject to advertising prohibition specified in Article 7 of the Advertising Law."

b) Point d Clause 4 is amended as follows:

"d) For advertisements using images and sounds, there must be a proposed advertising script (a copy confirmed by the organization or individual) and the proposed advertisement content recorded in the audio and video recordings; for advertisements in other media, there must be a mockup (sample content) of the proposed advertisement (a copy confirmed by the organization or individual).

In case the organization or individual responsible for placing the product on the market authorizes another organization or individual to sign the name on the advertising application, there must be a power of attorney (certified by 2 parties).

Documents required for the advertising application must be presented in Vietnamese.

- If document is in English, the organization or individual shall translate it into Vietnamese and take responsibility for the accuracy of the translated contents.

- For documents in foreign languages other than English, they must be translated into Vietnamese and authenticated with the translator's signature. In case it is impossible to translate into Vietnamese and authenticate, the organization or

individual must submit the translation into English and have the translator's signature certified in the country of origin or export; the organization or individual shall translate into Vietnamese and take responsibility for the accuracy of the translation contents;

Documents must be valid at the time to submit the application for registration of certification of advertising contents;"

c) Point b Clause 5 is amended as follows:

"b) Within a period of 10 days from the date of receiving a complete and valid application, the agency receiving the application is responsible for reviewing the application and returning the results according to Form No. 11 in Appendix I issued in conjuction with this Decree. This timeframe is calculated from the date of the agency's official stamp if the application is sent via postal service, submitted directly, or the date the complete application is received in the online public service system.

In the event of disagreement with the content of the advertisement of the organization or individual, or a request to modify or supplement the file, the receiving agency must provide a written document stating the reasons and legal grounds for the request.

Within 60 days from the date of receiving the request for amendments or supplements from the document-receiving agency, organizations or individuals must complete and submit the amended or supplemented documents. Organizations or individuals are only allowed to amend or supplement the documents no more than once. After this amendment or supplement period, the documents will no longer be valid. The document-receiving agency may only request amendments or supplements once for the organizations or individuals submitting the documents.

Within 10 days from the receipt of the amended and supplemented dossier, the dossier-receiving agency shall appraise the dossier and issue a certificate of advertisement content or send a written reply.

The certificate of food advertisement content shall be revoked when the receipt of Product Declaration registration is revoked under the provisions of Article 8b of this Decree or at the request of the organization or individual;"

21. Clause 3a and Clause 5 are added into Article 29 as follows:

a) Clause 3a is added after Clause 3 as follows:

"3a. In case the Certificate of Food Safety Eligibility meets the requirements of Good Manufacturing Practices (GMP) for Health Supplements is still valid,

there is a change in the name or address of the establishment on the Certificate or the name of the legal representative of the organization, individuals, but there is no change in the location of the facility and no change in the contents covered by the granted certificate, the organization or individual must notify the issuing authority immediately after the change."

b) Clause 5 of Article 29 is added as follows:

"5. Organizations and individuals producing Health Supplements shall make periodic reports every 12 months from the issuance date of the Certificate of Food Safety Eligibility which meets the requirements of Good Manufacturing Practices (GMP) of Health Supplements or equivalent certificates according to the form specified in Form No. 24, Appendix I issued in conjunction with this Decree and send it to the Ministry of Health (Vietnam Food Administration) within 15 days from the last day of the reporting period."

22. Clause 1 of Article 33 is amended as follows:

"1. Food additives can only be used from the list of food additives allowed for use in food as prescribed by the Ministry of Health."

23. Chapter XIa is added after Chapter XI as follows:

"**CHAPTER XIa. FOOD TESTING SERVING STATE MANAGEMENT**

Article 35a. Conditions for food testing establishments serving state management purposes and verifying establishments.

1. Food testing establishments for state management purposes must meet the following conditions:

a) Having been granted a Certificate of testing activities as prescribed in the Government's Decree No. 107/2016/ND-CP dated July 01, 2016 regulating conditions for business of conformity assessment services, including testing scopes in line with the ones registered for designation.

b) The quality management system has been recognized in conformity with ISO/IEC 17025.

c) Equipment and facilities are suitable for testing requirements and the scopes registered for designation.

d) There are at least 02 testers who are technical officers with university degrees suitable for the registered scopes of designation, trained and have practical experience in testing in the same scopes for 03 years or more.

dd) The testing methods are updated and validated for their usability, testing capacity of designated registration criteria to meet corresponding regulations or technical standards and other relevant requirements in accordance with the regulations of industry management ministries.

e) Proficiency testing or inter-laboratory comparison of the designated registration testing method must be carried out and satisfactory results must be obtained.

For testing methods that do not have a proficient testing organization or cannot perform inter-laboratory comparison because there are no testing facilities in the country, there must be a complete dossier of testing methods, certification of the use value of the testing method and reference standard or standard grades or standard materials for quality control test.

2. Verifying establishments on the list of verifying establishments eligible for operation announced by ministers of line ministries must satisfy the following conditions:

a) Being the State's testing establishment.

b) It has been designated as a food testing facility serving state management.

When there is a dispute as prescribed in Clause 1, Article 47 of the Law on Food Safety, the competent authority settling the dispute shall select a verifying establishment on the list of verifying establishments eligible for operation to carry out the test for verification.

Article 35b. Registratsion dossier for designation as Food Testing Facility serving state management.

1. Registration dossier for first-time designation comprises:

a) An application for first-time designation of a food testing establishment serving state management is specified in Form No. 17, Appendix I to this Decree.

b) Processes related to the scope of designation, the processes of receiving samples and returning test results (copies).

c) Dossier on Capacity:

- The report on the capacity of the testing establishment specified in Form No. 18, Appendix I to this Decree.

- Documents proving the quality assurance of testing (copies): results of proficiency testing or inter-laboratory comparisons or testing method records,

confirmation of the usability of the testing method and quality standards or reference standards or standard materials to control the quality of testing for the methods that do not have a proficiency testing organization or cannot conduct inter-laboratory comparisons; Report on the proficiency testing results of the testers for the registered scopes of designation.

2. Registration dossier for change or supplementation of the designed scope comprises:

a) An application for change or supplementation of the designated scopes for food testing facilities serving state management as specified in Form No. 18, Appendix I issued in conjunction with this Decree.

b) Processes for the designed scopes to be changed and added (copies);

c) Capacity dossier:

- Report on the capacity of the testing facility as prescribed in Form No. 19, Appendix I to this Decree.

- Documents proving the quality assurance of testing for the scope of change or supplementation (copy): proficiency test results or inter-laboratory comparison or test method dossiers, certification of the use value of test methods and standard substances or standard grades or standard materials for testing quality control for methods testing without a competent testing organization or unable to perform inter-room comparison; Report on the results of the proficiency test of the tester's skills.

3. Application dossier for extension of designed scopes:

The application for the extension of designed scopes applies only in cases where the scope of the extension is consistent with the scopes of the granted designation, including:

a) An application for extension of designed scopes of a food testing establishment serving state management specified in Form No. 18, Appendix I issued in conjunction with this Decree.

b) Report on the operation results of the testing establishment during the designated period specified in Form No. 19, Appendix I to this Decree.

Article 35c. Procedures of designation

1. The testing establishment shall submit 01 set of documents via the online public service system or postal service or directly to the competent authority

appointed by the provincial People's Committee (hereinafter referred to as the appointed agency).

For the extension of designed scopes, the testing establishment shall submit the dossier 90 days before the expiration of the designation decision.

2. The lead time for the appointing agency to review the dossier as prescribed in Article 35b is as follows:

a) Within 10 days for dossiers with up to 20 criteria registered for designation.

b) Within 30 days for a dossier with between 21 and a maximum of 50 criteria registered for designation.

c) Within 45 days for dossiers with more than 50 criteria registered for designation.

In case the dossier is incomplete and invalid as prescribed in Article 35b, the appointing agency shall request the testing facility to amend and supplement the dossier in writing and may only request amendment and supplementation once for each time the testing facility submits the dossier.

Within 60 days from the date of receiving the written request for amendment and supplementation from the appointing agency, the testing facility must complete and submit the dossier of amendment and supplementation. Testing establishments may only amend and supplement the dossier no more than 03 times. Past this time limit for amendment and supplementation, the dossier of the testing facility is no longer valid.

