

**THE MINISTRY OF
HEALTH**

No. 12/2024/TT-BYT

THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, July 18, 2024

CIRCULAR

Promulgating the National Technical Regulation QCVN 20-1:2024/BYT on the limits of contaminants for health supplements/ dietary supplements

Pursuant to the June 17, 2010 Law No. 55/2010/QH10 on Food Safety;

Pursuant to the Government's Decree No. 15/2018/ND-CP of February 2, 2018 detailing the implementation of a number of articles of the Law on Food Safety;

Pursuant to the Government's Decree No. 95/2022/NDD-CP of November 15, 2022 defining the functions, tasks, powers, and organizational structure of the Ministry of Health;

At the proposal of the Director General of the Food Safety Department;

The Minister of Health promulgates the National Technical Regulation QCVN 20-1:2024/BYT on the limits of contaminants for health supplements/ dietary supplements.

Article 1. Promulgation of National Technical Regulation

To promulgate together with this Circular: the “National Technical Regulation QCVN 20-1:2024/BYT on the limits of contaminants for health supplements/ dietary supplements”.

Article 2. Effect

This Circular takes effect from August 1, 2025.

Article 3. Transitional provisions

1. For health supplement products of which a certificate of registered product declaration has been granted, if they are manufactured before the effective date of this Circular, but not yet compliant with the regulations

promulgated with this Circular, organizations or individuals may continue to import, trade, and circulate the products until the expiration date of the products, except cases where there are warnings of food safety.

2. Dossiers of product declaration registration submitted before the effective date of this Circular shall continue to be processed according to the regulations in effect at the time of submission.

3. From the effective date of this Circular, for health supplement products of which a certificate of registered product declaration has been granted, if the manufacturer's standards are not yet compliant with the regulations promulgated with this Circular, organizations or individuals must adjust the manufacturer's standards to comply with the regulations and carry out the notification under Clause 4, Article 8 of the Government's Decree No. 15/2018/ND-CP of February 2, 2018 detailing the implementation of a number of articles of the Law on Food Safety.

Article 4. Reference clauses

In case the provisions referenced in this Circular are amended or replaced, the new document shall apply.

Article 5. Responsibilities for implementation

The Director General of the Department of Food Safety, Heads of units under the Ministry of Health; Directors of Departments of Health, Departments of Food Safety of provinces and centrally-run cities, and relevant agencies, organizations, and individuals shall implement this Circular.

Any difficulties arising during the process of implementation should be promptly reported to the Ministry of Health (Department of Food Safety) for consideration and resolution./.

**FOR THE MINISTER OF HEALTH
DEPUTY MINISTER**

Do Xuan Tuyen

THE SOCIALIST REPUBLIC OF VIETNAM
QCVN 20-1:2024/BYT
NATIONAL TECHNICAL REGULATION ON THE LIMITS OF
CONTAMINANTS FOR HEALTH SUPPLEMENTS/ DIETARY
SUPPLEMENTS

*(Issued together with Circular No. 12/2024/TT-BYT dated July 18, 2024, of the
Ministry of Health)*

HANOI - 2024

Preface

QCVN 20-1:2024/BYT is developed by the Drafting Committee for the National Technical Regulation on the limits of contaminants for health supplements/ dietary supplements, submitted by the Department of Food Safety, approved by the Ministry of Science and Technology, and promulgated by the Minister of Health together with Circular No. 12/2024/TT-BYT of July 18, 2024.

**NATIONAL TECHNICAL REGULATION ON THE LIMITS OF
CONTAMINANTS FOR HEALTH SUPPLEMENTS/ DIETARY
SUPPLEMENTS**

I. GENERAL PROVISIONS

1. Scope of regulation

This technical regulation prescribes the maximum limits of contaminants (heavy metals and microorganisms); sampling and test methods; requirements of management; and the responsibilities of organizations and individuals producing and trading in health supplements/ dietary supplements.

This technical regulation shall not apply to products of tonic wine declared as health supplements.

2. Subjects of application

This technical regulation applies to organizations and individuals producing and trading in health supplements/ dietary supplements within the territory of Vietnam and other relevant organizations and individuals.

3. Definition of terms and abbreviations

In this Technical Regulation, the following terms and abbreviations are understood as follows:

3.1. Health supplements are products defined in Clause 1, Article 3 of the Government's Decree No. 15/2018/ND-CP of February 2, 2018 detailing the implementation of a number of articles of the Law on Food Safety.

