UNOFFICIAL TRANSLATION

DRAFT DECREE AMENDING DECREE NO. 15/2018/ND-CP

GOVERNMENT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No: .../2025/NĐ-CP
Hanoi, date ... month ... year 2025

DECREE

AMENDING AND SUPPLEMENTING A NUMBER OF ARTICLES OF DECREE NO. 15/2018/ND-CP DATED FEBRUARY 2, 2018, OF THE GOVERNMENT DETAILING THE IMPLEMENTATION OF A NUMBER OF ARTICLES OF THE LAW ON FOOD SAFETY

Pursuant to:
The Law on Government Organization No. 63/2025/QH15 dated February 18, 2025, and the Law on Local Government Organization dated November 22, 2019;
The Law on Food Safety dated June 17, 2010;
At the proposal of the Minister of Health;
The Government hereby promulgates the Decree amending and supplementing certain articles of Decree No. 15/2018/ND-CP dated February 2, 2018, detailing the implementation of certain provisions of the Law on Food Safety.

Article 1. Amendments and Supplements to Certain Articles of Decree No. 15/2018/ND-CP

1. Amendment and supplementation of Article 2 as follows:

"Article 2. Applicable Subjects

This Decree applies to Vietnamese agencies, organizations, and individuals; foreign organizations and individuals in Vietnam engaged in food production and business; organizations and individuals providing or receiving food aid for charitable purposes and not for commercial purposes; and organizations and individuals engaged in activities related to food safety in Vietnam (hereinafter collectively referred to as organizations and individuals)."

2. Amendment and supplementation of Clauses 3, 4, and 8 of Article 3 as follows:

a) Amendment and supplementation of Clause 3 as follows:

"3. Food for Special Dietary Uses, intended for individuals on special diets, the elderly, children, pregnant women, and other specific groups as regulated by the Codex Alimentarius Commission (CODEX), refers to foods that are specially processed or formulated to meet particular dietary requirements based on physiological conditions, medical conditions, or specific disorders of the consumers. The composition of these foods must be distinctly different from that of conventional foods of the same nature, if applicable."

b) Amendment and supplementation of Clause 4 as follows:

"4. Scientific evidence refers to scientific information and documents that substantiate health claims related to a product or its ingredients. Such evidence must be derived from scientific research projects that have been approved by competent state regulatory authorities on scientific research, published in reputable national or international journals, ISI-indexed journals, or documented in traditional medicine, medicinal plants, pharmacopoeia, medical, pharmaceutical, or food-related literature published in scientific publications."

c) Amendment and supplementation of Clause 8 as follows:

"8. Small-scale primary production establishments refer to facilities engaged in cultivation, livestock farming, harvesting, fishing, or exploitation of food ingredients at the household or individual level. These establishments are not granted a Business Registration Certificate, Enterprise Registration Certificate, or Investment Certificate as prescribed by law."

3. Addition of Clauses 11, 12, 13, 14, 15, 16, 17, and 18 to Article 3 as follows:

"11. Organizations or individuals responsible for placing products on the market refer to manufacturers, product owners, or organizations and individuals authorized by the manufacturers or product owners to be listed on the product declaration dossier and to take responsibility for the product on the market.

12. A functional food introduced to the market for the first time refers to a functional food that contains a new substance responsible for its effects, a substance used as food for the first time globally, or a new combination of substances that contribute to the product's functionality, which have been previously marketed or used as food worldwide.

13. A testing laboratory is a legally recognized organization that conducts testing of quality and food safety indicators.

14. The quality management system of a testing laboratory includes a management and technical documentation system to ensure the quality, accuracy, and transparency of test

results, as well as all records related to testing activities. It also guarantees the quality of test results conducted at the laboratory within the registered scope, including personnel, equipment, facilities, and testing methods.

15. Interlaboratory comparison refers to the organization, implementation, and evaluation of testing methods on the same or similar subjects by two or more testing laboratories under predetermined conditions.

16. Proficiency testing is the assessment of participants' performance based on established criteria through interlaboratory comparison.

17. Testing laboratory assessment is the review of the compliance of the quality management system and analytical capabilities to meet the testing requirements for specific quality and food safety indicators.

18. A small-scale food production establishment refers to a food production facility operated by an individual, a group of individuals, or a household that registers as a household business and is not granted an Enterprise Registration Certificate or an Investment Certificate as prescribed by law."

4. Amendments to Article 4 as follows:

1. Organizations and individuals responsible for introducing products to the market must self-declare processed packaged foods, food additives, food flavorings, food processing aids, utensils directly contacting food, food packaging materials, and micronutrients (hereinafter referred to as products), except for products specified in Clause 2 of this Article and Article 6 of this Decree.

2. Products, raw materials for production or import, used solely for export or internal production by organizations or individuals not for domestic consumption, and imported products for charity and not for business purposes are exempt from the product self-declaration procedure.

