



4 March 2025

(25-1522)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>VIET NAM</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Vietnam Food Administration, Ministry of Health 138A Giang Vo, Ba Dinh District, Hanoi, Vietnam Tel: +(84 4) 3846 4489/ +(84 4) 3846 3702 Fax: +(84 4) 3846 3739 Email: <a href="mailto:phongtckn@gmail.com">phongtckn@gmail.com</a> Website: <a href="http://www.vfa.gov.vn">http://www.vfa.gov.vn</a> <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Food Products (Health supplement, supplemented food, Foodstuff, food additives, food processing aids, medical nutritional foods, foods for special diets, nutritional products for children up to 36 months old...)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Decree amending Decree No 15/2018/NĐ-CP dated 02 February 2018 of Government detailing the implementation of a number of articles of the Food Safety Law; (59 page(s), in Vietnamese), (58 page(s), in English)
<b>6. Description of content:</b> This draft Decree amends some article of Decree No 15/2018/NĐ-CP date 02 February 2018 of Government detailing the implementation of a number of articles of the Food Safety Law: I. Administrative procedure reform: 1. Eliminate the requirement for translation and notarization of English legal documents after consular legalization and accept electronic copies of legal documents. 2. Allow the use of the Testing Result for health supplement of production facilities that comply with Good Manufacturing Practices (GMP) without having to send to designated testing laboratories or recognized testing laboratories for testing. 3. Stipulate the number of times enterprises can submit additional request documents (maximum 03 times) and the deadline for enterprises to submit additional request documents (30 days) for the sequence of food groups that need to register product declarations according to the recommendation of the Government Inspectorate.

4. Adding a regulation for the import of food donated by organizations and individuals for charity purposes, not for business purposes, to simplify the process and procedures compared to the food business

5. Adding a regulation on assigning the Ministry of Health to develop unified management software from the Central to the local level to solve administrative procedures, product quality management in the health sector.

6. Adding a regulation on the registration of product declaration for mixed food additives with new uses, for food additives that are not on the list of additives permitted for use in food or that are not intended for the users prescribed by the Ministry of Health.

7. Reduction and simplification some administrative procedures:

- Simplify procedures for registration of advertising confirmation, issuance of Certificate of food safety qualified facilities.

- Adding 01 procedure for exemption from periodic inspection and supervision of testing facilities.

- Simplify the requirements for registration dossiers for designating testing facilities, which are currently regulated by Joint Circular 20/2013/TTLT-BYT-BCT-BNNPTNT stipulating conditions, procedures for the designation of food testing facilities for state management.

II. Strengthening decentralization and delegation of authority:

Decentralizing granting Certificates of Free Sale for food products, except health supplement; Health Certificate and other relevant certificates for exported foods to local authorities.

III. Strengthening post-inspection:

1. Regulations on only the manufacturing establishment or product owner being allowed to be named in the declaration dossier. In case it is not the above two entities, the organization or individual responsible for placing the product on the market must have a letter of authorization from the manufacturing facility or the product owner.

2. Controlling changes to products after announcement: adding cases where re-announcement is required if there is a change in the organization or individual responsible for placing the product on the market; manufacturing facility, origin; product name; ingredients; uses, subjects; dosage; concentration, content, the amount of ingredients responsible for the intended uses of the product, dosage form; quality and safety indicators and testing methods.

3. Adding provisions on the withdrawal and suspension of the acceptance of the Certificate of registration of product declaration, the Certificate of confirmation of food advertising content, withdrawal of the Certificate of food safety qualified facility, in which specific provisions are made on the cases of withdrawal and the authority to withdraw.

4. For functional foods, regulations on the Product Information File (PIF) include the records according to the regulations of the advanced management system that the functional food facility applies.

5. Requiring organizations and individuals to provide Standards including testing methods for safety indicators and quality indicators of the product in the registration dossier of the declaration so that the dossier receiving agency can provide them to public testing units to deploy sampling for monitoring on the market.

6. Adding regulations on Food Testing for State Management (including conditions for food testing facilities for State Management and verification testing facilities; registration dossier for designation of testing facilities; procedures for designation and cases of recalls.

IV. Implementation of the recommendations of Ministries, including the Government Inspectorate

1. Supplement and clarify the concept of functional foods placed on the market for the first time.

2. Amend and adding the concept of scientific evidence for the use of product.

<p>V. Some other contents:</p> <p>1. Amend and adding the concept of dietary supplements to control the features and uses of this product.</p> <p>2. Regarding self-declaration procedures for food products: clearly stipulate the responsibilities of the competent state management agency designated by the Provincial People's Committee to publish the self-declaration dossier on the unit's electronic information page within 07 days after receiving the dossier; At the same time, the records must be reviewed within 03 months after the organization or individual self-declares (regarding product classification, uses, users, ingredients) to ensure that the product has been declared correctly by its nature and in accordance with the regulations.</p>
<p><b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Decree No. 15/2018/NĐ-CP dated February 2, 2018 (replacing Decree No. 38/2012/NĐ-CP dated April 25, 2012) on detailing regulations for the implementation of certain articles of the Law on Food Safety and has been in effect for six years. However, during the implementation of Decree No. 15/2018/NĐ-CP, several urgent issues have arisen that need to be reviewed, amended, and supplemented to ensure compliance with practical needs and food safety management requirements, especially in the context of the ongoing administrative procedure reforms and the strengthening of post-inspection measures to improve food quality.</p> <p>At the meeting of the Central Inter-Sectoral Steering Committee for Food Safety on January 9, 2025, Deputy Prime Minister Le Thanh Long assigned the Ministry of Health to submit the amended Decree No. 15/2018/NĐ-CP within the first quarter of 2025. Given the urgency of this task, the Ministry of Health has reported to and sought the opinion of the Prime Minister, who approved the pressing and essential issues that need to be amended in Decree No. 15/2018/NĐ-CP, and agreed with the proposal to develop and promulgate the amended Decree following the simplified procedures as stipulated in the Law on the Promulgation of Legal Documents. Details are contained in Section 6. ; Protection of human health or safety</p>
<p><b>8. Relevant documents:</b></p> <ul style="list-style-type: none"> <li>- Law on Food Safety No. 55/2010/QH12 dated June 17, 2010.</li> <li>- 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.</li> <li>- Joint Circular 20/2013/TTLT-BYT-BCT-BNNPTNT date 01/8/2013 of Minister of Ministries: Health, Industry and Trade, Agriculture and Rural Development stipulating conditions, procedures for designating food testing facilities for state management.</li> </ul>
<p><b>9. Proposed date of adoption:</b> To be determined (Submit to the Government in Quarter I/2025)</p> <p><b>Proposed date of entry into force:</b> To be determined (Entry into force upon adoption)</p>
<p><b>10. Final date for comments:</b> 10 days from notification</p>
<p><b>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b></p> <p>Vietnam Food Administration, Ministry of Health.  Add: 138A Giang Vo, Ba Dinh District, Hanoi, Vietnam.  Tel: +(84 4) 3846 4489/ +(84 4) 3846 3702.  Fax: +(84 4) 3846 3739.  Email: <a href="mailto:qlsp.attp@moh.gov.vn">qlsp.attp@moh.gov.vn</a>  <a href="https://members.wto.org/crnattachments/2025/TBT/VNM/25_01787_00_e.pdf">https://members.wto.org/crnattachments/2025/TBT/VNM/25_01787_00_e.pdf</a>  <a href="https://members.wto.org/crnattachments/2025/TBT/VNM/25_01787_00_x.pdf">https://members.wto.org/crnattachments/2025/TBT/VNM/25_01787_00_x.pdf</a></p>