

THE MINISTRY OF HEALTH

**DECISION No. 42/2005/QĐ-BYT OF
DECEMBER 8, 2005, PROMULGATING THE
REGULATION ON STATEMENT OF FOOD
PRODUCT SPECIFICATIONS**

THE MINISTER OF HEALTH

*Pursuant to the Government's Decree No. 49/
2003/ND-CP of May 15, 2003, defining the
functions, tasks, powers and organizational
structure of the Health Ministry;*

Pursuant to Ordinance No. 12/2003/PL-

UBTVQH11 of July 26, 2003, on Food Hygiene and Safety, and the Government's Decree No. 163/2004/ND-CP of September 7, 2004, detailing the implementation of a number of articles of the Ordinance on Food Hygiene and Safety;

Pursuant to Ordinance No. 18/1999/PL-UBTVQH10 of December 24, 1999, on Goods Quality, and the Government's Decree No. 179/2004/ND-CP of October 21, 2004, stipulating the state management over quality of products and goods;

At the proposal of the director of the Vietnam Food Administration, the Health Ministry,

DECIDES:

Article 1.- To promulgate together with this Decision the Regulation on statement of food product specifications.

Article 2.- This Decision takes effect 15 days after its publication in "CONG BAO" and replaces the Health Minister's Decision No. 2027/2001/QD-BYT of May 30, 2001, promulgating the provisional regulation on statement of food quality, hygiene and safety standards.

Article 3.- *The director of the Office, the chief inspector, the director of the Legal Department of the Health Ministry, the director of the Vietnam Food Administration, the directors of the provincial/ municipal Health Services, the heads of the concerned units under the Ministry and the persons in charge of health in other branches shall have to implement this Decision.*

For the Health Minister
Vice Minister
TRINH QUAN HUAN

REGULATION ON STATEMENT OF FOOD PRODUCT SPECIFICATIONS

(Promulgated together with the Health Minister's Decision No. 42/2005/QD-BYT of December 8, 2005)

Chapter I

GENERAL PROVISIONS

Article 1.- Scope and subjects of application

1. Governing scope:

a/ This Regulation provides for dossiers and procedures for statement of product specifications and extension of the statement time limit; testing and inspection; the regime of fee collection and reporting on statement of product specifications.

b/ Food products subject to specification statement include:

- Foods, food additives, food processing enhancers, cigarettes and food raw materials manufactured at home or imported for sale and consumption in Vietnam.

- Products related to food safety (containers and packing materials in direct contact with foods and principal raw materials for manufacture thereof) and products for export only, which shall also be encouraged to have their specifications stated according to the provisions of this document.

- Domestically manufactured products for export, specifications of which must be stated at competent state agencies at the request of importing countries.

c/ Products of unstable quality, simply-packed products for daily use and products manufactured seasonally or on short-term orders and with an expiry duration of less than 10 days under normal

environmental conditions shall not be liable to statement of specifications under this Regulation.

2. Subjects of application: This Regulation shall apply to organizations and individuals that manufacture and/or trade in foods and have business registrations in Vietnam and to representatives of foreign companies which put their food products in circulation on the Vietnamese market (hereinafter referred to collectively as traders).

Article 2.- Interpretation of terms

In this Regulation, the terms and expressions below are construed as follows:

1. Product quality means a combination of properties (technical criteria and typical characteristics) of products, determined by measurable and comparable parameters, compatible with existing technical conditions, showing their ability to satisfy the requirements of society and individuals under definite production and consumption conditions and suitable to such products' utility.

2. Product quality standards mean technical documents defining technical properties and requirements of products, methods of testing such technical properties and requirements, requirements on packing, labeling, transport and preservation of products, and requirements for the quality control system and other matters related to product quality.

3. Food quality means a combination of properties of a food product which is identifiable and necessary for the state control, including: sensible criteria, principal quality criteria, quality indicators, physio-chemical and microbiological hygienic standards; composition of food raw materials and additives; expiry date; use and

preservation instructions; packing and packing material specifications; labeling contents.