3. Within 30 days from the date of receiving a complete and valid dossier, the appointing agency shall issue a decision on estalishing the evaluation team, notify the evaluation schedule and conduct the actual capacity evaluation at the testing facility. Based on the scope registered for designation, the evaluation team consists of 05 to 09 members with professional knowledge and experience in the field of evaluation and designation. The decision on establishing the evaluation team must clearly state the scope and contents of the evaluation, the responsibilities of each member conducting the evaluation at the testing facility. The content of actual evaluation:

a) The compliance of the testing facility with the conditions stipulated in Article 35a of this Decree and the relevant regulations.

b) Authenticity of the application dossier of designation.

c) Other activities relating to the scopes registered for designation.

The report on evaluating the testing facility is specified in Form No. 20, Appendix I issued in conjunction with this Decree.

4. Within **15** days from the date of receiving the report on evaluating the testing facility:

a) If it is determined that the testing facility meets the prescribed requirements, the appointing agency will issue a decision to designate the food testing facility serving state management.

b) If the testing facility is determined to not meet the prescribed requirements, the appointed agency will issue a written refusal of the designation.

5. If the report on evaluating the testing establishment concludes that the testing facility doesn't meet the requirements as prescribed and proposes the testing facility must rectify the shortages, within 60 days from the date of receiving the rectification request, the testing establishment must send a report on the result of remedial action to the appointing agency as specified in Form No. 21 Appendix I promulgated together with this Decree.

Within 30 days from the date of receiving the report on the results of remedial actions, if the testing facility satisfies the requirements as prescribed, the appointing agency shall issue a Decision on designation of the food testing establishment serving state management. If refusing, the appointing agency must notify the refusal reasons in writing to the testing establishment.

6. The appointing agency shall issue a Decision on the designation of food testing establishments serving state management as specified in Form No. 22, Appendix I issued in conjunction with this Decree. The designation decision is valid for 03 years from the date of signing the Decision.

Article 35d. Assignments on testing serving state management and testing for verification

1. When a request for testing arises to serve state management and there is no testing facility appointed, the provincial People's Committee and the sector managing ministry will select a testing facility to assign the testing in accordance with management requirements.

2. When a request for verification arises and the verifying establishments in the list of establishments eligible for verification fail to comply with the requirements, the dispute settlement agency shall propose the sector managing ministries to select and assign the verifying establishments to perform the testing.

Article 35dd. Issuance of testing facility codes

The appointing agency is responsible for granting and managing codes for food testing establishments serving state management. The code of the food testing establishment serving state management is indicated as follows:

(ordinal number)/(symbol of the provincial People's Committee)-KNTP

Article 35e. Responsibilities of appointing agencies and food testing establishments serving state management.

1. Responsibilities of the appointing agency:

a) Based on management needs, the appointing agency shall receive the dossier of registration for first-time designation, extend the registration for designation, register changes or supplements to the scope of designation of food testing establishments serving state management; organize the evaluation and designation of testing facilities;

b) Inspect food testing establishments serving state management in accordance with laws;

c) Ensure objectivity and fairness in evaluation, designation, inspection and audit activities;

d) Secure information and data related to testing facilities and verifying facilities;

dd) Grant, suspend, restore, revoke, partially or fully terminate a designation decision. After the food testing facility serving state management completes and reports on the required remedial actions, the appoitnting agency will review the restoration of the designation decision;

e) Announce the list of testing establishments to be designated, suspended, restored, revoked or rendered ineffective, together with the scope of designation, suspension, restoration, revocation or ineffectiveness;

g) Organize inspections and resolve complaints related to food testing facilities serving state management in accordance with legal regulations;

h) Archive dossiers of food testing establishments serving state management;

i) Collect and use fees for evaluation and designation of testing establishments in accordance with the law on fees.

2. Responsibilities of food testing establishments serving state management:

a) Take legal responsibilities for testing results;

b) Ensure that the Certificate of testing activities and the Decision/Certificate of accreditation of laboratory capacity meeting the requirements of ISO/IEC 17025 are valid throughout the designated term;

c) Comply with the requirements of Quality Management System that has been accredited in accordance with ISO/IEC 17025; maintain and comply with procedures related to the scope of designation;

d) Within the validity period of the designation decision, participate in the program of proficiency testing and inter-laboratory comparison at least once for the designated testing scopes;

dd) Notify the appointing agency of any changes to the accredited quality management system and reduce the scope of designation within 05 working days from the date of change;

e) Notify the appointing agency of the monitoring results of the accreditation organization (within 03 working days from the date the testing facility receives the monitoring results);

g) Make periodic, adhoc or special reports to the appointing agencies:

- The report form specified in Form No. 19, Appendix I issued in conjunction wit this Decree;

- Adhoc report or special report: as per request of the appointing agency.

h) In addition to the implementation of the above provisions, the testing establishment must also perform the following contents:

- Pay fees for appraisal of testing establishments in accordance with the law on fees;

- Ensure the truthfulness, objectivity and accuracy of test results; the test result sheet must contain all information as prescribed in Form No. 23, Appendix I issued with this Decree;

- Be subject to inspection and examination for testing activities when requested by the state management authority;

i) Perform other obligations specified in Article 20 of the Law on Product and Goods Quality.

Article 35g. Cases of partial or total expiration of the designation decision

The appointing agency shall notify the partial or total expiration of the designation decision in the following cases:

1. Being dissolved or having its legal status revoked by a competent authority or no longer possessing the functions, duties, and powers related to food testing as per decisions made by competent authority.

2. As per request of food testing establishments serving state management."

24. Clauses 5, 8, 9 and 10 of Article 37 are amended and added as follows:

a) Clause 5 is amended as follows:

"5. Organize the receipt and management of dossiers, issue Receipt of Product Declarations for Health Supplement, Certificates of Food Safety Eligibility that meet Good Manufacturing Practices (GMP) requirements for Health Supplement; Certificate of advertising content for Health Supplement."

b) Clauses 8, 9 and 10 are added as follows:

"8. Inspect and handle violations of the law on food safety in producing, exporting, importing and trading food in the assigned management area.

9. Within 30 days from the date of issuing the Receipt of Product Declaration registration, the competent authority shall provide the testing methods of the safety criteria and quality criteria of the manufacturer to the designated testing establishments serving state management of food safety for taking samples to monitor quality in the market.

10. Develop and implement the annual plan for periodic post-marketing inspection; conduct adhoc inspections when required in the assigned management area."

25. Clauses 11 and 12 are added to Article 38 as follows:

"11. Inspect and handle violations of the law on food safety in producing, exporting, importing and trading food in the assigned management area.

12. Develop and implement the annual plan for periodic post-marketing inspection; conduct adhoc inspections when required in the assigned management area."

26. Clauses 4, 10 and 11 of Article 39 are amended and added as follows:

a) Clause 4 is amended as follows:

"Food safety management for supermarkets, shopping centers, convenience stores, establishments belonging to the storage and distribution system, and other types of businesses. Inspect and supervise food advertising activities on e-commerce websites, e-commerce trading flatform, promptly detect and handle violations, and remove non-compliant content in accordance with regulations".

b) Clauses 10 and 11 are added as follows:

"10. Inspect and handle violations of Laws on Food Safety in the production, export, import, and trading of food within the assigned management areas. Inspect and handle violations in the production and trading of counterfeit goods, prohibited goods, smuggled goods, commercial fraud, and food sold on e-commerce websites and websites providing e-commerce services.

11. Develop and implement the annual plan for periodic post-marketing inspection; conduct adhoc inspections when required in the assigned management area."

27. Articles 39a, 39b, 39c and 39d are added after Article 39 as follows:

"**Article 39a. Responsibilities of the Ministry of Finance in State Management on food safety**

Is responsible for timely providing the Ministry of Health, the Ministry of Agriculture and Environment, the Ministry of Industry and Trade and the provincial People' Committees with the following information of enterprises operating in the food sector:

1. There are signs of abnormal fluctuations in revenue.

2. The change of the business location of the enterprise.

3. The enterprise ceases, suspends or dissolves its business.

4. Information related to shipments of imported products subject to the reduced inspection or exemption from state inspection of food safety on a 3-month basis or at the irregular request of specialized management ministries.