5. Amendments to Clauses 1 and 3 of Article 5 as follows:

a) Amendment to Clause 1 as follows:

1. The self-declaration dossier includes:

- A self-declaration of the product according to Form No. 01 Appendix I issued with this Decree (original copy).
- A test result certificate proving the food safety requirements of the product within 12 months before the submission date, issued by a designated laboratory or a laboratory accredited according to ISO 17025, including safety criteria issued by the Ministry of

Health based on risk management principles in compliance with international regulations, or safety criteria based on standards provided by the organization or individual in case no Ministry of Health regulations exist (original or notarized copy).
- A product self-declaration authorization from the manufacturer or product owner (if available) (original copy).

b) Amendment to Clause 3 as follows:

3. Documents in the product self-declaration dossier must be in Vietnamese. If documents are in English, organizations or individuals may self-translate them into Vietnamese and are responsible for the accuracy of the translation. If documents are in a foreign language other than English, they must be translated into Vietnamese and notarized. If product labels have multiple languages, only the language of the country of origin or export should be translated. Documents must be valid at the time of the self-declaration.

6. Amendments to Article 6 as follows:

Article 6: Product Declaration Registration

1. Organizations and individuals responsible for introducing products to the market must register a product declaration for the following products:

a) Health supplements, medical nutrition foods, foods for special dietary use.
b) Nutritional products for children up to 36 months (including nutritional products declared for multiple age groups, including those under 36 months).

2. Imported food products for charity and not for business purposes, as specified in Clause 1 of this Article, are exempt from the product declaration registration procedure.

7. Amendments to Clauses 1, 2, and 3 of Article 7 as follows:

a) Amendment to Clause 1 as follows:

1. The product declaration registration dossier for imported products includes:

- A product declaration as specified in Form No. 02 Appendix I issued with this Decree (original copy).
- A Certificate of Free Sale or Certificate of Exportation or Health Certificate or other relevant certificates for food exports from the competent authority of the exporting

country (original).
- A food safety test result certificate for the product within 12 months before the submission date, issued by a designated laboratory or an ISO 17025 accredited laboratory, or by a Good Manufacturing Practice (GMP) certified production facility (original or notarized copy).
- Scientific evidence proving the efficacy of the product or its active ingredients (original or notarized copy).

b) Amendment to Clause 2 as follows:

2. The product declaration registration dossier for domestically produced products includes:

- A product declaration as specified in Form No. 02 Appendix I issued with this Decree (original copy).
- A food safety test result certificate for the product within 12 months before the submission date, issued by a designated laboratory or an ISO 17025 accredited laboratory, or by a GMP certified production facility (original or notarized copy).
- Scientific evidence proving the efficacy of the product or its active ingredients (original or notarized copy).

c) Amendment to Clause 3 as follows:

3. Documents in the product declaration registration dossier must be in Vietnamese. If documents are in English, organizations or individuals may self-translate them into Vietnamese and are responsible for the accuracy of the translation. If documents are in a foreign language other than English, they must be translated into Vietnamese and notarized.

7**. Amend and supplement item a of clause 1, item c of clause 1, clauses 2, 3, 4, and 7 of Article 8 as follows:**

a) Amend item a of clause 1 as follows:

"a) Submit to the Ministry of Health for health protection food."

b) Amend and supplement item c of clause 1 as follows:

"c) In the case where an organization or individual has two or more production facilities producing the same product (except for health protection food), the

organization or individual shall register the product declaration at one local government authority where the production facility is located. Once a registration authority is selected, all subsequent registrations must be made at the same authority."

c) Amend and supplement clause 2 as follows:

"2. Within 7 (seven) working days from receiving the complete product declaration documents for medical nutrition food, food for special diets, nutrition products for children under 36 months old, and 21 (twenty-one) working days for health protection food, the authority receiving the registration shall evaluate the documents and issue the Product Declaration Registration Receipt according to Sample No. 03 Appendix I attached to this Decree.

The evaluation period is counted from the date the documents are submitted online or based on the received date stamp (in case of postal submissions or in-person submissions)."

d) Amend and supplement clause 3 as follows:

"3. If the authority disagrees with the product declaration submitted by an organization or individual or requests changes or additions, the receiving authority must issue a document outlining the reasons and legal basis for the request.

Within 30 (thirty) working days from receiving the request to amend or supplement from the authority, the organization or individual must complete and submit the amended documents. The organization or individual may only modify the documents up to 03 times.

The documents will be invalid if after thirty working days from receiving the request, the organization or individual does not make amendments or if they have made more than 03 amendments.

