

THE MINISTRY OF HEALTH

THE SOCIALIST REPUBLIC OF VIETNAM

Independence– Freedom – Happiness

No. 05/2012/TT-BYT

Hanoi, March 01, 2012

CIRCULAR

**PROMULGATING THE NATIONAL TECHNICAL REGULATIONS ON MICROBIOLOGICAL
CONTAMINANTS IN FOOD**

Pursuant to the Law of Food safety of June 17, 2010;

Pursuant to the Law on Technical regulations and standards of June 29, 2006 and the Government's Decree No. 127/2007/ND-CP of August 01, 2007 on detailing the implementation of a number of articles of the Law on Technical regulations and standards;

Pursuant to the Government's Decree No. 188/2007/ND-CP of December 27, 2007 on defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the proposal of the Director of the Department food safety and hygiene, the Director of the Department of Science and training, the Director of the Legal Department,

PRESCRIBES:

Article 1.

Promulgating together with this Circular the National Technical Regulation on microbiological contaminants in food.

Article 2. This Circular takes effect on September 01, 2012.

Article 3. The Director of the Department food safety and hygiene, the Heads of units belonging and affiliated to the Ministry of Health, the director of the Department of Health in central-affiliated cities and provinces, relevant organizations and individuals are responsible to implement this Circular./.

**FOR THE MINISTER
DEPUTY MINISTER**

Nguyen Thanh Long

QCVN 8-3: 2012/BYT

NATIONAL TECHNICAL REGULATION

National technical regulation on Microbiological contaminants in food

FOREWORD

QCVN No. 8-3:2012/BYT compiled by the Drafting Board National technical regulation on chemical and biological contamination, submitted by the Department of food safety and hygiene and promulgated under the Circular No. 05/2012/TT-BYT of March 01, 2012 by The Minister of Health.

NATIONAL TECHNICAL REGULATION

National technical regulation on Microbiological contaminants in food

I. GENERAL PROVISIONS

1. Scope of regulation

This Regulation prescribes the limits of microbiological contamination in food regarding the following kinds of food or group of food: milk and dairy, eggs, and products from eggs, meat and products from meat, aquacultural products, nutrition products for kids from 0 - 36 months old; bottled natural water, bottled water and instant-use ice; cream, vegetables and fruits, products from vegetables and fruits (hereinafter referred to as food) and the relevant management requirements.

2. Subjects of application

This Regulation is applicable to:

- 2.1. Organizations, individuals exporting, importing and trading the kinds of food prescribed in Clause 1.
- 2.2. Relevant State management agencies.

3. Interpretation of terms and abbreviations

The terms and abbreviations in this Regulation are construed as follows:

3.1. Limits of microbiological contamination in food is the maximum limits of microorganisms allowed in the food

3.2. Norm rating

Norm A: is the norm required to be tested during the conformity assessment.

Norm B: is the norm not being required to be tested during the conformity assessment if the producers already take risk control measures in the production (HACCP or GMP). If the producer omits to take risk control measures, these norms are compelled to be tested.

3.3. Abbreviations

- n: the number of samples from the consignments to be tested.
- c: the maximum amount of samples of which the test results are allowed to lie between m and M. For n samples tested, only c samples are allowed to have the test results lie between m and M.
- m: lower limit, it is considered passed if all the test results of n samples do not exceed m.
- M: upper limit, it is considered failed if only one test result of n samples exceeds M.
- TSVSVHK: the total amount of aerobic microorganisms
- KPH: not detected