5. Information related to the annual quantity and value of shipments of exported and imported products or at the irregular request of specialized management ministries.

Article 39b. Responsibilities of the Ministry of Science and Technology in State Management on food safety

1. Periodically, an annual plan is issued to develop national standards (TCVN) for food.

2. Timely provide information on the list of testing facilities that have registered testing activities for food products, have certificates of testing activities granted, suspended or revoked and have been handled violations to specialized management ministries.

3. Check and monitor the activities of the facilities that have registered testing activities for food products; inspect and supervise the activities of organizations that have registered for the accreditation of laboratories according to ISO/IEC 17025 standards.

Article 39c. Responsibilities of the Ministry of Culture, Sports and Tourism in State Management on food safety

1. Inspect and supervise food advertising in the online environment and in the press; inspect and supervise cross-border food advertising services in Vietnam, timely detect and handle violations and remove non-compliant advertisements as per regulations.

2. Inspect and supervise the advertising activities of advertising business entity, the advertiser, and influencers who carry out food advertising, timely detect and handle violations, and remove non-compliant advertisements as per regulations.

3. Develop and issue a code of conduct for food advertising activities."

28. Clauses 4, 8 and 9 of Article 40 are amended and Clauses 6a, 10, 11, 12 and 13 are added into Article 40 as follows:

a) Clause 4 is amended as follows:

"4. Organize propaganda and mobilization to implement the legal regulations on food safety in the locality; encourage the participation of industry associations, socio-political organizations, individuals, and the public to promptly report violations related to food safety in the locality."

b) Clause 6a is added after Clause 6 as follows:

"6a. Management of food safety conditions for establishments producing and trading in containers in direct contact with food, packaging materials in direct contact with food."

c) Clauses 8 and 9 are amended as follows:

"8. Organize the receipt and management of dossiers, issuance and revocation of Receipt of Product Declaration, certificates of advertising contents for medical nutrition products, foods used for special diets, supplemented foods, and nutritional products for children up to 36 months of age.

Within 30 days from the date of issuing the Receipt of Product Declaration, the competent authority shall provide the testing methods of the safety criteria and quality criteria of the manufacturer to the designated testing establishments serving state management of food safety for taking samples to monitor quality in the market.

9. Organize the receipt of Product Self-Declaration of products; to grant and revoke Certificates of Food Safety Eligibility; Certificate of Free Sales, Health Certificate and other relevant certificates for exported food as per request of organizations and individuals as assigned and decentralized."

d) Clauses 10, 11, 12 and 13 are added as follows:

"10. Grant, suspend, restore, revoke, or partially or fully terminate the effectiveness of the decision on designation of food testing facilities serving state management under the management of the Ministry of Health; Designate/assign tasks, suspend, revoke the decision to designate/assign tasks to the state inspection agency for food safety of imported products under the jurisdiction of the Ministry of Health.

11. Agencies receiving Product Self-Declaration shall develop and implement post-marketing inspection plan after organizations and individuals perform the self-declaration. In cases where self-declaration dossier is to be non-compliant with regulations, violations will be handled according to legal provisions. Based on the allocated funding at the local level, annually, the agency shall develop a plan to inspect and allocate funds for sampling and supervision of quality and safety criteria for products declared for circulation on the market, focusing on product groups used for high-risk subjects such as children, the elderly, pregnant women, the sick. Based on the results of the monitoring, post-marketing inspections will be conducted at production and business facilities, and any violations discovered will be addressed according to legal regulations.

12. Organize the implementation of receiving price declarations, updating the declared price information into the price database, using the declared price to summarize, analyze, and forecast market prices according to regulations; organize inspections to ensure compliance with the law on price declarations for food products assigned for management under the Price Law and Decree No. 85/2024/ND-CP dated

July 10, 2024, of the Government guiding the implementation of certain provisions of the Price Law.

13. Develop and implement annual post-marketing inspection plans; ad-hoc inspection when there is a request in the assigned management area."

29. Clauses 6 and 7 are added into Article 41 as follows:

"6. The Ministries of Health, Agriculture and Environment, Industry and Trade, Finance and provincial People's Committees are responsible for completing the connection and sharing of data with the National Public Service Portal to settle administrative procedures, manage food safety, uniformly manage food safety from the central to local levels.

7. The Ministries of Health, Agriculture and Environment, Industry and Trade, Science and Technology, and provincial People's Committees shall, according to their functions and tasks, be responsible for review, update, and promptly amend and supplement national technical regulations (QCVN), local technical regulations (QCDP), National Standards (TCVN) in the field of food quality and safety."

30. Articles 41a and 41b are added after Article 41 as follows:

"**Article 41a. Planned post-marketing inspection**

1. Annually, basing on the level of risk and history of compliance with regulations on food safety of production and business establishments, state management agencies shall formulate and promulgate post-marketing inspection plans including inspection contents and frequency, and organize the implementation of the plans.

2. Frequency of post-marketing inspection for production establishments, organizations and individuals authorized by the manufacturer or owner of food products to be applicant of product declaration of foods which is subject to registration of product declaration;

a) Once a year for medical nutritional foods, foods used for special diets, nutritional products for children under 36 months old, supplemented foods;

b) At least 01 time within 03 years for Health Supplements.

Article 41b. Unexpected post-marketing inspection

1. An irregular post-marketing inspection shall be conducted when there is one of the following grounds:

a) As per request of management or competent agencies, organizations and individuals in charge of food products;

b) When signs of violation of conditions for food production and business activities are detected, and during peak inspection periods for food safety.

c) When food safety incidents occur;

d) Information reported in any form by organizations and individuals both domestically and internationally regarding signs of violations related to food safety;

dd) Providing information and warnings about products circulating on the market that are not in accordance with the conditions prescribed for food safety;

e) Results of survey or quality inspection of food products circulating on the market and detecting that food products have labels that are not in accordance with regulations or show signs of quality inconsistent with the declared standards and corresponding technical regulations;

2. Contents of post-marketing inspection:

a) Inspect the conformity of products with technical regulations, declared standards, goods labels and the enclosed documents;

b) Inspect the traceability of products as prescribed by regulations;

c) Inspect other contents related to product quality and safety;

d) During the inspection, if the product shows signs of failure to ensure quality and safety, take samples as prescribed by regulations;

dd) For food products traded in e-commerce, besides the inspection as prescribed at Points a, b, c and d of this Clause, the consistency of information on websites versus the ones on actual products shall be inspected."

31. Form No. 01 and Form No. 02 of Appendix I are amended.

32. Forms No. 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 and 25 are added to Appendix I.

33. The notes in Order No. II of Appendix IV are corrected as follows:

"Excluding alcohol declared as a functional food managed by the Ministry of Health";

Article 2. Supplementing, replacing and annulling a number of phrases, points, clauses and articles of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 detailing the implementation of several articles of the Law on Food Safety

1. Add several phrases as follows:

a) Add the phrase "intended uses, intended subjects and dosage" before the phrase "organizations and individuals must perform the product re-declaration." in Clause 4, Article 8;

b) Add the phrase "food additives, food processing aids, micronutrients, catering service business" before the phrase "must have a Certificate of Food Safety Eligibility when operating, except for the case specified in Clause 1, Article 12 of this Decree." in Clause 1, Article 11;

c) Add the phrase "and organizations, individuals receiving aid" after the phrase "Rights and obligations of goods owners" in Article 21;

d) Adding the phrase "supplemented food" after the phrase "foods used for special diets" in Clause 1, Article 26; Clause 8, Article 40;

e) Add the phrase "except for medical nutritional foods, foods used for special diets, supplemented foods and nutritional products for children up to 36 months of age under the management of provincial People's Committees" to the notes in Order No. 2 of Appendix II.

e) Add the phrase "under the management of the provincial People's Committees" to the notes in Order Nos. 3, 4 and 6 of Appendix II.