4. Hygienic standards mean the limits or permitted maximum levels of chemical, physical and microbiological elements found in a product, in order to ensure stable product quality and safety for users.

5. Institute standards mean technical requirements on food quality of a product (under the same product name, brand, principal quality standards and hygienic standards) formulated and stated by traders themselves, who shall bear responsibility before law and consumers. Institute standards must usually not be lower than the Vietnamese standards and branch standards.

6. Principal quality criteria mean levels or quantities of substances decisive to nutritional values and typical characteristics of products, which are used to recognize, classify and distinguish them from food of the same type.

7. Quality indicators mean technical specifications through which the stability of product quality or contents of main ingredients of products can be determined.

8. Certificates of statement of product specifications (called product specification certificates for short) mean those granted by competent state agencies to traders that have stated their food quality, hygiene and safety standards in compliance with binding provisions of Vietnamese law. Such a certificate shall be valid for three (03) years after it is signed and stamped by a competent health agency.

9. Certification numbers mean those written in certificates of statement of product specifications granted by competent state agencies to traders that have made valid food quality, hygiene and safety standard statement for eligible circulation of the

latter's products on the market. Certification numbers are not meant to certify that the quality of every goods lot is up to the already stated specifications, the responsibility for which shall rest with traders.

10. Special foods mean a common term for a group of products of special natures or intended for use by special consumers, with a special usage or special effects on health. Special foods may be products of new technologies and include, for the purpose of this Regulation, the following types:

a/ Nutritious products intended for use by infants.

b/ Nutritious foods intended to be taken through catheters.

c/ Genetically modified foods.

d/ Radiation-treated foods.

e/ Functional foods.

11. Functional foods, depending on their specific utilities, contents of microelements and use instructions, may be given different names as follows:

a/ Nutritional supplements (supplements), which mean foods processed from raw materials with a high biological activity (nutritional supplements) and/or added with micronutrients (micronutrient-fortified foods), recommended for use by consumers of appropriate age according to regulations.

b/ Micronutrient-fortified foods, which mean ordinary foods fortified with micronutrients.

c/ Nutritious foods for medical use, which mean a special type of food which has been clinically tested and proved to have effects as stated by manufacturers and already permitted by competent authorities for circulation, and must be used with specific indications and instructions as well as

physicians' assistance and supervision.

d/ Health-supporting foods, which are referred to by Chinese manufacturers as an equivalent to functional foods.

Chapter II

DOSSIERS AND PROCEDURES FOR STATEMENT OF PRODUCT SPECIFICATIONS

Article 3.- Statement dossiers

1. For domestically manufactured foods and materials in direct contact with finished food products (their wrapping or packing), a dossier shall be made in two sets, each comprising:

a/ A written statement of product specifications (made according to a set form, not printed herein);

b/ A table of institute standards set out by the trader (affixed with stamp), including the following contents: sensible criteria (color, smell, state), principal quality criteria, quality indicators, hygienic criteria to physio-chemical, microbiological or heavy metal elements; material and food additive ingredients; expiry date, use and preservation instructions; packing materials and specifications (made according to a set form, not printed herein); manufacturing process.

c/ The business registration certificate, for Vietnamese traders, or the permit for setting up of representative office, for foreign manufacturing companies (notarized copies).

d/ A slip of testing results on principal quality criteria, quality indicators and hygienic criteria of the food subject to specification statement, issued by a testing laboratory accredited or designated by a competent state management agency. Particularly for natural mineral water, a slip of source water-testing results is required.

e/ Labeled samples and labels or draft contents to be inscribed in labels in compliance with the provisions of law on labeling (affixed with the trader's stamp).

f/ The institute's application for certificate of satisfaction of food hygiene and safety conditions to be granted by a competent state agency or already granted certificate (copy).

g/ A copy of the certificate of registered trademark (if any).

h/ Copies of receipts of payment of the dossier-examining fee and the certification number-issuing fee to the agencies competent to grant certificates.

i/ Particularly for radiation-treated foods, genetically modified foods, products of new technologies or products with ingredients containing genetically modified or radiation-treated materials, the statement dossiers must include copies of certificates of biological safety, radiation safety and explanations of manufacturing process.