Within 7 working days from receiving the amended documents, the receiving authority must evaluate the documents and issue the Product Declaration Registration Receipt or provide a written response. The authority may only request modifications once per submission, including amended documents if the documents do not meet the requirements."

e) Amend and supplement clause 4 as follows:

"4. If there is a change in the organization or individual responsible for placing the product on the market, product origin, product name, ingredients, uses, target audience, dosage, component weight, or form of preparation, the organization or individual must re-declare the product. Any other changes must be notified in writing to the receiving authority, and the product can be produced and sold immediately after the notification."

f) Add clause 7 as follows:

"7. The organization or individual responsible for placing the product on the market must retain the documents as prescribed in point g, clause 2 of Article 7 and point đ, clause 1 of Article 19 of the Food Safety Law and comply with Good Manufacturing Practices (GMP) for health protection food, Hazard Analysis and Critical Control Points (HACCP), ISO 22000, International Food Standards (IFS), Global Food Safety Standards (BRC), FSSC 22000 or equivalent systems if implemented and certified. These records must be available for inspection by authorities as required."

8. Add Articles 8a, 8b, and 8c as follows:

Article 8a. Provisions on Product Declaration Authorization

1. The language used for presentation is either Vietnamese, English, or both Vietnamese and English.

2. The authorization to register the product declaration must include the following:

a) Name and address of the manufacturing facility; if the product owner is the manufacturer, include the product owner's name and address along with the manufacturer's details. The product owner is the entity listed on the Certificate of Free Sale, Certificate of Exportation, Health Certificate, or other relevant certifications for export products.

b) Name and address of the authorized organization or individual;

c) Scope of the authorization (responsibility for product declaration and compliance in Vietnam);

d) Brand name or product name authorized;

đ) Authorization period;

e) Name, position, and signature of the representative of the granting party."

Article 8b. Cases of Invalid Product Declarations and Registration Receipts

1. Any document revoked by foreign authorities that is the basis for product declaration or registration in Vietnam;

2. Documents based on fraudulent or false information;

3. Product trademarks deemed to infringe intellectual property rights by authorities;

4. Products that have not been produced or sold within 3 consecutive years after receiving the Product Declaration Registration Receipt.

Article 8c. Suspension of Product Declaration Registration

1. The competent state authority may suspend the reception and processing of product declaration registration documents for organizations or individuals violating food safety laws until a violation decision is issued by the competent authority and the organization or individual complies with the decision.

2. After the suspension period ends, if the organization or individual has rectified the violations and submitted a report, the competent state authority will resume the reception and processing of the registration documents."

9. Amend and supplement clause 1 of Article 11 as follows:

"1. Food, food additives, food processing aids, micronutrients, and food service providers must have a Certificate of Food Safety Compliance when operating, except for cases specified in clause 1 of Article 12 of this Decree."

10. Add clause 3 to Article 11 as follows:

"3. The procedure for issuing the Certificate of Food Safety Compliance is regulated under points b, c, d, đ, e, clause 3, Article 6 amended by clause 3, Article 2 of Decree No. 155/2018/ND-CP on November 12, 2018, which amends several regulations related to investment conditions in areas managed by the Ministry of Health."

11. Amend and supplement point đ, clause 1, Article 12 as follows:

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

12. Add clause 6 to Article 21 as follows:

"6. Organizations and individuals receiving donations must notify the state food safety inspection authorities for sampling, testing food safety parameters, and verifying labeling content.

Organizations and individuals receiving donations can only accept the batch after receiving a positive safety test result and must be responsible for proper storage and usage according to the manufacturer’s instructions on the product label. Donations cannot be sold on the market."

13. Amend and supplement points d, đ of clause 4, and point b of clause 5 in Article 27 as follows:

a) Amend and supplement points d, đ of clause 4:

"d) For advertisements that use images or sounds, a proposed advertisement script (signed by the organization or individual) and the content of the proposed advertisement in both video and audio formats are required; for other media ads, a sample layout (approved by the organization or individual) must be provided.

- If an organization or individual authorizes another to register the product declaration, a letter of authorization (signed by both parties) must be provided."

đ) Any claims outside the product's declared uses must be substantiated with scientific documentation (certified copy). All submitted documents must be in Vietnamese. If documents are in English, they can be self-translated by the organization, with the organization bearing the responsibility for accuracy. Documents in other foreign languages must be translated into Vietnamese and notarized.

b) Amend and supplement point b of clause 5:

"b) Within 10 working days from receiving the complete and valid documents, the

receiving authority must review and respond with the results according to Sample No. 11, Appendix I of this Decree. This deadline is calculated from the date of receipt, whether by postal service, direct submission, or online submission."

14. Add clause 3a to Article 29 as follows:

"3a. In the case of a company name change or ownership change without altering production processes or facilities, the organization must notify the registration authority and submit updated documents through the online service system or by post."

15. Amend clause 1 of Article 33 as follows:

"1. Only food additives listed in the allowed food additives list by the Ministry of Health are permitted to be used in food products."