2. Replace some phrases as follows:

a) Replace the phrase "Agriculture and Rural Development" with the phrase "Agriculture and Environment";

b) Replace the phrase "micronutrients added to food" with the phrase "micronutrients" in Clause 6, Article 40, which has been amended and supplemented in Clause 2, Article 3 of the Government's Decree No. 155/2018/ND-CP dated November 12, 2018 amending and supplementing several regulations related to business investment conditions under the state management of Ministry's Health and in Appendix II;

c) Replace the phrase "Ministry of Health" with the phrase "Health sector" in the name of Appendix II;

d) Replace the phrase "additives, flavors and food processing aids" with the phrase "food additives (including food flavors), food processing aids" in Appendix II.

dd) Replace the phrase "Ministry of Agriculture and Rural Development" with the phrase "Sector of Agriculture and Environment" in Appendix III;

e) Replace the phrase "Ministry of Industry and Trade" with the phrase "Sector of Industry and Trade" in the name of Appendix IV;

3. Annul several phrases as follows:

a) Annul the phrase "mixed food additives with new uses, food additives not yet included in the list of additives permitted for use or not suitable for use in food as prescribed by the Minister of Health" in Clause 2, Article 8;

b) Annul the phrase ", Clause 1, Article 21" in Clause 1, Article 28;

c) Annul the phrase "in case of creating a new product with new intended uses, it is necessary to prove the intended uses, intended subjects and maximum dose" in Clause 2, Article 30;

d) Annul the phrase "Means of advertising" in Form No. 10 and Form No. 11 of Appendix I.

4. Annul several points, clauses and articles as follows:

a) Point c, Clause 1, Article 17.

b) Points b, c and dd, Clause 4, Article 27.

c) Article 32.

d) Clause 5, Article 38.

dd) Clause 5 of Article 39.

Article 3. Enforcement Terms

1. This Decree comes into effect from xxx xx, 2025.

2. Point d, Clause 28, Article 1 of this Decree is effective from xxx xx, 2025.

3. Transitional Clauses

a) For product declaration registration dossiers submitted before the effective date of this Decree and products for which the Certificate of Product Declaration Registration has been granted before the effective date of this Decree, within 18 months, organizations and individuals shall be responsible for amending, supplementing and completing the dossiers in accordance with the provisions of Articles 6, 7 and 7a of this Decree. After the above deadline, if the dossiers are not completed, the product declaration registration dossiers or the Certificate of Product Declaration Registration shall no longer be valid and products manufactured within 18 months after the effective date of this Decree shall continue to be circulated until

the end of the product's shelf life and organizations and individuals shall still be responsible for such products;

b) For products self-declared before the effective date of this Decree, within 06 months, they must amend and supplement the self-declaration dossiers in accordance with the provisions of Clause 1, Article 5 of this Decree; After 06 months from the effective date of this Decree, if the dossier is not completed, it will no longer be valid for production and import;

c) Establishments producing medical nutritional foods, foods for special diets, supplemented food, and nutritional products for children up to 36 months of age must apply the Certificate of Food Safety Eligibility meeting Good Manufacturing Practices (GMP) or the Hazard Analysis System and Critical Control Points (HACCP) or Food Safety Management System ISO 22000 or International Food Standard (IFS) or Global Standard for Food Safety (BRC) or Food Safety System Certification (FSSC 22000) or equivalent certification for food production and business activities from September 1, 2026.

d) Registration dossiers for designation, change or supplementation of the designaed scopes, designation extension for food testing establishments serving state management submitted before the effective date of this Decree shall be reviewed in accordance with the regulations effective at the time of submission; except for the cases where organizations and individuals voluntarily comply with the provisions of this Decree;

dd) The decision to designate food testing facilities serving state management or the decision to issue the list of certified verifying facilitites eligible to operate, issued before the effective date of this Decree shall be remain in effect until the expiration date indicated in the Decision;

4. This Decree annuls Clause 1, Article 24b of the Government's Decree No. 77/2016/ND-CP dated July 01, 2016 amending and supplementing a number of regulations on business investment conditions in the scope of international trading of goods, chemicals; industrial explosives, fertilizers, gas trading and food trading under the state management of the Ministry of Industry and Trade are supplemented in Article 13 of the Government's Decree No. 17/2020/ND-CP dated February 05, 2020 amending and supplementing a number of articles of Decrees related to business investment conditions under the state management of the Ministry of Industry and Trade.

5. In the event that the referenced documents in this Decree are amended, supplemented or replaced, the amended, supplemented or replaced documents shall apply.

Article 4. Enforcement responsibilities

Ministers, Heads of ministerial-level agencies, Heads of government-attached agencies, presidents of provincial People's Committees and relevant organizations and individuals shall be responsible for the implementation of this Decree./.

Recipients:
- Party Central Secretariat;- Deputy Prime Ministers;- Ministries, ministerial-level agencies, agencies attached to the Government;- People's Councils, People's Committees of provinces and centrally-run cities;- Office of the Central Committee and Committees of the Party;- Office of the General Secretary;- Office of the President;- Nationality Council and Committees of the National Assembly;- Office of the National Assembly;- Supreme People's Court;- Supreme People's Procuracy;- State Audit;- Bank for Social Policies;- Vietnam Development Bank;- Central Committee of the Vietnam Fatherland Front;- Central agencies of mass organizations;- Joint Stock Office: Organizing Committee, PCN, Assistant to the Central Committee, General Director of the E-Commerce Portal, Departments, Departments, affiliated units, etc Official Gazette;- Save: VT, KGVX (2b).vt.

TM. GOVERNMENT
PREMIER

Pham Minh Chinh

ADDENDUM

(Attached to the Government's Decree No. /2025/ND-CP dated May 2025 amending and supplementing a certain articles of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 detailing the implementation of a certain articles of the Law on Food Safety)

Form No. 01	Product Self-Declaration
Form No. 02	Product Declaration
Form No. 03	Receipt of Product Declaration registration
Model No. 15	Registration dossier of Product Declaration of Health Supplement
Model No. 16	Registration dossier of Product Declaration of supplemented food, medical nutritional foods, foods used for special diets
Model No. 17	Application for initial designation/change, supplementation of scope of designation/extension of designation of food testing facilities serving state management
Model No. 18	Report on Capacity of Testing facility
Model No. 19	Report on operation results of the testing facility
Model No. 20	Evaluation report of the testing facility
Form No. 21	Report on the results of corrective actions
Model No. 22	Decision on designation of food testing establishments serving state management
Model No. 23	Certificate of Analysis
Model No. 24	Report on Production of Health Supplement

Form No. 01

SOCIALIST REPUBLIC OF VIETNAMINDEPENDENCE - FREEDOM - HAPPINESS

PRODUCT SELF-DECLARATION

Number: ...../Name of enterprise/Year of announcement

I. Information about organizations and individuals self-declaring products

Name of organization or individual:
.....

Address:.....

Telephone:..... Fax:.....

E-mail.....

Business code:.....

Number of Certificate of Food Safety Eligibility: ..... Date of Issue/Place of Issue: ..... (for establishments that are subject to the issuance of the Certificate of Food Safety Eligibility as prescribed regulations)

II. Product Information

1. Product Name: .....

2. Composition: .....

3. Product quality criteria: .....

4. Product shelf life: .....

5. Pack size and packaging material: .....

6. Name and address of the product manufacturer (in case of renting a production facility):.....

.....

III. Sample of product label *(attached to the sample of the product label or sample of the expected product label)*

IV. Requirements on food quality and safety

1. Declare the conformity with in-house standards as prescribed in Article 23 of the Law on Product and Goods Quality and the guiding documents (in-house specifications and dossiers on development of in-house standards are attached)

2. Declare the satisfaction of food safety requirements according to:

- National Technical Regulation No....; or

- Circulars of ministries and branches; or

- Local technical regulations; or

- National standards (in case there is no national technical regulations; circulars of ministries, branches; local technical regulations); or

- Standards of the International Committee on Food Standards (Codex), Regional Standards, Foreign Standards (in case there are no national technical regulations, Circulars of ministries and branches, Local technical regulations, National standards); or

- In-house Specifications (in case there are no national technical regulations, circulars of ministries and branches, local technical regulations, national standards, standards of the International Food Standards Committee (Codex), regional standards, foreign standards)

We hereby commit to fully complying with all provisions of the law concerning food safety. We take full responsibility for the legality of the declaration dossier, as well as the quality and safety of the declared products.

.....day.... month.... year.....

REPRESENTATIVE OF ORGANIZATIONS AND INDIVIDUALS(

Signature, seal)

Form No. 02

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

PRODUCT DECLARATION

Number:.....

I. Information about organizations and individuals declaring products

Name of organization or individual: .....

Address:.....