II. TECHNICAL PROVISIONS

1. Limits of microbiological contamination in milk and dairy

No.	Product	Norm	Sampling plan		Allowed limit (CFU/ml or CFU/g)		Norm rating
			n	c	m	M	
1.1	Liquid dairy	Enterobacteriaceae	5	2	< 1	5	A
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
1.2	Powdered dairy	Enterobacteriaceae	5	0	10 ¹		A
		Staphylococci positive for coagulase	5	2	10 ¹	10 ²	A
		Staphylococcal enterotoxin	5	0	KPH ⁽²⁾		B
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
		Salmonella	5	0	KPH ⁽²⁾		A
1.3	Cheese						
1.3.1	Cheese from raw milk	Staphylococci positive for coagulase	5	2	10 ⁴	10 ⁵	A
		Staphylococcal enterotoxin	5	0	KPH ⁽²⁾		B
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
		Salmonella	5	0	KPH ⁽²⁾		A
1.3.2	Cheese from thermo-processed milk	E. coli	5	2	10 ²	10 ³	A
		Staphylococci positive for coagulase	5	2	10 ²	10 ³	A
		Staphylococcal enterotoxin	5	0	KPH ⁽²⁾		B
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
		Salmonella	5	0	KPH ⁽²⁾		A
1.3.3	Whey Cheese (From thermo-processed whey)	E. coli	5	2	10 ²	10 ³	A
		Staphylococci dương tính với coagulase	5	2	10 ²	10 ³	A
		Nội Độc tố của Staphylococcus(Staphylococcal enterotoxin)	5	0	KPH ⁽²⁾		B
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
1.3.4	Fresh cheese from milk or whey(thermo-processed milk or whey)	Staphylococci positive for coagulase	5	2	10 ¹	10 ²	A
		Staphylococcal enterotoxin	5	0	KPH ⁽²⁾		B
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
	Other products from cheese	L. monocytogens ⁽¹⁾	5	0	10 ²		A

1.4	Fat products from milk						
1.4.1	Cream and butter	E. coli	5	2	10 ¹	10 ²	A
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
		Salmonella	5	0	KPH ⁽²⁾		A
1.4.2	Milk fat, butter, dehydrated milk fat, dehydrated butter and viscous milk fat	L. monocytogens ⁽¹⁾	5	0	10 ²		A
1.5	Fermented dairy						
1.5.1	Thermo-processed fermented dairy	Enterobacteriaceae	5	2	< 1	5	A
		L. monocytogens ⁽¹⁾	5	0	10 ²		A
1.5.2	Fermented dairy not being thermo-processed	L. monocytogens ⁽¹⁾	5	0	10 ²		A

Notes:

⁽¹⁾ for instant-use products

⁽²⁾ in 25g or 25ml

2. Limits of microbiological contamination in eggs and products from eggs

No.	Product	Norm	Sampling plan		Allowed limit (CFU/ml or CFU/g)		Norm rating
			n	c	m	M	
2.1	Products from eggs	Enterobacteriaceae	5	2	10 ¹	10 ²	B
		Salmonella	5	0	KPH ⁽²⁾		A

3. Limits of microbiological contamination in meat and products from meat

No.	Products	Norm	Sampling plan		Allowed limit (CFU/g)		Norm rating
			n	c	m	M	
3.1	Instant-use meat and products from meat without thermo-processing	TSVSVHK	5	2	5x10 ⁵	5x10 ⁶	B
		E. coli	5	2	5x10 ¹	5x10 ²	B
		Salmonella	5	0	KPH ⁽²⁾		A
3.2	Meat and products from meat needing thermo-processing before use	TSVSVHK	5	2	5x10 ⁵	5x10 ⁶	B
		E. coli	5	2	5x10 ²	5x10 ³	B
		Salmonella	5	0	KPH ⁽²⁾		A
3.3	Gelatine và collagen	Salmonella	5	0	KPH ⁽²⁾		A

4. Limits of microbiological contamination in aquacultural product

No.	Product	Norm	Sampling plan		Allowed limit (CFU/g)		Norm rating
			n	c	m	M	
4.1	Alive bivalve mollusc, gastropods, echinoderms, tunicates	<i>E. coli</i>	1	0	230 ⁽³⁾	700 ⁽³⁾	B
		Salmonella	5	0	KPH ⁽²⁾		A
4.2	Shelled mollusc and crustacean or unshelled, heated mollusc and crustacean	<i>E. coli</i>	5	2	1	10 ¹	B
		Staphylococci positive for coagulase	5	2	10 ²	10 ³	B
		Salmonella	5	0	KPH ⁽²⁾		A

Note:

⁽²⁾ in 25g or 25ml

⁽³⁾ MPN/100g meat và endolymph

5. Limits of microbiological contamination in nutrition products for 0 – 36 months old kids

No.	Product	Norm	Sampling plan		Allowed limit (CFU/g)		Norm rating
			n	c	m	M	
5.1	Powdered nutrition products for kids up to 12 months old	Salmonella	30	0	KPH ⁽²⁾		A
		<i>Enterobacter sakazakii</i>	30	0	KPH ⁽⁴⁾		A
		Enterobacteriaceae	10	0	KPH ⁽⁴⁾		B
		<i>Bacillus cereus</i> giã Dĩnh	5	1	5x10 ¹	5x10 ²	B
5.2	Special medical-use nutrition products for for kids up to 12 months old	Salmonella	30	0	KPH ⁽²⁾		A
		<i>Enterobacter sakazakii</i>	30	0	KPH ⁽⁴⁾		A
		Enterobacteriaceae	10	0	KPH ⁽⁴⁾		B
		Assumed <i>Bacillus cereus</i>	5	1	5x10 ¹	5x10 ²	B
5.3	Nutrition products for supplementary feeding for kids from 6 to 36 months old	Enterobacteriaceae	5	0	KPH ⁽⁴⁾		B
		Salmonella	30	0	KPH ⁽²⁾		A
5.4	Food from cereals for kids from 6 to 36 months old	Coliform	5	2	< 3	20	A
		Salmonella	10	0	KPH ⁽²⁾		A

Note:

⁽²⁾ in 25g or 25ml

⁽⁴⁾ in 10g or 10ml

6. Limits of microbiological contamination in vegetables and fruit, products from vegetables and fruits

No.	Product	Norm	Sampling plan	Allowed limit (CFU/g)	Norm rating
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			n	c	m	M	
6.1	Sprout vegetable (for instant-use without thermo-processing)	Salmonella	5	0	KPH ⁽²⁾		A
6.2	Raw vegetables	E. coli	5	2	10 ²	10 ³	B
		Salmonella	5	0	KPH ⁽²⁾		A
6.3	Instant-use fruits	E. coli	5	2	10 ²	10 ³	B
		Salmonella	5	0	KPH ⁽²⁾		A

7. Limits of microbiological contamination in cream

No.	Product	Norm	Sampling plan		Allowed limit (CFU/ml or CFU/g)		Norm rating
			n	c	m	M	
7.1	Cream (for cream that contains milk)	Enterobacteriaceae	5	2	10 ¹	10 ²	B
		Salmonella	5	0	KPH ⁽²⁾		A

Note: ⁽²⁾ in 25g or 25ml

8. Limits of microbiological contamination in bottle natural water, bottled water and instant-use ice

8.1. First test						
No.	Norm	Sample amount (ml)	Requirement			Norm rating
8.1.1	Heat-resistant E. coli or coliform	1 x 250	KPH			A
8.1.2	Total Coliform	1 x 250	Under go seconde test if the number of bacteria (spores) ≥ 1 and ≤ 2 Eliminate if the number of bacteria (spores) > 2			A
8.1.3	Streptococci fecal	1 x 250				A
8.1.4	Pseudomonas aeruginosa	1 x 250				A
8.1.5	Spore of anti-sulfite anaerobic bacteria	1 x 50				A
8.2. Second test						
No.	Norm	Sampling plan		Allowed limit (CFU/ml)		Norm rating
		n	c	m	M	
8.2.1	Total Coliform	4	1	0	2	A
8.2.2	Streptococci fecal	4	1	0	2	A
8.2.3	Pseudomonas aeruginosa	4	1	0	2	A
8.2.4	Spore of anti-sulfite anaerobic bacteria	4	1	0	2	A

III. METHOD OF SAMPLING AND TESTING

1. Sampling

Sampling as guided in the Circular No. 16/2009/TT-BKHCN of June 02, 2009 of the Ministry of Science and Technology on the State inspection of circulating goods quality and other relevant law provisions.