3.2. Multi-ingredient products are health supplements containing a mixture of two or more types of ingredients, including:

a) Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and other biologically active substances;

b) Substances of natural origin, including animals, minerals, and plants in the form of extracts, isolates, concentrates, and metabolites;

c) Synthetic sources of the ingredients mentioned in points a and b above.

3.3. AOAC: Association of Official Analytical Collaboration.

3.4. ML: Maximum limit.

3.5. TSVSVHK: Total number of aerobic microorganisms.

3.6. TSNMNM: Total number of yeasts and molds.

II. TECHNICAL REGULATIONS

1. Regulations on Heavy Metals

The maximum limits of heavy metals for health supplements/ dietary supplements are prescribed as in Table 1.

Table 1. Regulations on Maximum Limits of Heavy Metals

No	Targets	Maximum limit (mg/kg or mg/L)	Note
1	Arsen (As)	5.0	Total As
		1.5	Inorganic As Inorganic As is only monitored when the total As content exceeds 1.5 mg/kg or mg/L
2	Cadmi (Cd)	3.0	Contains ingredients from seaweed or bivalve mollusks
		1.0	Does not contain ingredients from seaweed or bivalve mollusks
3	Lead (Pb)	10.0	
4	Mercury (Hg)	0.5	

2. Regulations on Microorganisms

The maximum limits of microorganisms for health supplements/ dietary supplements are prescribed as in Table 2.

Table 2. Regulations on Maximum Limits of Microorganisms

Group No.	Product Groups (*)	Targets	ML	Unit	Note
1	Health supplements containing plant ingredients must be treated with boiling water (soaked in boiling water, dipped in boiling water, etc.) according to the instructions before use (e.g., herbal tea).	Total number of aerobic microorganisms	5×10^7	CFU/g or CFU/ml	- The regulations in this group also apply to multi-ingredient products that do not contain ingredients from animals and/or minerals belonging to Group 3.
		Total number of yeasts and molds	5×10^5	CFU/g or CFU/ml	
		<i>Escherichia coli</i>	1×10^3	CFU/g or CFU/ml	
		<i>Salmonella</i> spp.	Not allowed	/25 g or /25 ml	
2	Health supplements containing plant ingredients.	Total number of aerobic microorganisms	5×10^4	CFU/g or CFU/ml	- The regulations in this group also apply to multi-ingredient products that do not contain ingredients from animals and/or minerals belonging to Group 3. - In case the products in this group contain probiotics: + If the product contains probiotics from the non-spore-forming bacteria group: additional regulation for non-
		Total number of yeasts and molds	5×10^2	CFU/g or CFU/ml	
		Enterobacteriaceae (Bile-tolerant Gram-negative bacteria)	1×10^2	CFU/g or CFU/ml	
		<i>Escherichia coli</i>	Not allowed	/1 g or /1 ml	
		<i>Salmonella</i> spp.	Not allowed	/25 g or /25 ml	

					<p>lactic acid bacteria is required according to the limits in Group 6.1 of this table, and no regulation for total aerobic microorganisms (TSVSVHK) is required.</p> <p>+ If the product contains probiotics from the spore-forming bacteria group: no regulation for total aerobic microorganisms (TSVSVHK) is required.</p> <p>+ If the product contains probiotics from the yeast group: no regulation for total yeasts and molds (TSNMNM) is required. The maximum limit for total aerobic microorganisms (TSVSVHK) in this group does not include yeast strains that are components of the product.</p>
3	Health supplements containing ingredients from animals or minerals, or a mixture of two or	Total number of aerobic microorganisms	2×10^4	CFU/g or CFU/ml	<p>- The regulations in this group also apply to multi-ingredient products.</p> <p>- In case the products in this group contain probiotics:</p>
		Total number of yeasts and molds	2×10^2	CFU/g or CFU/ml	

	more ingredients from animals, minerals, and plants.	Enterobacteriaceae (Bile-tolerant Gram-negative bacteria)	1 x 10 ²	CFU/g or CFU/ml	<p>+ If the product contains probiotics from the non-spore-forming bacteria group: additional regulation for non-lactic acid bacteria is required according to the limits in Group 6.1 of this table, and no regulation for total aerobic microorganisms (TSVSVHK) is required.</p> <p>+ If the product contains probiotics from the spore-forming bacteria group: no regulation for total aerobic microorganisms (TSVSVHK) is required.</p> <p>+ If the product contains probiotics from the yeast group: no regulation for total yeasts and molds (TSNMNM) is required. The maximum limit for total aerobic microorganisms (TSVSVHK) in this group does not include yeast strains that are components of the product.</p>
		<i>Escherichia coli</i>	Not allowed	/1 g or /1 ml	
		<i>Salmonella</i> spp.	Not allowed	/10 g or /10 ml	
		<i>Staphylococcus aureus</i>	Not allowed	/1 g or /1 ml	
4	Health supplements	Total number of aerobic	2 x 10 ²	CFU/g or CFU/ml	- The regulations in this group also

