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Technical Regulation on Microbiological MRLs in Food

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Report Highlights:

On March 1, 2012, the Ministry of Health published Circular 5/TT-BTY updating the maximum limits of microbiological contamination in certain food products. The Regulation entered into force on September 1, 2012.

Executive Summary:

This report provides unofficial translation of Vietnam Ministry of Health's (MOH) Circular 5/TT-BTY, dated March 1, 2012, regarding Vietnam National Technical Regulation QCVN 8-3: 2012/BYT on Microbiological Contaminated in Food. The Regulation entered into force on September 1, 2012.

Vietnam notified this Circular to the World Trade Organization Sanitary and Phytosanitary Committee on December 16, 2010 (G/SPS/N/VMN/23). As stated in the WTO notification, Vietnam did not follow CODEX standards, but rather used European Union and Australia – New Zealand standards to develop this Circular.

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

The Regulation applies to organizations and individuals importing, producing and trading the above-mentioned food products and to the relevant government authorities.

The Circular 5/2012/TT-BYT also describes the methods for sampling and testing of the above-mentioned products for micro-biological contamination.

Interpretation of terms and abbreviations in the Regulation:

- Allowed Limits of microbiological contamination in food is the maximum limits of microorganisms allowed in the food
- 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 taking risk control measures, these norms are compelled to be tested.
- 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

And the detailed limits for each food group are as below:

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
		<i>L. monocytogens</i> ⁽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
		<i>L. monocytogens</i> ⁽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
		<i>L. monocytogens</i> ⁽¹⁾	5	0	10 ²		A
		Salmonella	5	0	KPH ⁽²⁾		A
1.3.2	Cheese from thermo-processed milk	<i>E. coli</i>	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
		<i>L. monocytogens</i> ⁽¹⁾	5	0	10 ²		A
		Salmonella	5	0	KPH ⁽²⁾		A
1.3.3	Whey Cheese (From thermo-processed whey)	<i>E. coli</i>	5	2	10 ²	10 ³	A
		Staphylococci dương tính với coagulase	5	2	10 ²	10 ³	A
		Nội Độc tố của <i>Staphylococcus</i> (Staphylococcal enterotoxin)	5	0	KPH ⁽²⁾		B
		<i>L. monocytogens</i> ⁽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
		<i>L. monocytogens</i> ⁽¹⁾	5	0	10 ²		A
	Other products from cheese	<i>L. monocytogens</i> ⁽¹⁾	5	0	10 ²		A
1.4	Fat products from milk						
1.4.1	Cream and butter	<i>E. coli</i>	5	2	10 ¹	10 ²	A
		<i>L. monocytogens</i> ⁽¹⁾	5	0	10 ²		A
		Salmonella	5	0	KPH ⁽²⁾		A
1.4.2	Milk fat, butter, dehydrated milk fat, dehydrated butter and vicous milk fat	<i>L. monocytogens</i> ⁽¹⁾	5	0	10 ²		A
1.5	Fermented dairy						
1.5.1	Thermo-processed fermented dairy	Enterobacteriaceae	5	2	< 1	5	A
		<i>L. monocytogens</i> ⁽¹⁾	5	0	10 ²		A
1.5.2	Fermented dairy not being thermo-processed	<i>L. monocytogens</i> ⁽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	Gelatin and collagen	Salmonella	5	0	KPH ⁽²⁾		A

4. Limits of microbiological contamination in aquaculture products

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

Notes: ⁽²⁾ in 25g or 25ml; ⁽³⁾ MPN/100g meat and endolymp

5. Limits of microbiological contamination in nutrition products for 0 – 36 month old children

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
		Enterobacter sakazakii	30	0	KPH ⁽⁴⁾		A
		Enterobacteriaceae	10	0	KPH ⁽⁴⁾		B
		Bacillus cereus giã Dĩnh	5	1	5x10 ¹	5x10 ²	B
5.2	Special medical-use nutrition products for for kids up to 12 months	Salmonella	30	0	KPH ⁽²⁾		A
		Enterobacter	30	0	KPH ⁽⁴⁾		A

	old	sakazakii					
		Enterobacteriaceae	10	0	KPH ⁽⁴⁾		B
		Assumed Bacillus cereus	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

Notes: ⁽²⁾ in 25g or 25ml; ⁽⁴⁾ in 10g or 10ml

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

No.	Product	Norm	Sampling plan		Allowed limit (CFU/g)		Norm rating
			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 second test if the number of bacteria (spores) ≥ 1 and ≤ 2		A
8.1.3	Streptococci fecal	1 x 250			A
8.1.4	Pseudomonas aeruginosa	1 x 250	Eliminate if the number of bacteria (spores) > 2		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

Food products regulated in MOH's Decision 46/2007/QD-BYT, dated December 19, 2007 regarding "Regulation on maximum limit of biological and chemical contamination in food", that are not stipulated in this technical regulation shall continue to be subject to MOH's Decision 46/2007/QD-BYT (see [VM8055](#)). For products regulated in Decision 46/2007 which also have maximum limits for microbiological contamination stipulated in Technical Regulation QCVN 8-3: 2012/BYT, OCVN 8-3:2012/BYT does not supersede Decision 46, rather it complements Decision 46. Interested exporters should consult both Circular 05 and Decision No.46/2007 (see [VM8055](#)) for comprehensive guidance.

The full regulation in Vietnamese can be downloaded from the Vietnam Food Administration's (VFA) website:

<http://vfa.gov.vn/van-ban-phap-luat/quy-chuan-ky-thuat-quoc-gia-doi-voi-o-nhiem-vi-sinh-vat-trong-thuc-pham-165.vfa>