Telephone:..... Fax:.....

E-mail: .....

Business code: .....

Number of Certificate of Food Safety Eligibility: ..... Issue date/place: .....

(for establishments that are subject to the issuance of Certificate of Food Safety Eligibility as prescribed by regulations)

II. Product Information

1. Product Name: .....

2. Composition: .....

3. Product quality criteria: .....

4. Product shelf life: .....

5. Pack size and packaging material: .....

6. Name and address of the product manufacturer:
.....

III. Sample of product label *(attached to the sample of the product label or sample of the expected product label)*

IV. Requirements on food quality and safety

1. Declare the conformity with in-house standards as prescribed in Article 23 of the Law on Product and Goods Quality and the guiding documents (in-house standards and dossiers on development of in-house standards)

2. To declare the satisfaction of food safety requirements according to:

- National Technical Regulation No....; or

- Circulars of ministries and branches; or

- Local technical regulations; or

- National standards (in case there are no national technical regulations, circulars of ministries, branches, local technical regulations); or

- Standards of the International Committee on Food Standards (Codex), Regional Standards, Foreign Standards (in case there are no national technical regulations, Circulars of ministries and branches, Local technical regulations, National standards); or

- In-house standards (in case there are no national technical regulations, circulars of ministries and branches, local technical regulations, national standards, standards of the International Food Standards Committee (Codex), regional standards, foreign standards)

V. Explanation of the ingredients of the product

For Health Supplements, Supplemented Food, ingredients include active ingredients and auxiliary ingredients. Quantity is not required for auxiliary materials. Organizations and individuals shall explain information about the composition of the product according to the following table:

TT	Ingredient Name	Dosage per day	Quantity in the document	% vs quantity in documents	Document	Intended Use	Warnings (if any)
1							
2							
…							

Note: the information declared in the table above is for registration of product declarations.

We hereby commit to fully complying with all provisions of the law concerning food safety. We take full responsibility for the legality of the declaration dossier, as well as the quality and safety of the declared products and

only put the products into production after obtaining the Receipt of Product Declaration Registration./.

.....day.... month.... year.....
REPRESENTATIVE OF ORGANIZATIONS AND INDIVIDUALS(
Signature, seal)

Form No. 03

NAME OF THE MANAGING AGENCY
NAME OF THE AGENCY RECEIVING THE REGISTRATION OF THE PRODUCT ANNOUNCEMENT

SOCIALIST REPUBLIC OF VIETNAM
INDEPENDENCE - FREEDOM - HAPPINESS

.....day.... month.... year.....

RECEIPT OF REGISTRATION OF PRODUCT DECLARATION

Number: /year/Registration

…… (Name of the agency receiving the registration of the product declaration) ..... accknowlege the receipt of Product Declaration of: .....(name of the organization or individual) address..... telephone..... Fax..... Email..... For Products:..... by..... (name, address of manufacturer and country of origin) ..... Production is comply with technical regulations/regulations/standards... (number, symbol, name) .....

Enterprises must be fully responsible for the conformity of the declared product./.

Recipients:
- Organizations and individuals;- Archives.

AUTHORIZED REPRESENTATIVE OF THE PAPER-ISSUING AGENCY(
Signed, stamped)

Model No. 15

NAME OF ORGANIZATION OR INDIVIDUAL

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

REGISTRATION DOSSIER OF PRODUCT DECLARATION[1] FOR HEALTH SUPPLEMENT ...[2]

I. Name of the product and name of the organization or individual registering the Product Declaration:

II. Content of the dossier:

List of documents in the dossier.

III. General information:

Product Declaration.

IV. Legal documents:

1. Certificate of Free Sale or Certificate of Exportation or Health Certificate or other relevant certificates for exported food issued by a competent agency of the country of origin or export (applicable to cases where the product is an imported health food) (consular legalization or electronic version enclosed with self-search results from the website or English database of the issuing agency or competent agency of the country and stamped with the certification seal of the organization or individual);

2. Certificate of Food Safety Eligibility meeting Good Manufacturing Practice (GMP) requirements or equivalent certification in case the product is an imported Health Supplment (a copy affixed with the certification seal of the organization or individual or an electronic copy enclosed with the result of self-search from the website or language database Photographs of issuing agencies or competent agencies of countries and affixed with the certification seal of the organization or individual);

3. The power of attorney, issued the manufacturer or the owner of the food product for registration of the Product Declaration, contains all the information

[1] The dossier shall be made on the basis of the dossier components specified in Article 7 of this Decree
[2] Product name of health food

specified in Article 8a of this Decree (in case of authorization to register the product declaration) (a copy affixed with applicant's seal and the original copy will be provided for comparison when submitting or receiving results of administrative procedures; or certified electronic copies).

4. Certification of intellectual property rights (if any):

V. Sample product labels and instruction sheets

1. Sample product label:

- Label design on commercial packaging;

- Include all mandatory contents as prescribed by regulations.

2. Instruction sheet (if any):

Presented in the form of a document attached to the product, including:

- Ingredient

- Intended Uses of the product

- Target users

- Dosage

- Usage, when to use

- Warnings about allergies, interactions, cautions, contraindications (if any);

- Storage conditions

- Packaging specifications

- The product shelf-life … (e.g. tablets, hard capsules, bottled effervescent tablets, tubes, multi-dose liquid preparations (syrups, solutions, suspensions, gels...)

3. Commitment to the accuracy of information on labels and instructions for use:

Signed and certified by representatives of organizations and individuals that the content does not mislead consumers and is consistent with the submitted documents.

4. Photo of the real packaging (if any)

- Scanned copies or photos of the printed packaging (full 3 sides) can be submitted if available;

- Must conform to the design presented in the dossier.

VI. Report on product research and development:

1. Product development report:

- Basis for selecting the formula components that create effects, other components (if any), and additives;

- Research on the interaction and incompatibility of all ingredients of the product and primary packaging (packaging in direct contact with the product).

- An overview of the trials conducted (internal, clinical – if any).

2. Information of the ingredients, origin and use of each ingredient that creates the product intended use:

- Specify the composition of synthetic origin, or from plants, animals, minerals or microorganisms;

- Clearly explain the effect of each ingredient in the formula, contributing to the product intended use.

- Explain why the product is used for the subjects as stated on the label, the reason for the recommended dosage as stated on the label.

3. Scientific evidence proving the use of the product or of the ingredients making up the declared intended use (citing scientific evidence of contents related to the intended use and dosage) (a copy affixed with the seal of the organization or individual);

4. Clinical trial report for the product (if any)

5. A written commitment that all product components and auxiliary materials are not in the list of ingredients prohibited for use in the production and trading of food and health supplement.

VII. Documents on quality and safety standards

1. Product safety and quality standards

1.1. Product safety standards (indicators of heavy metals, microorganisms and other toxins... if any)

1.2. Product quality standards:

- Clearly state the appearance indicators (state, color, taste, flavor, etc.), other characteristics if any.

- Quantitative assay of the active ingredients (vitamins, minerals, amino acids, fatty acids, enzymes, probiotics or other biologically active substances) which makes the product intended use.

- For ingredients that make up the product intended use and derived from plants, minerals, microorganisms and animals: it is mandatory to have qualitative and quantitative indicators if there are already national standards or regulations on qualitative and quantitative for these ingredients or there are qualitative and quantitative methods approved by the competent authority for these components.

1.3. Testing Methods.

1.4. Certificate of Analysis (CoA) includes safety criteria and quality criteria.

2. Quality standards of each product component.

It can be in-house standards or national standards, ISO, pharmacopoeia (if any);

2.1. Names of components that make up the product

2.2. Quality standards of components that create intended use of the product

- Clearly state the appearance criteria (state, color, taste, etc.), other characteristics if any, qualitative and quantitative indicators the active ingredients (vitamins, minerals, or biologically active substances added) that make up the product intended use.

- For ingredients that make up the use of products and derived from plants, minerals, microorganisms and animals: it is mandatory to have qualitative and quantitative indicators if there are already national standards or regulations on qualitative and quantitative for these ingredients or qualitative and quantitative methods for these ingredients have been approved by the competent authority on food.

2.3. Standards of other components:

3. Information on packaging materials in direct contact with the product (primary packaging):

3.1. Description of the type of packaging:

- Specify the packaging directly contact with the product: bottles, jars, bags, blisters, aluminum film, etc.