2. For imported foods:

2.1. For imported foods other than special foods defined in Clause 10 of Article 2, a dossier shall be made in two sets, each comprising:

a/ Papers specified at Points a and b, Clause 1 of this Article.

b/ Business registration certificate, for Vietnamese traders, or permit for setting up of the representative office, for foreign manufacturing companies (notarized copies).

c/ Product specifications of the manufacturer or a slip of testing results (principal quality criteria, quality indicators and relevant hygienic standards) of the manufacturer or an independent testing agency of the country of origin.

d/ Product label or photos thereof and draft contents to be inscribed in the auxiliary label

(affixed with the trader's stamp); labeled samples (if requested for testing).

e/ Copy of one of the following certificates (if any): Good Manufacturing Practices (GMP); Hazard Analysis and Critical Control Points (HACCP); or an equivalent certificate, notarized by a Vietnamese or foreign notary public.

f/ Copies of receipts of payment of dossier-examining fee and certification number-granting fee to agencies competent to grant certificates.

g/ Copy of the commercial contract (if any).

h/ Particularly for radiation-treated foods, genetically modified foods or foods with ingredients containing genetically modified or radiation-treated materials, statement dossiers must have copies of certificates of exporting countries permitting such foods to be used for the same purpose within such countries' territories and explanations of manufacturing process.

2.2. For food additives and processing enhancers, a dossier comprises:

a/ Papers specified in Clause 1 of this Article;

b/ Certificate of free sale or health certificate granted by a competent state agency of the country of origin for a food additive or processing enhancer.

2.3. For special foods defined in Clause 10 of Article 2, a dossier shall be made in two sets, each comprising:

a/ Papers specified at Point 2.1, Clause 2 of this Article;

b/ Papers specifically required for special foods of all kinds, including:

- For foods being nutritious products intended for use by infants: Certificate of free sale or health certificate granted by a competent state agency of the country of origin, certifying that such products

are suitable to a certain age group or type of users.

- For nutritious foods for medical use: In addition to above-said papers, results of clinical research into such foods' functions are required.

- For nutritious foods intended to be taken through catheters: In addition to above-said papers, results of clinical research into safety of use through catheters and effects on health of indicated users are required.

- For functional foods: In addition to above-said papers, results of clinical research or documents evidencing special effects and safety of such foods are required.

2.4. For food additives restricted from use:

a/ For food additives outside Vietnam's list of food additives permitted for use but permitted for use in manufacturing countries or on the Codex list, the Health Ministry (the Vietnam Food Administration) shall consider to permit the statement of product specifications on a case-by-case basis or only permit the import thereof in shipment as for synthetic sweets specified in Item b, Point 2.4, Clause 2 of this Article.

b/ For synthetic sweets:

- If they are already in mixed forms or put in per-serving packs: Traders shall state their specifications as for food additives permitted for use in Vietnam.

- If they are packaged for multiple consumption: Traders shall only be permitted to import them lot by lot under import consignment notes of manufacturers of dietary foods (for use by sick people, obese people and people who do not want to gain weight) or under contracts with manufacturers of dietary foods. For subsequent import shipments, traders must produce invoices or vouchers proving that they sell such foods only

for dietary food manufacturers and for other purposes.

7. For materials in direct contact with finished food products (their wrapping or packing), food additives imported only in service of production within importing enterprises and products imported for trading only at hotels and supermarkets of importing enterprises, such enterprises shall state the products' specifications according to the enclosed list (not printed herein).

8. All dossiers specified in this Article, if written in foreign languages, must be enclosed with their Vietnamese translations made by traders themselves, or with lawfully valid Vietnamese translations, if so requested by competent health agencies.

Article 4.- Procedures for statement

1. Traders shall state their products' specifications with "product specification statements," made according to a set form (not printed herein) and enclosed with the institute standard tables, made according to a set form (not printed herein).