16. Add Chapter XIa as follows:

Chapter XI: Food Testing for State Management
Article 35a. Conditions for food testing establishments serving state management and verification testing establishments

1. Conditions for food testing establishments serving state management:

a) The establishment has been granted a Certificate of Registration for Testing Activities according to the provisions in Decree No. 107/2016/ND-CP dated July 1, 2016 of the Government, which specifies the conditions for business services related to conformity assessment, including testing within the scope of designated registration;

b) The quality management system has been accredited according to National Standard TCVN ISO/IEC 17025 or International Standard ISO/IEC 17025;

c) Equipment and facilities suitable for testing requirements and the scope of designated registration;

d) The establishment must have at least two (2) laboratory technicians with a relevant bachelor's degree and at least three (3) years of practical experience in testing within the same field as the designated scope;

e) Testing methods are updated and their validity confirmed, and the testing capabilities for designated indicators must meet regulatory or technical standards and other related requirements according to the regulations of the relevant sector authority;

f) The establishment must perform proficiency testing or interlaboratory comparisons for the designated testing methods and achieve satisfactory results.

For testing methods that do not have a proficiency testing organization or cannot perform interlaboratory comparisons due to the lack of domestic testing establishments, a complete method validation record must be available, confirming the method's validity and the reference materials used to control testing quality.

2. Conditions for verification testing establishments in the Verification Testing List published by the Minister of the relevant sector:

a) The establishment must be a state-run testing facility;

b) The establishment must be designated as a food testing facility for state management.

In case of disputes under Article 47, Food Safety Law, the authorized body resolving the dispute will select a verification testing establishment from the list to carry out the verification testing.

For verification testing outside the scope of the list, the dispute resolution agency will propose the relevant ministry to select and assign a testing establishment to carry out the verification task.

Article 35b. Registration dossier for designating food testing establishments serving state management

1. First-time registration dossier:

a) Application for designation of food testing establishment serving state management according to Form No. 15 in Appendix I issued with this Decree;

b) Technical documents, dossiers, and processes related to the designated indicators (copies);

c) Competency dossier:

- Capability report for the testing establishment according to Form No. 16 in Appendix I issued with this Decree;

- Documents proving testing quality assurance (copies): proficiency testing or interlaboratory comparison results; report on the proficiency testing results of the laboratory technicians for the designated indicators;

For testing methods without a proficiency testing organization or interlaboratory comparison, a complete method validation record must be provided, confirming the validity of the testing method and reference materials.

2. Dossier for changing or supplementing the designated scope:

a) Application for changing or supplementing the designated scope of the food testing establishment according to Form No. 15 in Appendix I issued with this Decree;

b) Technical documents, dossiers, and processes for the changed or supplemented scope (copies);

c) Competency dossier:

- Capability report for the testing establishment according to Form No. 16 in Appendix I issued with this Decree;

- Documents proving testing quality assurance for the changed or supplemented scope (copies): proficiency testing or interlaboratory comparison results; report on the proficiency testing results of laboratory technicians.

3. Dossier for extending the designation:

A dossier for extending the designation applies when the registration scope is consistent with the scope designated in the existing designation decision, including:

a) Application for extension of designation according to Form No. 15 in Appendix I issued with this Decree;

b) Report on the performance of food testing for state management during the

designation period according to Form No. 17 in Appendix I issued with this Decree.

4. In case of requiring testing for state management:

If a request arises for testing an indicator not yet designated for state management, the ministry will choose a designated testing establishment to perform the testing task.

Article 35c. Procedures for designation

1. The testing establishment submits one (1) dossier through the online public service system, by post, or directly to the relevant state management agency (hereafter referred to as the designating authority).

For designation extensions, the testing establishment must submit the dossier 90 (ninety) days before the designation decision expires.

2. Within 10 (ten) days of receiving the dossier, if the dossier is incomplete or invalid, the designating authority will request the testing establishment to modify or supplement the dossier in writing. Only one modification request can be made per submission.

3. From the time the designating authority receives a complete and valid dossier, it will set up an evaluation team to assess the testing establishment's capability.

Article 35d. Issuance of testing establishment codes

The designating authority is responsible for issuing and managing codes for food testing establishments serving state management.

Article 35đ. Responsibilities of the designating authority and food testing establishments serving state management

1. Responsibilities of the designating authority:

a) Receive and process dossiers for first-time registration, designation extension, and scope changes;

b) Monitor and inspect designated testing establishments as required by law;

c) Ensure fairness and objectivity in evaluating, designating, inspecting, and auditing;

d) Ensure confidentiality of information and data related to testing establishments;

e) Issue, suspend, restore, or revoke designation decisions.

2. Responsibilities of the food testing establishments serving state management:

a) Ensure legal accountability for testing results;

b) Comply with quality management standards as required;

c) Notify the designating authority of any changes to the quality management system or designated scope.

