THE MINISTRY OF HEALTH OF VIETNAM ---	THE SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ---
No. 12/2024/TT-BYT	*Hanoi, July 18, 2024*

CIRCULAR

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

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

Pursuant to the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of some Articles of the Law on Food Safety;

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

At the request of the Director General of the Vietnam Food Administration;

The Minister of Health hereby promulgates 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

Promulgated together with this Circular is the "National Technical Regulation QCVN 20-1:2024/BYT on the limits of contaminants for health supplements/ dietary supplements".

Article 2. Effect

This Circular comes into force from August 01, 2025.

Article 3. Transitional clause

1. For health supplements/dietary supplements which are granted a certificate of registered product disclosure and manufactured before the effective date of this Circular but has yet to conform to the technical regulation promulgated together with this Circular, organizations or individuals may continue to import, trade and circulate such health supplements/dietary supplements until their expiry dates, unless there if a food safety warning.

2. Any application for registration of product disclosure submitted before the effective date of this Circular shall continue to be processed in accordance with regulations in force at the time of submission.

3. From the effective date of this Circular, for health supplements/dietary supplements granted a certificate of registered product disclosure, if the manufacturer's standard is yet to conform to the technical regulation promulgated with this Circular, organizations or individuals must adjust the manufacturer's standard to make it conformable with the technical regulation and submit a notification as prescribed in clause 4 Article 8 of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of some Articles of the Law on Food Safety.

Article 4. Terms of reference

In the cases where any of the legislative documents referred to in this Circular is amended or replaced, the newest one shall apply.

Article 5. Responsibility for implementation

Director General of Vietnam Food Administration, heads of units owned by and affiliated to the Ministry of Health; Directors of Departments of Health and Directors of Food Safety Departments of provinces and central-affiliated cities, and relevant agencies, organizations, and individuals are responsible for the implementation of this Circular.

Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Health (Vietnam Food Administration) for consideration and resolution./.

PP. THE MINISTER
THE DEPUTY MINISTER

Do Xuan Thuyen

QCVN 20-1:2024/BYT

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

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

Foreword

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

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

I. GENERAL

1. Scope

This Technical Regulation provides for the maximum limits of contaminants (heavy metals and microorganisms); sampling and test methods; managerial requirements; responsibilities of producers and traders of health supplements/dietary supplements.

This Technical Regulation does not apply to tonic wines declared as health supplements/dietary supplements.

2. Regulated entities

This Technical Regulation applies to producers and traders of health supplements/dietary supplements within the territory of Vietnam and other relevant organizations and individuals.

3. Interpretation of terms and abbreviations

For the purposes of this Technical Regulation, the following terms and abbreviations shall be construed as follows:

3.1. “health supplement/dietary supplement” means the product defined in clause 1 Article 3 of the Government’s Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of some Articles of the Law on Food Safety.

3.2. “multi-ingredient product” means a health supplement/dietary supplement containing a mixture of two or more ingredients, consisting of:

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

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

c) Sources of the substances mentioned in point a and point b above.

3.3. AOAC: Association of Official Analytical Collaboration.

3.4. ML: Maximum Limit.

3.5. TAMC: total aerobic microbial count.

3.6. TYMC: total combined yeast and mould count.

II. TECHNICAL REGULATIONS

1. Regulations on heavy metals

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

Table 1. Regulations on maximum limits of heavy metals

No.	Indicator	ML (mg/kg or mg/L)	Note
1	Arsenic (As)	5,0	Total As
		1,5	Inorganic As Monitor inorganic As only when the total As content exceeds 1.5 mg/kg or mg/L
2	Cadmium (Cd)	3,0	Containing ingredients from seaweed or bivalve mollusks
		1,0	Not containing 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 provided for in Table 2.

Table 2. Regulations on maximum limits of microorganisms

Group No.	Product group (*)	Indicator	ML	Unit	Note
1	Health supplements/dietary	TAMC	5×10^7	CFU/g or CFU/mL	- The regulation in this group also applies to