2. Traders trading in bottled natural mineral water, cigarettes or special foods and traders importing foods, food raw materials and additives and materials in direct contact with foods shall carry out procedures for stating the specifications of such products at the Health Ministry (the Vietnam Food Administration). Specifications of home-made ordinary products for export may be stated at the Health Ministry (the Vietnam Food Administration) if so requested by importing countries.

3. Traders manufacturing and/or trading in foods not specified in Clause 2 of this Article shall submit dossiers for specification statement to the Health Services of the provinces or centrally-run cities

where their manufacturing establishments are located or agencies authorized by the Health Services.

4. Competent state agencies defined in Clauses 2 and 3 of this Article or their authorized agencies shall receive dossiers and examine their compliance with the State's regulations, and within 15 working days after the receipt of complete and valid dossiers, have to:

a/ Grant product specification certificates (made according to set forms, not printed herein) or extended product specification certificates (made according to set forms, not printed herein) if contents of statement dossiers are compliant with the Health Ministry's current regulations on food quality, hygiene and safety and return to each trader one dossier set (affixed with seals of granting agencies).

b/ Notify and guide in writing the traders for completion of dossiers if contents of institute standards or product labels are incompliant with current regulations on food quality, hygiene and safety.

Article 5.- Method of inscribing specification statement certification numbers

1. For products with certificates issued by the Health Ministry, the inscribing principle shall be as follows: Serial number of granted certificate + slash + year of issue + slash + YT. For example: 234/2003/YT.

2. For products with certificates issued by local health agencies: The inscribing principle shall be the same, except for the acronym (YT) which shall be added with the first capital letters of names of provinces or cities. For example: Certificate No. 123/2004/YTHN means certificate numbered 123, granted in 2004 by the Health Service of Hanoi

city. For names of some provinces having the same first letters, acronyms thereof shall be added with second letters of the second words in lower case.

For example: Quang Nam – QNa; Quang Ngai – QNg; Quang Ninh – QNi; Hanoi – HN; Ha Nam – HNa. Acronyms of names of the provinces and cities are specified in an appendix to this Regulation (not printed herein).

Article 6.- Responsibilities of traders

1. To state product specifications at competent state agencies decentralized by the Health Ministry as defined in Article 4 of this Regulation; to ensure that specifications stated for application satisfy the regulations binding on products and to bear responsibility for the accuracy and truthfulness of their statements.

2. To ensure that stated names of products are true to the products' natures and do not cause confusion with the quality of products of the same type on the market.

3. To guarantee full satisfaction of requirements on conditions of manufacturing establishments according to the provisions of law and technological equipment corresponding to stated quality.

4. To ensure that quality, labeling contents and advertising information of circulated products are true to the statements.

5. To ensure fair competition according to the provisions of law.

6. To take initiative in conducting or propose periodical tests to be conducted in strict compliance with Article 9 of the Regulation.

7. To pay fees for inspection of establishments and periodical tests of products to agencies competent or authorized to conduct inspections and tests, except for inspection and testing fees in case

of extraordinary inspections or tests without advance notices according to the provisions of law or where no test result is returned to them.

Chapter III

DOSSIERS AND PROCEDURES FOR EXTENSION OF TIME LIMIT FOR PRODUCT SPECIFICATION STATEMENT

Article 7.- Dossiers

Traders shall have their certificates extended after three years counting from the dates such certificates are granted or extended. An extension application dossier comprises:

a/ A written request for extension of product specification certificate (made according to a set form, not printed herein) enclosed with the granted product specification certificate and institute standard certificate (the originals or notarized copies).

b/ Slips on results of periodical tests, for domestically manufactured products and imported special foods (issued by accredited or designated Vietnamese testing agencies for product samples sent by traders themselves or by inspecting agencies which have taken such samples at manufacturing or distributing establishments) or notices on import quality satisfaction by goods lots, for imported ordinary foods, issued by agencies in charge of state inspection of imported foods.

c/ One sample of labeled product currently in circulation (enclosed with auxiliary labels for imported foods).

d/ Copy of certificate of satisfaction of common hygienic conditions by the food establishment (for domestically manufactured products) issued by a competent state agency.

e/ Copies of receipts of payment of dossier-examining fee and certification number-granting fee to state agencies competent to grant certificates.