Article 35e. Suspension, Restoration, Revocation of the Appointment Decision

Based on the results of inspection, audit, or notification of changes from the testing facility; depending on the severity of the violations of the provisions in this Decree, the appointing authority shall consider and take the following measures:

1. Suspend the implementation of the Appointment Decision in whole or in part. After the testing facility completes and reports the corrective actions as required, the appointing authority shall consider restoring the Appointment Decision.

2. Revoke the Appointment Decision in the following cases:

a) The organization is dissolved, its legal status is revoked by a competent authority, or it no longer has the functions, tasks, and powers to test food products as determined by the competent authority;

b) Falsifying documents of the agency or organization to submit to the appointing authority;

c) Past the deadline for correction, and failure to rectify violations as required by the inspection agency;

d) At the request of the testing facility serving the state management.

17. Amendment and Supplementation of Clause 5, Clause 8 of Article 37 as follows:

a) Amendment and Supplementation of Clause 5 as follows:

"The organization that receives and manages the dossiers, issues, and revokes the Receipt Registration Certificate for health food products, the certificate of facility meeting food safety requirements according to Good Manufacturing Practices (GMP) for health food; Certificate confirming advertisement content for health food products; Certificate of free circulation, medical certificates, and other related certificates for health food products as requested by the organization or individual."

b) Supplementation of Clause 8 as follows:

"8. Develop a unified online public service system for food safety management from central to local levels to handle administrative procedures and manage food safety according to the assigned fields of management."

18. Supplementation of Clause 11 Article 38 as follows:

"11. Develop a unified online public service system for food safety management from central to local levels to handle administrative procedures and manage food safety according to the assigned fields of management."

19. Supplementation of Clause 10 Article 39 as follows:

"10. Develop a unified online public service system for food safety management from central to local levels to handle administrative procedures and manage food safety according to the assigned fields of management."

20. Supplementation of Clause 6b Article 40 as follows:

"6b. Manage the conditions ensuring food safety for the production and trading of containers that directly contact food, packaging materials directly contacting food. Organize the issuance and revocation of food safety certificates according to the assigned delegation."

21. Amendment and Supplementation of Clause 8, Clause 9 of Article 40 as follows:

a) Amendment and Supplementation of Clause 8 as follows:

“8. Organize the reception and management of dossiers, issuance, and revocation of the Receipt Registration Certificate for product announcement, Certificate confirming the advertisement content for medical nutrition products, foods for special dietary use, nutrition products for children up to 36 months old; Certificate of free circulation, medical certificates, and other related certificates (except certificates related to health food products) for food exports as requested by the organization or individual.”

b) Amendment and Supplementation of Clause 9 as follows:

“9. Organize the reception of self-declared product dossiers and publish the names of the organizations, individuals, and self-declared products on the agency’s website within 07 (seven) working days from the receipt of the dossiers.

Within 03 (three) months from the receipt of self-declared dossiers, the receiving agency is responsible for reviewing the legality of the received dossiers. If any document does not comply with the regulations, the receiving agency will notify and require the organization or individual to withdraw the dossier; simultaneously, remove the product information from the agency’s website and handle any violations in accordance with the law (if any).”

22. Supplementation of Clause 11 Article 40 as follows:

“11. Develop an online public service system linked with the national online public service system to manage food safety from central to local levels, resolve administrative procedures, and manage food safety.”

23. Amendment of Forms 01, 02, 10, 11 in Appendix I issued with Decree No. 15/2018/ND-CP in the Appendix issued with this Decree.

24. Supplementation of Forms 15, 16, 17, 18, 19, 20, 21 in Appendix I issued with Decree No. 15/2018/ND-CP in the Appendix issued with this Decree.

25. Amendment of the note in Serial No. II of Appendix IV issued with Decree No. 15/2018/ND-CP dated February 2, 2018, as follows:

“Does not include functional food products managed by the Ministry of Health.”

26. Amendment of the phrase “Ministry of Agriculture and Rural Development” in Decree No. 15/2018/ND-CP dated February 2, 2018, as follows:

“Ministry of Agriculture and Environment.”

Article 2. Abolition of certain provisions in the legal documents issued by the Government

Abolish, replace certain phrases in the Articles, Clauses, Points, Appendices of Decree No. 15/2018/ND-CP dated February 2, 2018, as follows:

1. Abolish Point b, c of Clause 4, Article 27;

2. Abolish Article 32;

3. Abolish Clause 5, Article 38;

4. Abolish Clause 5, Article 39;

5. Abolish the phrase “in case of creating a new product with new effects, it must prove the function, target users, and maximum usage level” in Clause 2, Article 30;

6. Abolish the phrase “Advertising means” in Form 10, Form 11 in Appendix I of Decree No. 15/2018/ND-CP dated February 2, 2018;

7. Replace the phrase “Food additives, flavorings, food processing aids” with “Food additives (including food flavorings), food processing aids” in Appendix II issued with Decree No. 15/2018/ND-CP dated February 2, 2018.