<p>containing one or more types of ingredients: vitamins, minerals, amino acids, fatty acids, enzymes, biologically active substances that are chemically defined, and not belonging to groups 1, 2, and 3 above.</p> <p>Water-containing forms (water is a component of the product formula) (e.g., aqueous solutions, syrups, suspensions, emulsions, jellies, etc.).</p>	microorganisms			apply to multi-ingredient products that do not contain ingredients from groups 1, 2, and 3.
	Total number of yeasts and molds	2 x 10 ¹	CFU/g or CFU/ml	- In case the products in this group contain probiotics: + If the product contains probiotics from the non-spore-forming bacteria group: additional regulation for non-lactic acid bacteria is required according to the limits in Group 6.1 of this table, and no regulation for total aerobic microorganisms (TSVSVHK) is required. + If the product contains probiotics from the spore-forming bacteria group: no regulation for total aerobic microorganisms (TSVSVHK) is required. + If the product contains probiotics from the yeast group: no regulation for total yeasts and molds (TSNMNM) is required. The maximum limit for total
	<i>Escherichia coli</i>	Not allowed	/1 g or /1 ml	

					aerobic microorganisms (TSVSVHK) in this group does not include yeast strains that are components of the product.
5	Health protection foods containing one or more types of ingredients: vitamins, minerals, amino acids, fatty acids, enzymes, biologically active substances that are chemically defined, and not belonging to groups 1, 2, and 3 above. Non-water-containing forms (water is not a component of the product formula) (e.g., tablets (regular tablets, effervescent tablets, film-coated tablets), soft	Total number of aerobic microorganisms	2×10^3	CFU/g or CFU/ml	<ul style="list-style-type: none"> - The regulations in this group also apply to multi-ingredient products that do not contain ingredients from groups 1, 2, and 3. - In case the products in this group contain probiotics: <ul style="list-style-type: none"> + If the product contains probiotics from the non-spore-forming bacteria group: additional regulation for non-lactic acid bacteria is required according to the limits in Group 6.1 of this table, and no regulation for total aerobic microorganisms (TSVSVHK) is required. + If the product contains probiotics from the spore-forming bacteria group: no regulation for total aerobic microorganisms (TSVSVHK)
		Total number of yeasts and molds	2×10^2	CFU/g or CFU/ml	
		<i>Escherichia coli</i>	Not allowed	/1 g or /1 ml	

	capsules, hard capsules, granules, powders, films, gummy candies, oil solutions, etc.).				is required. + If the product contains probiotics from the yeast group: no regulation for total yeasts and molds (TSNMNM) is required. The maximum limit for total aerobic microorganisms (TSVSVHK) in this group does not include yeast strains that are components of the product.
6	Health supplements containing only probiotics				
6.1	Products containing only non-spore-forming probiotics	Non-lactic acid bacteria	5×10^3	CFU/g or CFU/ml	- In case the product contains probiotics from groups 6.1 and 6.2: only the criteria for TSNMNM, <i>E. coli</i> , and <i>Salmonella</i> spp. are regulated according to the maximum limits in group 6.1.
		Total number of yeasts and molds	1×10^2	CFU/g or CFU/ml	
		<i>Escherichia coli</i>	Not allowed	/10 g or /10 ml	
		<i>Salmonella</i> spp.	Not allowed	/10 g or /10 ml	
6.2	Products containing only spore-forming probiotics	Total number of yeasts and molds	1×10^2	CFU/g or CFU/ml	- In case the product contains probiotics from groups 6.1 and 6.3: only the criteria for non-lactic acid bacteria, <i>E. coli</i> , and <i>Salmonella</i> spp. are regulated according to the maximum limits in group 6.1.
		<i>Escherichia coli</i>	Not allowed	/10 g or /10 ml	
		<i>Salmonella</i> spp.	Not allowed	/10 g or /10 ml	
6.3	Products containing only yeast probiotics	Total aerobic microorganisms (excluding added	1×10^3	CFU/g or CFU/ml	

		yeast strains)			- In case the product contains probiotics from groups 6.2 and 6.3 or from groups 6.1, 6.2, and 6.3: only the criteria for <i>E. coli</i> and <i>Salmonella</i> spp. are regulated according to the maximum limits in group 6.2.
		<i>Escherichia coli</i>	Not allowed	/10 g or /10 ml	
		<i>Salmonella</i> spp.	Not allowed	/10 g or /10 ml	

(*) The classification of products in this table is based on product ingredients but does not include ingredients that are food additives, excipients, or capsule shells.