- For food products, for which slips of receipt of dossiers for statement of food quality, hygiene and safety standards under the Health Minister's Decision No. 2027/2001/QĐ-BYT of May 30, 2001 have been issued for a valid duration of three years after their signing, traders shall, upon expiration of such valid duration, have to make re-statements according to the provisions of this Regulation.

- In case of changes in the already stated contents, traders shall have to make restatements. Where only label presentations or packaging specifications are changed, changed labels shall be additionally submitted together with written requests for addition of new labels or replacement of labels currently in circulation.

Article 8.- Procedures for extension

Traders shall apply for extension of valid duration of product specification statements at agencies where they have made such statements.

Chapter IV

TESTING, INSPECTION AND REGIME OF FEE COLLECTION AND REPORTING

Article 9.- Regime of periodical testing

Competent state management agencies shall have to organize periodical tests and urge periodical tests of quality of products to be conducted. One of slips of periodical test results must be made for nearly expired products or even newly expired products for proving that the stated expiry date is true. The periodical testing regime shall be as follows:

a/ Once every three years, for products of establishments granted with GMP, GHP or HACCP certificates or certificates of equivalent systems.

b/ Once a year, for products of establishments having their own food testing and quality control laboratories.

c/ Twice a year, for products of establishments having no food testing and quality control laboratories.

d/ Four times a year, for products of business households.

e/ Once a year and state quality control agencies' certificates of quality of import goods lots, for imported ordinary products.

f/ Once a year and state quality control agencies' certificates of quality of imported special food lots.

Article 10.- Method of taking samples for periodical inspections

The inspection of quality of foods processed on industrial chains shall be conducted on typical samples being finished products or semi-finished products of the same group of products having common principal quality criteria and main ingredients. For manually processed products, only finished products shall be tested.

Article 11.- Decentralization of periodical inspection

Periodical inspections for purpose of taking samples for testing may be conducted at concerned establishments or on samples sent to testing laboratories by traders themselves, provided that they must bear full responsibility for the typicality of such samples, as follows:

1. For domestically manufactured food products which are managed and granted the certification

numbers by the Health Ministry (the Vietnam Food Administration), the provincial preventive medicine centers shall have to conduct periodical inspections at manufacturing establishments located in their localities in order to take by themselves samples of products which need special preservation or seal up samples to be sent by traders for testing.

2. Provincial/municipal Health Services shall assign responsibilities to provincial and district preventive medicine units for inspecting domestic manufacturing establishments located in their localities. Provincial preventive medicine centers shall have to conduct tests. When the testing goes beyond their capability, samples shall be sent to regional functional institutes or accredited laboratories for testing.

Article 12.- Extraordinary tests and inspections

Competent state agencies shall conduct extraordinary tests or inspections of establishments upon detecting signs of violations or receiving complaints or denunciations about violations of regulations on food quality, hygiene and safety under directions of competent authorities.

Article 13.- Fee collection and reporting regime

Competent state agencies defined in Article 4 shall open books for monitoring the situation of statement of product specifications and coordinate with market managing offices of the same management level in controlling the quality of products circulated in the market.

1. To organize the collection of fees and charges for testing, inspection and certification of product specification statements according to the Finance Ministry's current regulations. Not to collect charges in case of re-inspection, extraordinary inspection or testing of products circulated in the market.

2. To issue documents authorizing competent agencies to conduct periodical food hygiene inspections at food establishments and periodical tests of product quality and hygiene, and concurrently notify such agencies of the authorization. In case of violations, inspecting agencies shall have to make written records thereon and send them to competent agencies for handling.

3. Once every six months, provincial/municipal Health Services shall have to sum up and report on the management of food quality and hygiene in their localities to the Health Ministry (the Vietnam Food Administration) for monitoring and sum-up.

For the Minister of Health
Vice Minister
TRINH QUAN HUAN