8. Abolish Clause 1 of Article 24b added in Article 13 of Decree No. 17/2020/ND-CP dated February 5, 2020, regarding the conditions for business investment in the Ministry of Industry and Trade.

Article 3. Effectiveness

This Decree takes effect from the day ... month ... year ....

Article 4. Transitional provisions

1. Dossiers for announcement, dossiers for food safety certification, dossiers for

appointment registration, dossiers for change, supplementation of appointment scope, dossiers for extension registration of food testing facilities serving state management submitted before the effective date of this Decree shall continue to be processed according to the provisions at the time of dossier submission, except when organizations or individuals voluntarily apply the provisions of this Decree. Food testing facilities that have been issued an Appointment Decision before the effective date of this Decree shall continue their food testing for state management purposes until the expiration date specified in the Appointment Decision.

2. Products that have been produced or imported according to dossiers submitted before the effective date of this Decree but do not comply with the provisions of this Decree may continue to circulate until the expiration date of the product.

Article 5. Responsibility for enforcement

The Ministers, Heads of Ministries, Heads of Governmental Agencies, Presidents of Provincial People's Committees, and related organizations and individuals are responsible for the enforcement of this Decree.

Recipients: The Secretariat of the Central Committee of the Communist Party; The Prime Minister and Deputy Prime Ministers; Ministries, ministerial-level agencies, and agencies under the Government; People's Councils and People's Committees of provinces and centrally governed cities; The Central Office and Party Committees; The Office of the General Secretary; The Office of the President; The Ethnic Council and Committees of the National Assembly; The Office of the National Assembly; The Supreme People's Court; The Supreme People's Procuracy; The State Audit Office of Vietnam; The Vietnam Bank for Social Policies; The Vietnam Development Bank; The Central Committee of the Vietnam Fatherland Front; Central agencies of mass	**ON BEHALF OF THE GOVERNMENT** **DEPUTY PRIME MINISTER** *(Signed: Lê Thành Long)*

organizations; The Government Office: Minister-Chairman, Deputy Ministers, Assistants to the Prime Minister, General Director of the Government Portal, Departments, Bureaus, affiliated units, and the Official Gazette; Archives: VT, KGVX (2b).vt.	

ANNEX I

AMENDMENTS AND SUPPLEMENTS TO THE TEMPLATES SPECIFIED IN ANNEX I ISSUED TOGETHER WITH DECREE NO. 15/2018/NĐ-CP

(**Attached to Decree No. .../2025/NĐ-CP dated ... month ... year 2025 of the Government**)

Template No. 02 Annex I Product Declaration

Template No. 15 Annex I Application for Designation/Supplementation/Extension of Designation of a Food Testing Facility for State Management

Template No. 16 Annex I Report on the Capacity of the Testing Facility

Template No. 17 Annex I Report on the Operational Results of the Testing Facility

Template No. 18 Annex I Assessment Record of the Testing Facility

Template No. 19 Annex I Report on the Implementation of Corrective Measures

Template No. 20 Annex I Decision on the Designation of a Food Testing Facility for State Management

Template No. 21 Annex I Testing Result Certificate

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PRODUCT DISCLOSURE FORM

No: ……..

I. Information about the organization or individual disclosing the product

Name of organization/individual: .....

Address: .....

Phone:…… Fax: .....

E-mail: .....

Business registration number: .....

Food safety certification number: …… Date of issue/Issued by:
.....

(for facilities that are required to have a food safety certification according to regulations)

II. Product Information

1. Product name: .....

2. Product formula:

- Ingredients: ……..

- Excipients:……...

- Capsule shell ingredients (if any): ……

3. Product quality specifications

The organization or individual producing and trading food products commits that the product meets quality requirements according to the attached product standards (including the testing method).

4. Product shelf life: .....

5. Packaging specifications and materials: .....

6. Name and address of the manufacturing facility: .....

III. Product Label Sample

(authenticated copy by the organization or individual)

IV. Food Safety Requirements

The organization or individual producing and trading food products must meet food safety requirements according to:

- National technical regulation No....; or

- Circulars of ministries or sectors; or

- Local technical regulations; or

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

- Standards from the Codex Alimentarius Commission, regional standards, foreign standards (if there are no national technical regulations, circulars from ministries or sectors, local technical regulations, national standards); or

- Manufacturer's standards (if there are no national technical regulations, circulars from ministries or sectors, local technical regulations, national standards, Codex Alimentarius standards, regional standards, or foreign standards).

