

Draft of Sanitation Standard for Microbiological in Foods

Article 1

This Standard is prescribed in accordance with the provisions of Article 17 of the Act Governing Food Safety and Sanitation.

Article 2

The scopes of this standard include food microorganisms and their toxins or metabolites, not include fungi and mycotoxins.

Article 3

The limits for food microorganisms and their toxins or metabolites shall meet the requirements in the table on Annex.

Article 4

This Standard shall be implemented from January 1, 2020.

Annex

Note.

1. The meaning of the symbol in the "sampling plan" and "Limits":

“n” means number of units comprising the sample.

“c” means number of sample units giving values between m and M.

“m” means a microbiological limit that acceptable quality.

“M” means a microbiological limit above which sampling results are unacceptable.

2. The detected results allowable between m and M from $\leq c$ sample quantity. Unacceptable $\geq M$ for any sample.

3. If "m=M", means unacceptable $\geq m$ or M for any sample.

Table1. Milk and dairy products

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
1.1 Milk, flavored milk and milk drink 1.2 Milk powder, flavored milk powder and whey powder as raw material for food processing. 1.3 Fermented milk 1.4 Condensed milk, except of canned condensed milk listed in 1.6	Enterobacteriaceae	5	0	10 CFU/mL(g)	
	<i>Salmonella</i>	5	0	Negative	
	<i>Listeria monocytogenes</i>	5	0	Negative	
	Staphylococcal enterotoxins	5	0	Negative	
1.5 Cheese, butter and cream	¹ <i>Escherichia coli</i>	5	2	10 MPN/g(mL)	100 MPN/g(mL)
	<i>Salmonella</i>	5	0	Negative	
	<i>Listeria monocytogenes</i>	5	0	Negative	
	Staphylococcal enterotoxins	5	0	Negative	
1.6 Canned food ² : Sterilized milk, sterilized flavored milk, sterilized milk drink and condensed milk	-	5	0	Passes inspection by incubation test (37°C for 10 days): Shall not growth of microorganisms cause of swelling, transform or pH value abnormal.	

¹The test item of *Escherichia coli* here, not applicable cheese.

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
² Canned food here refers to those canned food meet the commercial sterility requirements in Regulations on Good Hygiene Practice for Foods.					

Table2. Infant foods¹

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
2.1 Infant formula 2.2 Follow-up infant formula 2.3 Infant formula for special medical purposes	Enterobacteriaceae	10	0	10 CFU/g(mL)	
	<i>Salmonella</i>	10	0	Negative	
	<i>Listeria monocytogenes</i>	10	0	Negative	
	² <i>Cronobacter</i> spp. ; <i>Enterobacter sakazakii</i>	10	0	Negative	
2.4 Other infant food ³ , except list in 2.5	Coliform	5	2	<3 MPN/g(mL)	10 MPN/g(mL)
	<i>Salmonella</i>	5	0	Negative	
	<i>Listeria monocytogenes</i>	5	0	Negative	
2.5 Canned food ⁴ : Other ready-to-eat canned infant foods. For example, the ready-to-feed liquid infant formula, meat puree, fruit puree, vegetable puree.	-	5	0	Passes inspection by incubation test (37°C for 10 days): Shall not growth of microorganisms cause of swelling, transform or pH value abnormal.	

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
¹ Infant food referred to in this table means the food sold exclusively for infants less than 12 months of age. ² The test item of <i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>) here, just applicable food sold exclusively for infants less than 6 months of age. ³ Other infant foods mean other foods sold exclusively for infants less than 12 months of age, include cereal-based foods, milk-based drinks and similar products. ⁴ Canned food here refers to those canned food meet the commercial sterility requirements in Regulations on Good Hygiene Practice for Foods.					

Table3. Raw ready-to-eat foods¹ and ready-to-eat foods contain both raw and processed food ingredient at once²

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
3.1 Raw ready-to-eat aquatic products	<i>Salmonella</i>	5	0	Negative	
3.2 Ready-to-eat foods contain both raw aquatic products and processed food ingredient at once	<i>Vibrio parahaemolyticus</i>	5	0	100 MPN/g	
3.3 Fresh/raw ready-to-eat fruit and vegetables	<i>Escherichia coli</i>	5	0	10 MPN/g	
3.4 Ready-to-eat foods contain both fresh/raw fruit or vegetables and processed food ingredient at once	³ <i>Escherichia coli</i> O157:H7	5	0	Negative	
	<i>Salmonella</i>	5	0	Negative	
3.5 Ready-to-eat not fully cooked eggs, and ready-to-eat foods that contain not fully cooked eggs	<i>Salmonella</i>	5	0	Negative	

¹ Ready-to-eat food means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level the microorganisms of concern.

² Ready-to-eat foods contain raw aquatic products, fresh/raw fruit and vegetables, and eggs not fully cooked, must merge all related inspection items.

³ *Escherichia coli* test results if negative, do not need to test *Escherichia coli* O157:H7.