	supplements which contain plant-based ingredients and 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).	TYMC	5×10^5	CFU/g or CFU/mL	multi-ingredient products that do not contain ingredients from animals and/or minerals belonging to Group 3.
		Escherichia coli	1×10^3	CFU/g or CFU/mL	
		Salmonella spp.	Not allowed	/25 g or /25 mL	
2	Health supplements/dietary supplements containing plant-based ingredients.	TAMC	5×10^4	CFU/g or CFU/mL	- The regulation in this group also applies 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 products contain probiotics in the non-spore-forming bacteria group: the indicator "non-lactic acid bacteria" within the limits in Group 6.1 of this table is required but the indicator "TAMC" is not required. + If the products contain probiotics in the spore-forming bacteria group: the indicator "TAMC" is not required. + If the products contain probiotics in the yeast group: the indicator "TYMC" is not required. The indicator "TAMC" within the maximum limits in this group does
		TYMC	5×10^2	CFU/g or CFU/mL	
		Enterobacteriaceae (Bile-tolerant Gram-negative bacteria)	1×10^2	CFU/g or CFU/mL	
		Escherichia coli	Not allowed	/1 g or /1 mL	
		Salmonella spp.	Not allowed	/25 g or /25 mL	

					not include yeast strains that are ingredients of the products.
3	Health supplements/Dietary supplements containing ingredients from animals or minerals or a mixture of two or more ingredients from animals, minerals, and plants.	TAMC	2×10^4	CFU/g or CFU/mL	- The regulation in this group also applies to multi-ingredient products. - In case the products in this group contain probiotics: + If the products contain probiotics in the non-spore-forming bacteria group: the indicator "non-lactic acid bacteria" within the limits in Group 6.1 of this table is required but the indicator "TAMC" is not required. + If the products contain probiotics in the spore-forming bacteria group: the indicator "TAMC" is not required. + If the products contain probiotics in the yeast group: the indicator "TYMC" is not required. The indicator "TAMC" within the maximum limits in this group does not include yeast strains that are ingredients of the products.
		TYMC	2×10^2	CFU/g or CFU/mL	
		Enterobacteriaceae (Bile-tolerant Gram-negative bacteria)	1×10^2	CFU/g or CFU/mL	
		Escherichia coli	Not allowed	/1 g or /1 mL	
		Salmonella spp.	Not allowed	/10 g or /10 mL	
		Staphylococcus aureus	Not allowed	/1 g or /1 mL	
4	Health supplements/Dietary supplements which contain one or more ingredients: vitamins, minerals, amino acids, fatty	TAMC	2×10^2	CFU/g or CFU/ml	- The regulation in this group also applies to multi-ingredient products that do not contain ingredients in groups 1, 2, and 3.
		TYMC	2×10^1	CFU/g or CFU/mL	
		Escherichia coli	Not allowed	/1 g or /1 mL	

	acids, enzymes, probiotics and other biologically active substances chemically defined and do not belong to groups 1, 2, and 3 above. Aqueous form (water is an ingredient in the formulation of a product) *(e.g., aqueous solutions, syrups, suspensions, emulsions, jellies, etc.).*				- In case the products in this group contain probiotics: + If the products contain probiotics in the non-spore-forming bacteria group: the indicator "non-lactic acid bacteria" within the limits in Group 6.1 of this table is required but the indicator "TAMC" is not required. + If the products contain probiotics in the spore-forming bacteria group: the indicator "TAMC" is not required. + If the products contain probiotics in the yeast group: the indicator "TYMC" is not required. The indicator "TAMC" within the maximum limits in this group does not include yeast strains that are ingredients of the products.
5	Health supplements/Dietary supplements which contain one or more ingredients: vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other biologically active substances chemically defined, and do not belong to groups 1, 2, and 3 above.	TAMC	2 x 10^3	CFU/g or CFU/ml	- The regulation in this group also applies to multi-ingredient products that do not contain ingredients in groups 1, 2, and 3. - In case the products in this group contain probiotics: + If the products contain probiotics in the non-spore-forming bacteria group: the indicator "non-lactic acid bacteria"
		TYMC	2 x 10^2	CFU/g or CFU/mL	
		Escherichia coli	Not allowed	/1 g or /1 mL	