V. Explanation of Product Ingredients

Product ingredients should include only those that contribute to the product's effectiveness and those that stabilize the formula (e.g., antioxidants, substances to avoid interactions, incompatibilities with active ingredients). (Applicable for health protection foods). The organization or individual must explain the information on the product ingredients in the following table:

No	Ingredient Name	Daily Dosage	Dosage in Documentation	% of Documentation	Documentation Used

If the product contains vitamins or minerals, the organization or individual must provide information on the maximum tolerable intake levels and the Recommended Nutrient Intake (RNI) for each vitamin and mineral according to the following table:

Vitamin/Mineral	Age Group	From ... to ... years	From ... to ... years	From ... to ... years	Daily Dosage

We commit to complying fully with food safety regulations and take full responsibility for the legality of the product disclosure document and the food safety and quality of the disclosed product, ensuring that the product is only produced and sold once the Product Disclosure Registration Certificate has been issued.

……. Date… Month… Year……

REPRESENTATIVE OF THE ORGANIZATION/INDIVIDUAL

(Signature, Seal)

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FORM NO. 15 APPENDIX I

TESTING FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No: ……/……

....., dated ..... month ..... year .....

APPLICATION FOR DESIGNATION/AMENDMENT, SUPPLEMENT OF DESIGNATED SCOPE/EXTENSION OF DESIGNATION FOR FOOD TESTING FACILITY FOR PUBLIC MANAGEMENT

To: (Designating agency)

1. Name of the testing facility:

Address:

Phone: Fax: E-mail:

2. Full name, position of the person responsible for the testing facility:

Address:

Phone: Fax: E-mail:

3. Testing activity registration certificate number: ....., date of issue: .....

4. Decision/Certification number ....., date of issue .....

5. Type of application

Registration for designation Registration for amendment/supplement
Registration for extension

6. Proposed designated scope:

No. Product, Goods Indicator Name Testing Method Detection Limit/Quantification Limit/Measurement Range (if any) Accreditation Organization Name (if any)*

* Specify the accreditation organization corresponding to the recognized method in this column.

7. Proposed start date for evaluation: date .... month .... year ....

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

Head of the Unit
(Sign, full name, and seal)

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FORM NO. 16 APPENDIX I

TESTING FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No: ……/……

....., dated ..... month ..... year .....

REPORT

CAPACITY OF THE TESTING FACILITY

1. Name of the testing facility:

Address:

Phone: Fax: E-mail:

2. Full name, position of the person responsible for the testing facility:

Address:

Phone: Fax: E-mail:

3. Staff of the testing facility:

No. Full Name Professional Training Certificate Management System Training Certificate Current Assignment Experience in Testing Remarks

4. Equipment

4.1. Equipment to be calibrated/certified

No. Equipment Name Measurement Range, Accuracy Class
Calibration/Certification Period Last Calibration/Certification Date
Calibration/Certification Agency Remarks

4.2. Other Equipment

No. Equipment Name Technical Specifications Date Put into Use
Remarks

5. Area and Environment of the Testing Facility

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

5.2. Environmental conditions of the sections of the testing facility

- Air conditioning;

- Ventilation and toxic gas exhaust capacity;

- Other safety conditions (vibration, dust, noise, light, radiation...).

5.3. Protective and labor safety conditions for the staff of the testing facility

6. List of Proposed Designated Indicators:

No. Product, GoodsIndicator Name Testing Method Detection Limit/Quantification Limit/Measurement Range (if any) Proficiency Testing Results/Inter-laboratory Comparisons*

* Specify the program name, indicator, method, sample matrix, participation, and result.

7. Testing Facility Performance in the Last Year:

No. Product, GoodsIndicator Name Testing Method Total Samples
Remarks

8. The testing facility commits to:

- Implementing the Designation Decision and managing the operation of the testing facility;

- Meeting the requirements of the evaluation agency when the testing facility is evaluated.

Head of the Unit

(Sign, full name, and seal)

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FORM NO. 17 APPENDIX I

TESTING FACILITY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No: ……/……

....., dated ..... month ..... year .....

REPORT

ACTIVITY REPORT OF THE TESTING FACILITY

(ANNUAL/IN THE DESIGNATED PERIOD)

1. Name of the testing facility:

Address:

Phone: Fax: E-mail:

2. Full name, position, person responsible for the testing facility:

Phone: Fax: E-mail:

3. Training: Enhancing the professional qualifications of the testing facility staff

No.	Full Name	Position	Training Course	Duration	Result	Remarks

4. Equipment

4.1. Calibrated/Certified Equipment

No. Equipment Name Measurement Range, Accuracy Class
Calibration/Certification Period Last Calibration/Certification Date
Calibration/Certification Agency Remarks

4.2. Newly Added Equipment

No. Equipment Name Technical Specifications Date Put into Use
Remarks

5. Designated Testing Indicators and Methods:

No. Product, Goods Indicator Name Testing Method Detection Limit/Quantification Limit/Measurement Range (if any) Remarks

6. Ensuring the Quality of Testing Results (Participation in Proficiency Testing/Inter-laboratory Comparisons):

No. Indicator Name Testing Method Sample Matrix Organization Unit
Participation Time Result

7. Results of Food Testing Activities for Public Management

No. Product, Goods Indicator Name Testing Method Total Samples Non-compliant Samples

Head of the Unit
(Sign, full name, and seal)

Responsible for the Testing Facility
(Sign and full name)

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FORM NO. 18 APPENDIX I

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

....., dated ..... month ..... year .....