- Material: plastic (PP, PE, PET...), glass, metal, paper, composite film...

3.2. Material Composition Information

- The main composition of the packaging (e.g., 100% PET, or PET outer layer, PE inner layer, aluminum foil middle layer)

3.3. Specification of packaging directly contact with products (primary packaging):

VIII. Documentation on Manufacturing Process

1. Ingredients (formula) for 01 smallest packing unit and for 01 production batch:

- Clearly state the name of each ingredient (product ingredients and auxiliary materials);

- Specify the content or content limit for the ingredients that make up the product intended use

- Classification of ingredient functions: ingredients that create uses, ingredients that stabilize the formula including antioxidant ingredients, avoid interactions, incompatibility of ingredients that create uses, other ingredients of product ingredients, auxiliary materials (thickeners, lubricants, colorants, fragrance regulators, etc).

2. Diagram of the production process:

A flowchart that shows the entire production process - Critical Control Points (CCPs).

3. Description of the production process and production conditions:

- Step-by-step summary description: from raw materials → preliminary processing → blending → forming → packaging

- Including sub-stages such as drying, crushing, filling, packaging processing, etc.

- If the product uses new technology (nano, liposome, phytosome, etc.), it is necessary to provide quality records, including Technological process, quality standards, stability of raw materials, intermediate finished products and finished products. In addition, it is necessary to provide documents on the toxicity and safety of intermediate raw materials and finished products (if any).

4. Production equipment and production conditions:

- List of main equipment used (write the type of machine, equipment with parameters, it is not mandatory to write the trade name or serial of the machine).

- Environmental conditions in the production area at each stage of production (temperature, air humidity, etc.).

5. In process control (IPC)

Certain criteria for inspection in the production process (in process control - IPC): Moisture content of powder or bare tablets (not included), active ingredient quantity (if quantitative) in a semi-finished unit, hardness, disintegration, abrasion (with tablets), density with syrup, etc.

IX. Report on the results of the product stability study:

Study the stability in storage conditions (long-term) (30^0C, 25^0C) to determine the shelf life of the finished product. Study on accelerated conditions (harsh, forced) (40^0C / 75% RH (Relative humidity)) of the product to prognosticate the stability of the finished product. In addition, it is necessary to study the stability of the finished product after opening the cap/lid (stability in use). For example, tablets, hard capsules, bottled effervescent tablets, tubes, multi-dose liquid preparations (syrups, solutions, suspensions, gels, etc.).

X. Other documents:

1. Other documents related to product technical evaluation

In the dossier of registration of the declaration of health supplement, this is a flexible content. Organizations and individuals can provide further if there are special technical factors or at the request of the professional subcommittee in the process of approval.

2. Additional test results at the request of the regulatory authority (if required)

When evaluating registration dossiers od product declaration of health supplement, the professional subcommittee may request the implementation of a number of additional quality indicators such as: pH of the solution, solubility of active ingredients, etc.

3. Other technical explanations (if any)

Documents explaining and clarifying the contents of the dossier may be misunderstood, or not specified in the standards.

Model No. 16

NAME OF ORGANIZATION OR INDIVIDUAL	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness**

REGISTRATION DOSSIER OF PRODUCT DECLARATION[3] MEDICAL NUTRITIONAL FOODS, FOODS FOR SPECIAL DIETS, SUPPLEMENTS, NUTRITIONAL PRODUCTS FOR CHILDREN UP TO 36 MONTHS OF AGE...[4]

I. Name of the product and name of the organization or individual registering the declaration:

II. Content of the dossier:

List of documents in the dossier.

III. General information:

Product Declaration.

IV. Legal documents:

1. Certificate of Free Sale or Certificate of Exportation or Health Certificate or other relevant certificates for exported food issued by a competent agency of the country of origin or export (applicable to cases where the product is an imported food) (consular legalization or electronic version enclosed with self-search results from the website or English database of the issuing agency or competent agency of the country and stamped with the certification seal of the organization or individual);

2. Certificate of Good Manufacturing Practice (GMP) or Hazard Analysis and Critical Control Points (HACCP) or ISO 22000 Food Safety Management System or International Food Standard (IFS) or Global Standard for Food Safety (BRC) or Food Safety System Certification (FSSC 22000) or equivalent certification for supplements, medical nutritional foods, foods used for special diets (a copy affixed with the certification seal of the organization or individual or an electronic copy enclosed with the result of self-search from the website or English database of the

[3] The dossier shall be made on the basis of the dossier components specified in Article 7 of this Decree
[4] Food Product Name

issuing agency or competent agency of other countries and affixed with the certification seal of the organization or individual);

3. The power of attorney, issued the manufacturer or the owner of the food product for registration of the Product Declaration, contains all the information specified in Article 8a of this Decree (in case of authorization to register the product declaration) (a copy affixed with applicant's seal and the original copy will be provided for comparison when submitting or receiving results of administrative procedures; or certified electronic copies).

4. Certification of intellectual property rights (if any):

V. Sample product labels and instruction sheets

1. Sample product label:

- Label design on commercial packaging;

- Include all mandatory contents as prescribed.

2. Instruction sheet (if any):

Presented in the form of a document attached to the product, including:

- Ingredient:

- The product intended use of medical nutritional foods, foods used for special diets, nutritional products for children up to 36 months of age. For supplemented food, only the additional ingredients are inscribed in the announcement of health claims.

- Intended sers:

- Instructions for use:

- Usage and when to use:

- Warnings about allergies, interactions, cautions, contraindications (if any);

- Storage conditions

- Packaging specifications

- Product expiration date

3. Commitment to the accuracy of information on labels and instructions for use:

Signed and certified by representatives of organizations and individuals that the content is not misleading to consumers and is consistent with the submitted documents.

4. Photo of real packagings (if any)

- Scanned copies or photos of the printed packaging (full 3 sides) can be submitted if available;

- Must conform to the design presented in the dossier.

VI. Report on the process of product research and development:

1. Report on Product development:

- Basis for the selection of formula components that create effects, other components (if any), and additives;

- An overview of the trials conducted (internal, clinical – if any).

2. Explanation of the ingredients, origin and use of each product component:

- Specify the composition of synthetic origin, or from plants, animals, minerals or microorganisms;

- Clearly explain the effects of each ingredient in the recipe.

- Explain why the product is intended for the following purposes as indicated on the label, and the reason for the recommended dosage as indicated on the label.

3. Scientific evidence proving the product intended use or the ingredients that make up the declared use for medical nutritional foods, foods used for special diets, nutritional products for children up to 36 months of age (citing scientific evidence, contents related to the use and recommended dosage) or Scientific evidence proving the announcement of health claims of the supplement ingredients (a copy affixed with the certification seal of the organization or individual);

4. Clinical trial report for the product (if any)

5. A written commitment that all ingredients are not on the list of ingredients banned from use in food production and trading.

VII. Quality and Safety Documentation

1. Product safety and quality standards

1.1. Product safety standards (indicators of heavy metals, microorganisms, mycotoxins, other pollutants, etc.) if any).

1.2. Product quality standards:

- Clearly state the appearance indicators (state, color, taste, etc.), other characteristics if any.

- Quantification of active ingredients (vitamins, minerals, or biologically active substances are added).

The maximum content of vitamins and minerals in the product calculated according to the manufacturer's recommended daily dose must not exceed the maximum tolerance threshold of vitamins and minerals as prescribed by the Ministry of Health.

- For ingredients that make up the product intended use and derived from plants, minerals, microorganisms and animals: it is mandatory to have qualitative and quantitative indicators if there are already national standards or regulations on qualitative and quantitative for these ingredients or there are qualitative and quantitative methods approved by the competent authority for these components.

- Other quality indicators (if any)

- For nutritional products for children under 36 months of age and other products manufactured in accordance with national regulations: specify the number of the national regulation applied instead of section 1.1; 1.2 and 1.3 of this Section.

1.3. Quality testing Methods.

1.4. The Certificate of Analysis must includes safety criteria and product quality indicators.

2. Quality standards of product components.

It can be in-house standards or national standards, ISO, pharmacopoeia (if any);

2.1. Names of components that make up the product

2.2. Quality standards of components that make up the product intended use

- Clearly state appearance indicators, (state, color, taste, etc.), other characteristics if any.