	Non-aqueous form (water is not an ingredient in the formulation of a product) *(e.g., tablets (regular tablets, effervescent tablets, film-coated tablets), soft capsules, hard capsules, granules, powders, films, gummy candies, oil solutions, etc.).*				within the limits in Group 6.1 of this table is required but the indicator "TAMC" is not required. + If the products contain probiotics in the spore-forming bacteria group: the indicator "TAMC" is not required. + If the products contain probiotics in the yeast group: the indicator "TYMC" is not required. The indicator "TAMC" within the maximum limits in this group does not include yeast strains that are ingredients of the products.
6	Health supplements/dietary supplements containing probiotics only				
6.1	Products containing non-spore-forming probiotics only	Non-lactic acid bacteria	5 x 10^3	CFU/g or CFU/mL	- If the products contain probiotics in groups 6.1 and 6.2, only indicators "TYMC", "*E. coli*" and "*Salmonella* spp." within the maximum limits in group 6.1 are required. - If the products contain probiotics in groups 6.1 and 6.3, only indicators "non-lactic acid bacteria", "*E. coli*" and "*Salmonella* spp." within the maximum limits in group 6.1 are required. - If the products contain probiotics in groups 6.2 and 6.3 or groups 6.1, 6.2 and 6.3, only indicators
		TYMC	1 x 10^2	CFU/g or CFU/mL	
		Escherichia coli	Not allowed	/10 g or /10 mL	
		Salmonella spp.	Not allowed	/10 g or /10 mL	
6.2	Products containing spore-forming probiotics only	TYMC	1 x 10^2	CFU/g or CFU/mL	
		Escherichia coli	Not allowed	/10 g or /10 mL	
		Salmonella spp.	Not allowed	/10 g or /10 mL	
6.3	Products containing yeast probiotics only	TAMC (excluding added yeast strains)	1 x 10^3	CFU/g or CFU/mL	
		Escherichia coli	Not allowed	/10 g or /10 mL	
		Salmonella spp.	Not	/10 g or	

			allowed	/10 mL	"TYMC", "E. *coli*" and "*Salmonella* spp." within the maximum limits in group 6.2 are required.

(*) The grouping of products in this table relies on the product ingredients exclusive of the ingredients that are food additives, excipients and capsule shells.

III. SAMPLING AND TEST METHODS

1. Sampling

Sampling of health supplements/dietary supplements shall adhere to the guidelines set out in the Circular No. 01/2024/TT-BKHCN dated January 18, 2014 of the Minister of Science and Technology providing for state inspection of quality of goods circulating on the market and other relevant regulations of law.

2. Sampling methods

The technical requirements specified under this Technical Regulation shall be fulfilled adopting the test methods below:

2.1. Methods for determination of heavy metal indicators

2.1.1. Methods for determination of arsenic content

2.1.1.1. Methods for determination of total arsenic content

- TCVN 10912:2015 (EN 15763:2009). Foodstuffs - Determination of trace elements - Determination of arsenic, cadmium, mercury and lead in foodstuffs by inductively couple plasma mass spectrometry (ICP-MS) after pressure digestion[(1)].

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

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

- 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. Multielement Method.

2.1.1.2. Methods for determination of inorganic arsenic content

-*TCVN 12346:2018 (EN 16802:2016).* Foodstuffs - Determination of elements and their chemical species - Determination of inorganic arsenic in foodstuffs of marine and plant origin by anion-exchange HPLC-ICP-MS(1).

2.1.2. Methods for determination of content of cadmium and lead

- TCVN 10912:2015 (EN 15763:2009). Foodstuffs - Determination of trace elements - Determination of arsenic, cadmium, mercury and lead in foodstuffs by inductively couple plasma mass spectrometry (ICP-MS) after pressure digestion(1).

- TCVN 10643:2014 (AOAC 999.11). Foodstuffs - Determination of lead, cadmium, copper, iron, and zinc - Atomic absorption spectrophotometric method after dry ashing;

- TCVN 8126: 2009. Foods - Determination of lead, cadmium, zinc, copper, and iron - Atomic absorption spectrophotometry after microwave digestion.

- TCVN 7929:2008 (EN 14083:2003). Foodstuffs - Determination of trace elements - Determination of lead, cadmium, chromium and molybdenum by graphite furnace atomic absorption spectrometry (GFAAS) after pressure digestion.

- AOAC 2015.01. Heavy Metals in Food. Inductively Coupled Plasma - Mass Spectrometry.

- 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. Methods for determination of mercury content

- TCVN 10912:2015 (EN 15763:2009). Foodstuffs - Determination of trace elements - Determination of arsenic, cadmium, mercury and lead in foodstuffs by inductively couple plasma mass spectrometry (ICP-MS) after pressure digestion(1).

- TCVN 7993:2009 (EN 13806:2002). Foodstuffs - Determination of trace elements - Determination of mercury by cold - vapour atomic absorption spectrometry (CVAAS) after pressure digestion.

- TCVN 7604: 2007. Foods - Determination of mercury content by flameless atomic absorption spectrophotometric method.

- AOAC 2015.01. Heavy Metals in Food. Inductively Coupled Plasma - Mass Spectrometry.