2. Test methods

The technical requirements in this Regulation shall be tested using the following methods (these methods are not compulsory, it is possible to use other equivalent methods):

- TCVN 4884: 2005 (ISO 4833:2003) Microorganisms in food and breeding feed – Method of enumerating microorganisms on agar plates – Colony counting technique at 30° C.
- TCVN 4829: (ISO 6579: 2002) Microorganisms in food and breeding feed – Method of detecting Salmonella on agar plates.
- TCVN 7924-1: 2008 (ISO 16649 -1: 2001) Microorganisms in food and breeding feed - Method of enumerating positive Escherichia coli β - glucuronideaza, Part 1: Colony counting technique at 44° C using filter membrane and 5- bromo-4-chloro-3-indolyl β -D-glucuronide.
- TCVN 7924-2: 2008 (ISO 16649 -2: 2001) Microorganisms in food and breeding feed - Method of enumerating positive Escherichia coli β - glucuronideaza, Part 2: Colony counting technique at 44° C using 5- bromo-4-chloro-3-indolyl β -D-glucuronide.
- TCVN 7924-3: 2008 (ISO 16649 -3: 2001) Microorganisms in food and breeding feed - Method of enumerating positive Escherichia coli β - glucuronideaza, Part 3: Most probable number method using 5- bromo-4-chloro-3-indolyl β -D-glucuronide
- TCVN 7700-2: 2007 (ISO 11290-2:1998, With amd 1: 2004) Microorganisms in food and breeding feed – Methods of detecting and enumerating Listeria monocytogenes, Part 2: Quantitative method.
- TCVN 4830-1:2005 (ISO 6888-1:1999, with Amd, 1:2003) Microorganisms in food and breeding feed - Methods of enumerating Staphylococci positive for coagulase (Staphylococcus aureus and other kinds) on agar plates, Part 1: Using Baird-Parker environment.
- TCVN 4830-2:2005 (ISO 6888-2:1999, with Amd, 1:2003) Microorganisms in food and breeding feed - Methods of enumerating Staphylococci positive for coagulase (Staphylococcus aureus and other kinds) on agar plates, Part 2: Using fibrinogen agar environment from rabbit serum.
- TCVN 4830-3:2005 (ISO 6888-3: 2003) Microorganisms in food and breeding feed - Methods of enumerating Staphylococci positive for coagulase (Staphylococcus aureus and other kinds) on agar plates, Part 3: Detecting and using Most probable number method (MPN) to count small quantities.
- TCVN 6191-2:1996 (ISO 6461-2:1986) Water quality – Detecting and counting spores of anti-sulfite anaerobic bacteria (Clostridia), Part 2: Filter membrane method
- TCVN 4882:2007 (ISO 4831: 2006) Microorganisms in food and breeding feed - Methods of enumerating coliforms - Most probable number method.
- TCVN 6848:2007 (ISO 4832: 2006) Microorganisms in food and breeding feed - Methods of enumerating coliforms – Colony counting method.
- TCVN 5518-1:2007 (ISO 21528-1: 2004) Microorganisms in food and breeding feed – Method of detecting and enumerating Enterobacteriaceae, Part 1: Detecting and enumerating using MPN with pre-proliferation.
- TCVN 7850-2008 (ISO/TS 22964:2006) Microorganisms in food and breeding feed – Method of detecting and enumerating Enterobacter sakazakii.
- ISO 16266:2006 Water quality - Detection and enumeration of Pseudomonas aeruginosa - Method by membrane filtration - ISO 7899-2:2000 Water quality - Detection and enumeration of intestinal enterococci, Part 2: Membrane filtration method.

IV. PROVISIONS ON MANAGEMENT

The food prescribed in Section II must undergo quality and safety inspections in order to ensure that the microbiological contamination does not exceed the limits prescribed in this Regulation.

The food prescribed in the “Regulation on maximum limit of biological and chemical contamination in food” promulgated together with the Decision No. 46/2007/QĐ-BYT of December 19, 2007 of the Ministry of Health not being regulated in the regulation shall continue to apply the Decision No. 46/2007/QĐ-BYT.

V. RESPONSIBILITIES OF ORGANIZATIONS AND INDIVIDUALS

Organizations and individuals are only allowed to produce, trade, export and import the food conformable with the limits of microbiological contamination prescribed in this Regulation.

VI. Organizing the implementation

1. The the Department food safety and hygiene shall cooperate with relevant functional agencies to guide and organize the implementation of this Regulation.
2. Depending on the management requirement, the Department food safety and hygiene shall submit proposal to the Ministry of Health to amend and supplement this Regulation.
3. In case the standards and law provisions being cited in this Regulation are changed, supplemented or superseded, the new documents shall apply./.