- Quantify the active ingredients (vitamins, minerals, or biologically active substances added) that make up the product intended use.

- For ingredients that make up the product intended use and derived from plants, minerals, microorganisms and animals, it is mandatory to have qualitative and quantitative indicators if there are already national standards or regulations on qualitative and quantitative for these ingredients or qualitative and quantitative methods for these ingredients have been approved approved by the competent authority on food.

2.3. Additive standards:

- If food additives (flavor enhancers, stabilizers, preservatives, etc.) are used, the names and standards of such substances must be clearly inscribed.

- Comply with the corresponding standards or technical regulations.

3. Information about packaging materials in direct contact with the product (primary packaging)

3.1. Description of the type of packaging used:

- Specify the type of packaging in direct contact with the product: bottles, jars, bags, blisters, aluminum film, etc.

- Material: plastic (PP, PE, PET...), glass, metal, paper, composite film...

3.2. Standards of packaging directly contact with food:

3.4. Commitment: all packaging used ensures food safety and hygiene and ensures that the primary packaging does not interact with the food to produce harmful substances to users.

VIII. Documentation on the production process

1. Composition (Formula) for 01 expected production batch:

- Clearly state the name of each ingredient (product ingredients and auxiliary materials);

- Clearly state the volume of components that make up the use for 01 expected production batch.

- Classification of component functions: product ingredients, additives (colorants, conditioners, etc.).

2. Diagram of the production process:

A flowchart showing the entire production process - Critical Control Points (CCPs).

3. Description of the production process and production conditions:

- Step-by-step summary description: from raw materials → preliminary processing → mixing → dosing → packaging

- Including sub-stages such as drying, crushing, filling, packaging processing, etc.

- If the product uses new technology (nano, liposome, phytosome, etc.), it is necessary to provide quality records, including Technological process, quality standards, stability of raw materials, intermediate finished products and finished products. In addition, it is necessary to provide documents on the toxicity and safety of intermediate raw materials and finished products (if any).

4. Production equipment and production conditions:

- List of main equipment used (the type of machine, equipment with parameters, it is not mandatory to write the trade name or serial of the machine).

- Environmental conditions in the production area at each stage of production (temperature, air humidity, etc.).

5. Inspection in process control (IPC): some key indicators in the production process.

6. Commitment: implement the production process in accordance with Good Manufacturing Practice (GMP) standards or Hazard Analysis and Critical Control Points (HACCP) standards or ISO 22000 Food Safety Management System or International Food Standards (IFS) or Global Food Safety Standards (BRC) or Food Safety System Certification (FSSC) 22000) and corresponding standards.

IX. Report on the results of the product stability study:

Study the stability under storage conditions (long-term) (30^0C or 25^0C or 2^0C - 8^0C) to determine the life and shelf life of finished products. Research in accelerated conditions (40^0C / 75% RH (Relative humidity)) of the product to prognosticate the stability of the product.

X. Other documents:

Documents explaining and clarifying the contents of the dossier may be misunderstood or not specified in the current standards

Model No. 17

TESTING FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number:...../.....

.....day..... month.....year.....

APPLICATION FOR FIRST-TIME DESIGNATION/CHANGE OR **SUPPLEMENTATION OF DESIGNATED SCOPE /EXTENSION OF DESIGNATION OF FOOD TESTING ESTABLISHMENTS SERVING OF STATE MANAGEMENT**

To: (Designated Agency)

1. Name of testing facility:

Address:

Phone: Fax: E-mail:

2. Full name and title of the person in charge of the testing facility:

Address:

Phone: Fax: E-mail:

3. Certificate of registration of testing operation No.: ..... Issue Date.....

4. Decision/Certificate of Recognition No.....date of issue.....

5. Forms of request for designation

Registration of appointment for the first time ☐

Registration of change and supplementation ☐

Registration for extension ☐

6. Scope of request for designation

TT	Food products and goods	Name of the indicator	Test Methods	Detection Limit/Quantitative Limit/Measurement Range (if applicable)	Name of Accreditation Organization (if any)*

* Write the name of the accreditation organization corresponding to the accredited methods in this column.

7. Proposed time for evaluation: *date.... month.... year...*

8. We commit to fully comply with the provisions of Clause 19, Article 1 of Decree No..../2025/ND-CP dated ..... month..... in 2025 of the Government.

Head of unit

(Signed, full name and sealed)

Model No. 18

TESTING FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number:...../.....

.....day..... month.....year.....

REPORT ON
CAPACITY OF TESTING FACILITIES

1. Name of testing facility:

Address:

Phone: Fax: E-mail:

2. Full name and title of the person in charge of the testing facility:

Address:

Phone: Fax: E-mail:

3. Officials and employees of testing establishments:

TT	Full name	Professional Training Certificate	Management System Training Certificate	Current Assignments	Seniority in the field of testing	Notes

4. Equipment

4.1. Equipment to be inspected/calibrated

TT	Equipment Name	Measurement scopes and accuracy	Vadidation and calibration cycle	Date of the last validation and calibration	Validation/ calibration agent	Notes

4.2. Other equipment

TT	Device Name	Technical characteristics	Date of introduction	Notes

5. Area and environment of the testing facility

5.1. Floor plan and area of each part of the testing facility

5.2. Environmental conditions of parts of the testing facility

- Air conditioning;

- Capability of ventilation and toxic gas discharge;

- Other guarantee conditions (against vibration, dust, noise, light, radiation, etc.).

5.3. Conditions for labor protection and workplace safety of testing facilities

6. List of indicators to be designated:

No.	Food products and goods	Name of the indicator	Test Methods	Detection limit/quantitative limit/measurement range (if applicable)	Proficiency test results/inter-room comparison*

* Clearly state the name of the program, criteria, methods, participation samples, and results.

7. Operation results of the testing facility in the last 01 (one) year:

No.	Food products and goods	Name of the indicator	Test Methods	Total Samples	Notes

8. Commitment of the testing facility

- Execute the Decision on designation and oversee testing activities;

- Comply with the requirements of the evaluation agency when conducting the assessment of the testing facility.

Head of the facility
(Signed, clearly stating full name and seal)

Model No. 19

TESTING FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number:...../.....

.....day..... month.....year.....

REPORT

TESTING FACILITIES OPERATION RESULTS

(ANNUAL/ DURING THE SPECIFIED PERIOD)

1. Name of testing facility:

Address:

Phone: Fax: E-mail:

2. Full name, title and person in charge of the testing facility:

Phone: Fax: E-mail:

3. Training: Improve professional skills for staff of testing facilities

No.	Full name	Job Title	Training Course	Time	Results Achieved	Notes

4. Equipment

4.1. Equipment validated/calibrated

TT	Device Name	Accurate measurement and grading range	validation and calibration cycle	Date of the last validation and calibration	Validation/ calibration agent	Notes

4.2. New equipment added

TT	Device Name	Technical characteristics	Date of introduction	Notes

5. Designated testing criteria and methods:

TT	Food products and goods	Name of the indicator	Test Methods	Detection limit/quantitative limit/measurement range (if applicable)	Notes

6. Ensuring the quality of test results (participating in proficiency testing/inter-room comparison):

TT	Name of the indicator	Test Methods	Sample Background	Organizer	Participation Period	Result

7. Results of food testing activities serving state management

TT	Food products and goods	Name of the indicator	Test Methods	Total Samples	Unsatisfactory number of samples

Head of facility
(Signed, clearly stating full name and seal)

In charge of the testing facility
(Sign and specify full name)

Model No. 20

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

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

RECORD OF ASSESSMENT OF TESTING FACILITIES

The team evaluating the testing facility..... is established under Decision No. .... /QD-.... day... month... year... of the appointing agency, including:

(Full name, name of the Lead of the assessment team, secretary, members)

1. Name of testing facility:

Address: Phone: Fax: E-mail:

2. Conclusions of the assessment team

2.1. Suitability:

2.2. Non-conformity (if any):

No,	Non-conformity	Level 1	Level 2	Bases/Standards

In which:

- Level 1: cannot be remedied within the time prescribed by the Decree.

- Level 2: can be remedied within the time specified by the Decree.