Table4. Packaged/containerized drinking water and beverage

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
4.1 Packaged drinking water and containerized drinking water	Coliform	5	0	Negative	
	Fecal Streptococci	5	0	Negative	
	<i>Pseudomonas aeruginosa</i>	5	0	Negative	
4.2 Carbonated beverages, for example, the soft drinks, cola and other sugary carbonated beverages	Enterobacteriaceae	5	0	Negative	
4.3 Reconstituted fruit and vegetable juices, fruit and vegetable juice drinks, puree ¹ and other similar, except listed in 4.7, 4.8	Enterobacteriaceae	5	0	Negative	
4.4 Beverages containing coffee, cocoa, tea or cereals, legumes and other food materials, except listed in 4.7, 4.8					
4.5 Unpasteurized fresh fruit and vegetable juices. Unpasteurized fresh fruit and vegetable juices containing milk less than 50%	<i>Escherichia coli</i>	5	0	10 MPN/mL	
	² <i>Escherichia coli</i> O157:H7	5	0	Negative	
	<i>Salmonella</i>	5	0	Negative	
4.6 Fermented fruit and vegetable juice, flavored acidic beverages containing lactic acid or fermentation broth (contain active probiotics) , except	Enterobacteriaceae	5	0	Negative	

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
listed in 4.7					
4.7 Beverages that is made on the spot, unpasteurized, and the shelf-life less than 24 hours, except listed in 4.5	Enterobacteriaceae	5	2	10 CFU/mL	100 CFU/mL
	<i>Salmonella</i>	5	0	Negative	
4.8 Canned foods ³ : Canned beverages	-	5	0	Passes inspection by incubation test (37°C for 10 days): Shall not growth of micro-organisms cause of swelling, transform or pH value abnormal.	

¹ Fruit juice syrup (which contain reconstituted fruit juices or natural fruit juices above 50%, sugary and total soluble solids above 50° Brix , must be diluted drink) not applicable.

² *Escherichia coli* test results if negative, do not need to test *Escherichia coli* O157:H7.

³ Canned food here refers to those canned food meet the commercial sterility requirements in Regulations on Good Hygiene Practice for Foods.

Table5. Frozen foods and ice products

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
5.1 Ice cubes, food grade 5.2 Frozen ready-to-eat foods ¹ , include: -Ice products include ice cream, gelato, popsicle, shaved ice, sundae, sorbet, smoothie etc. -Frozen fruits	Enterobacteriaceae	5	2	10 CFU/g(mL)	
5.3 Frozen cooked ² foods, may provide ready-to-eat after thawing or re-heat, except listed in 5.6, include: -Frozen cooked vegetables	<i>Salmonella</i>	5	0	Negative	
5.4 Frozen non ready-to-eat foods -Frozen food that must be cooked ² before provide. -Frozen raw aquatic products that not provide ready-to-eat.	<i>Escherichia coli</i>	5	0	50 MPN/g	
5.5 Frozen raw aquatic products that provide ready-to-eat.	<i>Salmonella</i>	5	0	Negative	
	<i>Vibrio parahaemolyticus</i>	5	0	100 MPN/g	
5.6 Frozen cooked ² aquatic products, may provide ready-to-eat after	<i>Vibrio parahaemolyticus</i>	5	0	Negative	

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
thawing or re-heat.					
<p>¹ Ready-to-eat food means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level the microorganisms of concern.</p> <p>² Cooked means heat-treated food thoroughly to make sure foods keep the minimum internal temperature above 75°C and may provide ready-to eat.</p>					

Table6. Other ready-to-eat foods

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
6.1 Foods that can eat after rehydration list other than table1 to 5.	<i>Staphylococcus aureus</i>	5	1	100	1000
6.2 Ready-to-eat foods that stored at hot holding or room temperature list other than table1 to 5.				CFU/g(mL)	CFU /g(mL)
6.3 Ready-to-eat foods that stored at refrigeration or below room temperature list other than table 1 to 5, include:	<i>Salmonella</i>	5	0	Negative	
-Ready-to-eat foods that stored at refrigeration or below room temperature, can re-heat before eat. For example, 18°C delicatessen. -dessert, sauces etc.	¹ <i>Listeria monocytogenes</i>	5	0	100 CFU /g(mL)	
6.4 Canned foods ² list other than table1 to 5.	-	5	0	Passes inspection by incubation test (37°C for 10 days): Shall not growth of micro-organisms cause of swelling, transform or pH value abnormal.	

Food category	Microorganisms and their toxins or metabolites	Sampling plan		Limits	
		n	c	m	M
<p>¹ The test item of <i>Listeria monocytogenes</i> is not applied the sugar, honey, confectionery (including cocoa and chocolate products) and food grade salt.</p> <p>² Canned food here refers to those canned food meet the commercial sterility requirements in Regulations on Good Hygiene Practice for Foods.</p>					