III. SAMPLING AND TEST METHODS

1. Sampling

The product sampling of health supplements is carried out according to the guidelines in Circular No. 01/2024/TT-BKHHCN dated January 18, 2024, of the Minister of Science and Technology, providing the state inspection of the quality of goods in circulation and other relevant law regulations.

2. Test Methods

The technical requirements in this Technical Regulation are implemented according to the test methods specified below:

2.1. Methods for Determining Heavy Metal Indicators

2.1.1. Method for Determining Arsenic Content

2.1.1.1. Method for Determining Total Arsenic Content

- National Standards TCVN 10912:2015 (European Standards EN 15763:2009). Food - Determination of trace elements - determination of arsenic, cadmium, mercury, and lead by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion⁽¹⁾.

- National Standards TCVN 9521:2012 (EN 14627:2005). Food - Determination of trace elements. Determination of total arsenic and selenium content by hydride generation atomic absorption spectrometry (HGAAS) after pressure digestion.

- National Standards TCVN 8427:2010 (EN 14546:2005). Food - Determination of trace elements. Determination of total arsenic by hydride generation atomic absorption spectrometry (HGAAS) after ashing.

- Association of Official Analytical Collaboration AOAC 2015.01. Heavy Metals in Food. Inductively Coupled Plasma - Mass Spectrometry.

- AOAC 986.15. Arsenic, Cadmium, Lead, Selenium, and Zinc in Human and Pet Foods. Multi-element Method.

2.1.1.2. Method for determining the content of inorganic Arsenic

- National Standards TCVN 12346:2018 (EN 16802:2016). Food - Determination of Elements and Their Chemical Compounds - Determination of Inorganic Arsenic in Foodstuffs of Plant and Marine Animal Origin by Anion-Exchange HPLC-ICP-MS⁽¹⁾.

2.1.2. Method for determining the content of Cadmium and Lead

- National Standards TCVN 10912:2015 (EN 15763:2009). Food - Determination of trace elements - determination of arsenic, cadmium, mercury, and lead by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion⁽¹⁾.

- National Standards TCVN 10643:2014 (AOAC 999.11). Food - Determination of lead, cadmium, copper, iron, and zinc content - Atomic absorption spectrometry method after dry ashing;

- National Standards TCVN 8126:2009. Food - Determination of lead, cadmium, zinc, copper, and iron content - Atomic absorption spectrometry method after microwave digestion.

- National Standards TCVN 7929:2008 (EN 14083:2003). Food - Determination of Trace Elements - Determination of Lead, Cadmium, Chromium, and Molybdenum by Graphite Furnace Atomic Absorption Spectrometry (GF-AAS) after Pressure Digestion.

- AOAC 2015.01. Heavy Metals in Food. Inductively Coupled Plasma - Mass Spectrometry (ICP-MS).

- European Standards (EN) 14082:2003. Foodstuffs - Determination of trace elements - Determination of lead, cadmium, zinc, copper, iron and chromium by atomic absorption spectrometry (AAS) after dry ashing.

- EN 14084:2003 Foodstuffs - Determination of trace elements - Determination of lead, cadmium, zinc, copper and iron by atomic absorption spectrometry (AAS) after microwave digestion.

2.1.3. Method for determining the content of Mercury

- National Standards TCVN 10912:2015 (EN 15763:2009). Food - Determination of trace elements - Determination of arsenic, cadmium, mercury, and lead by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) after pressure digestion⁽¹⁾.

- National Standards TCVN 7993:2009 (EN 13806:2002). Food - Determination of trace elements - Determination of mercury by Cold Vapor Atomic Absorption Spectrometry (CV-AAS) after pressure digestion.

- National Standards TCVN 7604:2007. Food - Determination of Mercury content by flameless atomic absorption spectrometry.

- AOAC 2015.01. Heavy Metals in Food. Inductively Coupled Plasma - Mass Spectrometry (ICP-MS).