2.2. Test methods for determination of microorganisms

2.2.1. Methods for determining total aerobic microbial count

- 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 (ISO 4833-1:2013). Microbiology of the food chain - Horizontal method for the enumeration of microorganisms - Part 1: Colony count at 30 degrees C by the pour plate technique

- TCVN 4884-1:2015 (ISO 4833-1:2013/Cor 1:2014). Microbiology of the food chain - Horizontal method for the enumeration of microorganisms - Part 2: Colony count at 30 degrees C by the surface plating technique.

- The Vietnamese pharmacopoeia 2017, volume V, Appendix 13.6, item 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. Methods for determining total combined yeast and mould count

- 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). Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of yeasts and moulds - Part 1: Colony count technique in products with water activity greater than 0,95.

- TCVN 8275-2:2010 (ISO 21527-2:2008). Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of yeasts and moulds - Part 2: Colony count technique in products with water activity less than or equal to 0,95.

- The Vietnamese pharmacopoeia 2017, volume V, Appendix 13.6, item 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. Methods for determination of *Escherichia coli*: Qualitative method

- 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). Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of presumptive Escherichia coli - Most probable number technique.

- The Vietnamese pharmacopoeia 2017, volume V, Appendix 13.6, item 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 cell* - Most probable number technique - Amendment 1: Inclusion of performance testing of culture media and reagents.

2.2.4. Methods for determination of *Escherichia coli*: 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): Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of β-glucuronidase-positive *Escherichia coli* - Part 2: Colony-count technique at 44 ºC using 5-bromo-4-chloro-3-indolyl β-D-glucuronide.

- TCVN 9975:2013. Foodstuffs – Enumeration of coliforms and Escherichia coli using Petrifilm™ count plate.

2.2.5. Methods for determination of *Staphylococcus aureus*

- United States Pharmacopeia and National Formulary 2023 <2022>. Microbiological procedures for the absence of specified microorganisms in nutritional and dietary supplements) [(1)].

- The Vietnamese pharmacopoeia 2017, volume V, Appendix 13.6, item 2. Determination of pathogenic microorganisms.

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

2.2.6. Methods for determination of *Salmonella* spp.

- 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): Microbiology of the food chain - Horizontal method for the detection, enumeration and serotyping of *Salmonella* - Part 1: Detection of *Salmonella* spp.

- The Vietnamese pharmacopoeia 2017, volume V, Appendix 13.6, item 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 MSRV and SC).

2.2.7. Methods for determination of Enterobacteriaceae (Bile-Tolerant Gram-Negative Bacteria)

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

- TCVN 5518-2:2007 (ISO 21528-2:2004). Microbiology of food and animal feeding stuffs - Horizontal methods for the detection and enumeration of Enterobacteriaceae - Part 2: Colony-count method.

2.2.8. Method for determination of total aerobic microbial count (excluding yeast strains as product ingredients) in products containing probiotic components in 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. Methods for determination of 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 for food testing to serve state management.

IV. MANAGERIAL REQUIREMENTS

1. The labeling of health supplements/dietary supplements shall comply with the Government's Decree No. 43/2017/ND-CP dated April 14, 2017 on goods labels; the Government's Decree No. 111/2021/ND-CP dated December 9, 2021 on amendments to some Articles of the Government's Decree No. 43/2017/ND-CP dated April 14, 2017 on goods labels and other relevant regulations of law.

2. Organizations and individuals must register the disclosure of their health supplements/dietary supplements based on the testing result given by the designated laboratory or a laboratory recognized to conform ISO 17025 as prescribed in Article 7 of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of some Articles of the Law on Food Safety. Applications and procedures for registration of product disclosure are specified in Articles 7 and 8 of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of some Articles of the Law on Food Safety.

V. RESPONSIBILITIES OF ORGANIZATIONS AND INDIVIDUALS

Producers and traders of health supplements/dietary supplements shall take the responsibility for the health supplements/dietary supplements they produce and trade, ensuring that such products comply with the requirements of this Technical Regulation and other relevant regulations of law.

VI. ORGANIZING IMPLEMENTATION

1. The Vietnam Food Administration is assigned to preside over and cooperate with related competent authorities in providing guidance on and organize the implementation of this Technical Regulation.

2. The Vietnam Food Administration shall, according to managerial requirements, review, consolidate, report and suggest amendments to this Technical Regulation to the Ministry of Health.

3. In the cases where any of regulations of law and documents referred to in this Technical Regulation is amended or replaced, the newest one shall apply.