MINUTES
ASSESSMENT OF TESTING FACILITY

The evaluation team for the testing facility ..... was established according to Decision No. ...../QĐ-.... dated ..... month ..... year ..... of the designating agency, consisting of:

(Name of the head of the evaluation team, secretary, and members)

1. Name of the testing facility:

Address: Phone: Fax: Email:

2. Conclusion of the Head of the Evaluation Team

2.1. Conformities:

2.2. Non-conformities:

No. Non-conformity Level 1 Level 2 Reference/Standard

...

Where:

- Level 1: cannot be corrected within the time limit specified in the Decree.

- Level 2: can be corrected within the time limit specified in the Decree.

2.3. Recommend the competent public management agency designate (name of the testing facility), located at ....., as a food testing facility serving public management in the following designated scope after the testing facility completes the corrective actions for all non-

conformities mentioned above:

No. Product, Goods Indicator Name Testing Method Detection Limit/Quantification Limit/Measurement Range (if any)

...

3. This report was approved with the consent of ..... members of the evaluation team.

4. Other remarks if any (specify content and names of those who made the remarks)

5. Other documents attached to the report include: ……..

Representative of the Testing Facility
(Sign, full name, and seal)

Secretary of the Evaluation Team
(Sign and full name)

Head of the Evaluation Team
(Sign and full name)

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FORM NO. 19 APPENDIX I

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

....., dated ..... month ..... year .....

REPORT
RESULTS OF CORRECTIVE ACTIONS IMPLEMENTED

To: (Designating agency)

1. Name of the tested facility being evaluated:

2. Designation Code (if any):

3. Non-conformity found: Severity level:

4. Cause:

5. Corrective action:

6. Any changes made to improve the management system (if any):

Head of the Unit
(Sign, full name, and seal)

Reporter
(Sign, full name)

7. Evaluation remarks from the assessment team members (sign and full name):

……

……

8. Remarks of the Secretary of the Evaluation Team (sign and full name):

……

……

9. Conclusion of the Head of the Evaluation Team:

……

……

....., dated ..... month ..... year .....
Head of the Evaluation Team
(Sign, full name)

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MINISTRY OF SPECIALIZED MANAGEMENT
DESIGNATED AGENCY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No: .../QĐ-...

Hanoi, dated ... month ... year ...

DECISION

ON DESIGNATING A FOOD TESTING FACILITY
FOR PUBLIC MANAGEMENT

Pursuant to the Food Safety Law dated June 17, 2010;
Pursuant to Decree No. ……/2025/NĐ-CP dated ... month ... year 2025 of the Government amending and supplementing several articles of Decree No. 15/2018/NĐ-CP dated February 02, 2018 of the Government detailing the implementation of certain provisions of the Food Safety Law;
(The head of the designated agency) ……..

DECIDES:

Article 1. Designate ..... (name of testing facility), located at ....., to be responsible for food testing to serve public management in relation to the criteria listed in the attached List of this Decision.
- Testing facility code: .....

Article 2. This Decision takes effect from ....., from the signing date.

Article 3. (Name of testing facility) under ..... is responsible for conducting testing to serve public management when required and must comply with the provisions and guidelines of the relevant public management authorities.

Recipient:
- As above;
- Relevant organizations (for information);

- Archive: Designating agency.

HEAD OF THE DESIGNATING AGENCY
(Sign, full name, and seal)

LIST OF DESIGNATED INDICATORS
(Attached to Decision No. ……/QĐ-…… dated ..... month ..... year ..... of the designating agency)

No.	Indicator Name	Product, Goods	Testing Method	Detection Limit/Quantification Limit/Measurement Range (if any)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
...				
.....				
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Form No. 21 – Appendix I

TESTING LABORATORY

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: ……/……..

TEST REPORT

(The test results are only valid for the tested sample)

1. **Sample name**: (Specify the name of the tested sample)
2. **Sample code**:
3. **Sample description**: (Condition of the sample upon receipt, sample weight, production date, expiration date, sample retention status)
4. **Sample retention period**:
5. **Sampling date**:
6. **Sample receipt date**:
7. **Testing period**:
8. **Sample sender**:
9. **Accompanying documents**: (Specify details, number, date, and reference of any accompanying documents)
10. **Test results** *(As per designated testing indicators of the laboratory)*:

No.	Testing Indicator	Testing Method	Unit	Result	Compared to QCVN.../ TCVN.../ Decision...

11. **Conclusion**: ……
    (Clearly state whether the sample meets the required standards or not)
12. **Notes**: (if any)

Head of the Unit
(Signature, full name, and official seal)

Head of the Testing Laboratory
(Signature and full name)