2.2. Method for Testing Microorganisms

2.2.1. Method for Determining total aerobic microorganism count

- United States Pharmacopeia 2023 <2021>, Microbiological Examination of Non-Sterile Products: Quantification of bacteria in nutritional supplements and foods for special dietary use (United States Pharmacopeia and National Formulary 2023 <2021 > Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests for Nutritional and Dietary Supplements)⁽¹⁾.

- TCVN 4884-1:2015 (International Organization for Standardization (ISO) 4833-1:2013). Microorganisms in the food chain - Methods for the enumeration of microorganisms - Part 1: Colony-count at 30°C by the pour plate technique.

- TCVN 4884-2:2015 (ISO 4833-2:2013 technical amendment 1:2014). Microorganisms in the food chain - Methods for the enumeration of microorganisms - Part 2: Colony-count at 30°C by surface inoculation technique.

- Vietnam Pharmacopoeia V, 2017, Appendix 13.6, Section 1. Determination of Total Microorganisms.

- The British pharmacopoeia 2024, volume V, Appendix XVI, item F. Microbiological examination of herbal medicinal products for oral use and extracts used in their preparation.

- ISO 4833-1:2013/Amd 1:2022. Microbiology of the food chain - Horizontal method for the enumeration of microorganisms - Part 1: Colony count at 30°C by the pour plate technique - Amendment 1: Clarification of scope.

- ISO 4833- 2:2013/Amd 1:2022. Microbiology of the food chain - Horizontal method for the enumeration of microorganisms - Part 2: Colony count at 30°C by the surface plating technique - Amendment 1: Clarification of scope.

2.2.2. Method for Determining total yeasts and molds indicators

- United States Pharmacopeia 2023 <2021>, Microbiological Examination of Non-Sterile Products: Quantification of bacteria in nutritional supplements and foods for special dietary use (United States Pharmacopeia and National Formulary 2023 <2021 > Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests for Nutritional and Dietary Supplements)⁽¹⁾.

- TCVN 8275-1:2010 (ISO 21527-1:2008). Microorganisms in food and animal feed - Methods for the enumeration of yeasts and molds. Part 1: Colony-count technique in products with water activity greater than 0.95

- TCVN 8275-2:2010 (ISO 21527-2:2008). Microorganisms in food and animal feed - Methods for the enumeration of yeasts and molds. Part 2: Colony-count technique in products with water activity less than or equal to 0.95

- Vietnam Pharmacopoeia V, 2017, Appendix 13.6, Section 1. Determination of Total Microorganisms.

- The British pharmacopoeia 2024, volume V, Appendix XVI, item F. Microbiological examination of herbal medicinal products for oral use and extracts used in their preparation.

2.2.3. Method for Determining *Escherichia coli* Indicators: Qualitative Method

- United States Pharmacopeia 2023 <2022>, Microbiological examination of non-sterile products: Quantification of bacteria in nutritional supplements and foods for special dietary use (United States Pharmacopeia and National Formulary 2023 <2022> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests for Nutritional and Dietary Supplements)⁽¹⁾.

- TCVN 6846:2007 (ISO 7251:2005). Microorganisms in food and animal feed - methods for detection and enumeration of presumptive *escherichia coli* - most probable number technique.

- Vietnam Pharmacopoeia V, 2017, Appendix 13.6, Section 2. Determination of Pathogenic Microorganisms.

- The British pharmacopoeia 2024, volume V, Appendix XVI, item B. Microbiological Examination of Non-sterile Products.

- ISO 7251:2005/Amd 1:2023. Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of presumptive *Escherichia coli* - Most probable number technique - Amendment 1: Inclusion of performance testing of culture media and reagents.

2.2.4. Method for Determining *Escherichia coli* Indicators: Quantitative Method

- The British pharmacopoeia 2024, volume V, Appendix XVI, item F. Microbiological examination of herbal medicinal products for oral use and extracts used in their preparation⁽¹⁾.

- TCVN 7924-2:2008 (ISO 16649-2:2001): Microorganisms in Food and Animal Feed - Method for the Enumeration of β -Glucuronidase-Positive *Escherichia coli* - Part 2: Colony-Count Technique at 44°C Using 5-Bromo-4-Chloro-3-Indolyl β -D-Glucuronide.

- TCVN 9975:2013. Food - Enumeration of Coliforms and *Escherichia*

coli by the Petrifilm Plate Method.