2.3. To request competent authority (in 1 of 3 cases):

Case 1: Designate *(name of testing facility)*, which is ..... is a food testing facility serving state management for the scope of the following designation:

TT	Food products and goods	Name of the indicator	Test Methods	Detection limit/quantitative limit/measurement range (if applicable)

Case 2: Designate *(name of testing establishment)*, which is ..... is a food testing facility serving state management, for the scope of designation below after the testing facility completes the remedy of all the above non-conformities:

TT	Food products and goods	Name of the indicator	Test Methods	Detection limit/quantitative limit/measurement range (if applicable)

Case 3: Not designate *(name of testing facility)*, belonging to ..... is a food testing facility serving state management.

3. This Minutes is adopted with the consent of the ..... members of the evaluation team.

Other opinions, if any: .....

4. Opinions of testing facilities: .....

5. Other documents enclosed with the minutes include:
.....

Representative of the testing facility *(Signed, clearly stating full name and seal)*	**Secretary of the assessment team** *(Sign and specify full name)*	**The assessment team Leader** *(Sign and specify full name)*

Form No. 21

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

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

REPORT

THE RESULTS OF CORRECTIVE ACTIONS

To: (Appointing Agency)

1. Name of the testing facility to be assessed:

2. Designated codes (if any):

3. Non-conformity detected: Degree:

4. Causes

5. Corrective actions

6. Results of corrective actions

7. Accompanying changes to complete the management system (if any)

Head of facility	**Reporter**
(Signed, clearly stating full name and seal)	*(Signed, full name)*

7. Appraisal opinions of the assessment team members (sign and clearly state their full names):

……

……

8. Conclusions of the Assessment Team Leader

……

……

.....day..... month.....year.....
The assessment team leader
(Signed, full name)

Form No. 22

MINISTRIES MANAGING SPECIALIZED **AGENCIES APPOINTING AGENCIES**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness**
No.: .../QD-...	*Hanoi, on .... month.....year....*

DECIDE
ON THE DESIGNATION OF FOOD TESTING FACILITIES SERVING STATE MANAGEMENT

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

Pursuant to the Government's Decree No. ...../2025/ND-CP dated xxx xx, 2025 amending and supplementing a certain articles of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 detailing the implementation of a certain articles of the Law on Food Safety;

Pursuant to the application form ……..

Pursuant to the Record of assessment of the ..... testing facility

Pursuant to the report on the results of remedial actions (if any) .....

As per request of.....

(Heads of appointing agencies) .....,

DECIDE:

Article 1. Designate ..... (*name of testing establishment*), belonging..... address..... is the food testing facility serving state management according to the scope of designation attached to this Decision.

- Code of testing facility: .....

Article 2. This Decision is valid ..... from the signing date.

Article 3. (Name of testing facility) in ..... shall be responsible for carrying out testing work serving state management upon request and must comply with regulations and guidelines of competent authorities.

Recipient: -Ditto; - Related organizations (to know); - Save: Designated agency.	**HEAD OF THE APPOINTING AGENCY** *(Signed, clearly stating the full name and seal)*

SCOPE OF DESIGNATION

(Attached to Decision No. ...../QD-..... day.... month..... year..... of the appointing agency)

TT	Name of the indicator	Food products and goods	Test Methods	Detection limit/quantitative limit/measurement range (if any)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
…	……	…….	……	……..

Form No. 23

TESTING FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number:...../.....

CERTIFICATE OF ANALYSIS

(Test results are only valid for test samples)

1. Sample name: *(Write the name of the test sample)*

2. Sample code:

3. Sample Description: *(sample status upon receipt, sample volume, production date, expiration date, sample storage status)*

4. Sample storage time:

5. Sampling date:

6. Sample receipt date:

7. Testing time:

8. Where to send samples:

9. Enclosed documents: *(clearly stating the contents, number, date of the enclosed papers/ documents)*

10. Test results (specified criteria of the testing facility):

TT	Testing criteria	Test Methods	Unit	Result	Compared to QCVN.../ TCVN.../QD...

11. Conclusion: .....

(It is necessary to specify whether the sample is complied or not)

12. Notes: *(if any)*

Head of the establisment
(Signed, clearly stating full name and seal)

In charge of the testing facility
(Sign and specify full name)

Form No. 24

NAME OF PRODUCTION FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number:...../.....

.....day..... month..... Year 20.....

REPORT
PRODUCTION ACTIVITIES OF HEALTH SUPPLEMENT
(From ...../...../20... to ...../ ...../ 20...)

1st reporting period (first 12 months from the date of issuance) ☐
2nd reporting period (next 12 months) ☐
3rd reporting period (next 12 months) ☐

1. Name and address of the establishment producing health supplements: .....

Certificate Number: ...../...../..... Issuing agency: ..... Issued Date: *...../ ...../ 20…*

2. Personnel and training

Content	Time of issuance/ Previous reporting period)	Now
Number of employees: Quality control (Quality Assurance- QA and Quality Control- QC)/ Production (direct)/ Other indirect/ Total number of employees of the facility	…../ …../ …../ …..	…../ …../ …../ …..
Number of employees who have been provided knowledge on food safety / trained on Basic GMP/ Relevant professional toipcs/ Total number of employees	…../ …../ …../ …..	…../ …../ …../ …..
Full name, and professional qualifications:	From ..... to .....:..... /…..	From ..... to .....:..... /…..
- Person in charge of the facility's expertise	From ..... to .....:..... /…..	From ..... to .....:..... /…..
	From ..... to .....:..... /…..	From ..... to .....:..... /…..
- Head of Production	From ..... to .....:..... /…..	From ..... to .....:..... /…..
	From ..... to .....:..... /…..	From ..... to .....:..... /…..
- Head of quality control department (or QA, QC)	From ..... to .....:..... /…..	From ..... to .....:..... /…..

3. Facilities

Diagram and List of Main Devices	No change	Subject to change[5]
- Overall floor plan of the facility	□	□
- Arrangement of the premises, workshop(s) (with) the production of health supplement.	□	□
- Laboratory layout	□	□
- Factory equipments used for production health supplement	□	□
- IPC monitoring equipment of the workshop(s) (with) health supplement production and testing equipment	□	□
- Other equipment (HVAC, RO, compressed air...) of the workshop (with) health supplement production	□	□

4. Published data (still valid) and production results (in the reporting period)

TT	Product Name[6]	Main ingredients[7] (mg content, IU.../ tablets, tubes...)	Receipt No. (date of issue)	Declared by the establishment itself	Other organizations and individuals authorized to submit Product Declaration (specify their names)	Number and submssion date of the notice of relocation to production at the facility (if any)	Batches produced in the reporting period	Produced[8]	Sampling[10]	Released for sales[10]	Inventory[10]	Violations and handling [9] (if any)
	Tablets											
1.	…….	B1: ..... Mg	…/…	□	……	…/…	Batch...	….. v	….. v	….. v	….. v	…..
		B12: ..... IU					Batch...	….. v	….. v	….. v	….. v	…..
2.	…….	…..: ….. Mg	…/…	□	……	…/…	Batch...	….. v	….. v	….. v	….. v	…..
		…..: ….. Mg					Batch...	….. v	….. v	….. v	….. v	…..
	Pipe Break											
3.	…….	…..: ….. Mg	…/…	□	……	…/…	Batch...	….. v	….. v	….. v	….. v	…..
		…..: ….. Mg					Batch...	….. v	….. v	….. v	….. v	…..
Amount			….. sp	….. sp	….. sp		… batch	….. Participant		.. … Participant		

[5] For changes that have an impact on product safety and quality at the level that the establishment can self-assess, appraise and control but not to the extent of changing the scope already granted or not to the extent that it must be approved by the issuing agency (attached to the diagrams, Categories with changes and corresponding self-assessment reports)

[6] Ordered by group with dosage form

[7] Has nutritional value or biological effects

[8] Finished products (pellets, tubes (liquid), jars (semi-solid), jars/bottles (liquid), bags/packages (powder, liquid, semi-solid), boxes (powder, liquid)...) are sampled for testing and/or sent for testing for evaluation before shipment and for stability monitoring.

[9] Clearly state the number of the Decision, the name of the Inspection Team; the form of violation, the number of receipts withdrawn, the lot number of the recalled lot, the corresponding number of recalled products, a fine (million VND million).

Owner of the establishment
(Signed, stamped and clearly stated full name)