2.2.5. Method for Determining *Staphylococcus aureus* Indicators

- United States Pharmacopeia 2023 <2022>. Procedures for determining the absence of specific microorganisms in nutritional supplements and foods for special dietary use (United States Pharmacopeia and National Formulary 2023 <2022>. Microbiological procedures for the absence of specified microorganisms in nutritional and dietary supplements)⁽¹⁾.

- Vietnam Pharmacopoeia V, 2017, Appendix 13.6, Section 2. Determination of Pathogenic Microorganisms.

- The British pharmacopoeia 2024, volume V, Appendix XVI, item B. Microbiological Examination of Non-sterile Products.

2.2.6. Method for Determining *Salmonella* spp. Indicators

- United States Pharmacopeia 2023 <2022>. Procedures for determining the absence of specific microorganisms in nutritional supplements and foods for special dietary use (United States Pharmacopeia and National Formulary 2023 <2022>. Microbiological procedures for the absence of specified microorganisms in nutritional and dietary supplements)⁽¹⁾.

- TCVN 10780-1:2017 (ISO 6579-1:2017): Microorganisms in the Food Chain - Methods for Detection, Enumeration, and Serotyping of *Salmonella* - Part 1: Detection Method for *Salmonella* spp.

- Vietnam Pharmacopoeia V, 2017, Appendix 13.6, Section 2. Determination of Pathogenic Microorganisms.

- The British pharmacopoeia 2024, volume V, Appendix XVI, item B. Microbiological Examination of Non-sterile Products.

- ISO 6579-1:2017/Amd 1:2020: Microbiology of the food chain - Horizontal method for the detection, enumeration and serotyping of *Salmonella* - Part 1: Detection of *Salmonella* spp. - Amendment 1: Broader range of incubation temperatures, amendment to the status of Annex D, and correction of the composition of MSR and SC.

2.2.7. Method for Determining Enterobacteriaceae (Bile-Tolerant Gram-Negative Bacteria) Indicators

- ISO 21528-2:2017. Microbiology of the food chain - Horizontal method for the detection and enumeration of Enterobacteriaceae - Part 2: Colony-count technique⁽¹⁾.

- National Standards TCVN 5518-2:2007 (ISO 21528-2:2004). Microorganisms in Food and Animal Feed - Methods for Detection and Quantification of Enterobacteriaceae - Part 2: Colony-Count Technique.

2.2.8. Method for determining total aerobic microorganism count (excluding yeast strains as product components) in products containing probiotic components from the yeast group

- European pharmacopoeia 9.7. Appendix 2.6.36. Microbiological examination of live biotherapeutic products: Tests for enumeration of Microbial contaminants⁽¹⁾.

2.2.9. Method for Determining Non-Lactic Acid Bacteria

- European pharmacopoeia 9.7. Appendix 2.6.36. Microbiological examination of live biotherapeutic products: Tests for enumeration of microbial contaminants⁽¹⁾.

Note:

(1) The method is used in activities of food testing to serve state management.

IV. REQUIREMENTS OF MANAGEMENT

1. The labeling of health supplements/ dietary supplements shall comply with the Government's Decree No. 43/2017/ND-CP of April 14, 2017 on goods labels; the Government's Decree No. 111/2021/ND-CP of December 9, 2021 amending and supplementing a number of articles of the Government's Decree No. 43/2017/ND-CP of April 14, 2017 on goods labels and other relevant law regulations.

2. Organizations or individuals must register product declaration of their products of health supplements/ dietary supplements based on test results from designated laboratory or a laboratory complying with ISO 17025 as prescribed in Article 7 of the Government's Decree No. 15/2018/ND-CP of February 2, 2018 detailing the implementation of a number of articles of the Law on Food Safety. The dossier and procedures for product declaration registration shall comply with Article 7 and Article 8 of the Government's Decree No. 15/2018/ND-CP of February 2, 2018 detailing the implementation of a number of articles of the Law on Food Safety.

V. RESPONSIBILITIES OF ORGANIZATIONS AND INDIVIDUALS

Organizations and individuals producing or trading in health

supplements/ dietary supplements shall take the responsibilities for their products, ensuring that such products comply with the requirements of this technical regulation and other relevant law provisions.

VI. ORGANIZATION OF IMPLEMENTATION

1. Assign the Department of Food Safety to take the prime responsibility for and coordinate with relevant functional agencies in, guiding, carrying out, and organizing the implementation of this technical regulation.

2. Based on the requirements of management, the Department of Food Safety shall review, summarize, report, and propose amendments to this technical regulation to the Ministry of Health.

3. In case the law regulations and reference documents in this technical regulation are amended or replaced, the new documents shall apply.