CONSULTATION ON DRAFT FOOD (AMENDMENT NO. Y) REGULATIONS 2023 (PROPOSED MICROBIOLOGICAL STANDARDS FOR NON-READY-TO-EAT (NON-RTE) FOOD)

Posted on: 17 February 2023 | Closing Date: 18 April 2023

<u>Aim</u>

1 The Singapore Food Agency (SFA) is seeking feedback from stakeholders and interested parties on the proposed microbiological standards for non-ready-to-eat (non-RTE) food, which is targeted to come into effect in the fourth quarter of 2023.

Background

- 2 Non-RTE food refers to food which is not included in the definition of RTE food¹ under Regulation 35 of the Food Regulations.
- 3 Certain non-RTE food such as raw meat, seafood and eggs may become contaminated with various pathogens during primary production and/or processing, and these pathogens may subsequently be transmitted to humans through consumption of contaminated food.
- Although non-RTE food are typically consumed cooked, certain products such as bivalve molluscan shellfish and shell eggs are frequently consumed undercooked by consumers, while others may be directly used by consumers without further heating (e.g. pasteurised egg products in mayonnaise). If the pathogen loads in such non-RTE foods are not reduced to safe levels, their presence could pose a food safety concern due to the low infective doses as well as the high severity of disease caused by a number of these pathogens.
- SFA currently adopts a set of microbiological standards for non-RTE meat and meat products which can be found on our website². These standards are subjected to regular review based on the latest scientific evidence, data as well as international practices and guidelines to protect consumers from foodborne pathogens and meet the changing needs of the food industry. These proposed changes are part of our regular review process.
- In our review, SFA considered a variety of factors including the nature (e.g. occurrence and severity) of the pathogenic microorganisms, local consumption patterns as well as global and local clinical data. We have also taken reference from principles adopted by Codex and the International Commission on Microbiological Specifications for Foods (ICMSF) for establishing microbiological standards, as well

¹ RTE food means "any article of food that is made available for sale for direct human consumption without the need for cooking or any other form of processing to eliminate, or reduce to a microbiological standard specified in the Eleventh Schedule, any pathogenic or other micro-organism of concern in the article of food", and "includes cup noodles, fruit juice cordial, squash or syrup, powdered beverages and other concentrated food which are meant to be reconstituted or diluted with fluids before consumption".

² https://www.sfa.gov.sg/regulatory-limits/limits-for-incidental-constituents-in-food

as standards/guidelines from the major developed countries, namely Australia, Canada, the European Union, Japan, New Zealand and the United States, with adaptation to Singapore's context.

Proposed Changes to Existing Standards

7 Based on the review, SFA proposes the following changes to the existing microbiological standards for non-RTE food (<u>Table 1</u>). A detailed comparison of the existing and proposed microbiological standards can be found in <u>Annex A</u>.

Table 1: Summary of Proposed Changes to Existing Microbiological Standards

S/N	Proposed Change	Rationale
1	Removal of microbiological standards for hygiene indicator microorganisms (e.g. Total Plate Count, Escherichia coli Count, Coagulase positive Staphylococcus aureus Count) across all product categories, with the proposed standards to focus on pathogens only.	Most countries set and enforce microbiological standards only for pathogens in their legislation. Where microbiological standards for hygiene indicator microorganisms are set, these standards are used to recommend improvements in production hygiene, and not used to reject lots / consignments of finished product.
2	Standardisation of the number of sampling units (n) to 5, except for small consignments (defined in paragraph 9) where 1 sampling unit will be taken.	Improves sampling accuracy, reducing the chances of false results.
3	Inclusion of standards for emerging pathogens which are known to pose significant food safety concern, such as non-O157 Shiga-toxin producing Escherichia coli and Vibrio vulnificus.	To protect consumers from emerging pathogens based on the latest scientific evidence and trends.
4	Removal of standards for pathogens-product combinations which are not known to pose significant food safety concern, including Listeria monocytogenes in meat and meat products, and Escherichia coli O157:H7 in meat and meat products (excluding non-intact beef products) and egg products.	Allows SFA, overseas authorities and the industry to focus their efforts and resources on areas of higher food safety concern as only microorganisms deemed to be of high food safety concern are included in the standards.

Proposed Microbiological Standards for Non-RTE Food

- 8 The proposed microbiological standards for the various non-RTE product categories are in <u>Tables 2 to 6</u> below. The parameters used to set the standards (n, c, m, M) are defined in <u>Annex B</u>, while the test methodology used by SFA for the various testing parameters are listed in Annex C.
- 9 In Tables 2 to 6 below, "small consignment" means
 - (a) for a consignment of shell eggs, a consignment that does not exceed 10,000 shell eggs; and
 - (b) for a consignment of any other article of food, a consignment that does not exceed 100 kg or 50 units of the article of food.

Table 2 — Beef Products (non-intact³)

	Pathogen	n	С	m	М
1.	Escherichia coli O157:H7	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g
2.	Non-O157 Shigatoxin producing Escherichia coli (O26, O45, O103, O111, O121, O145)	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g

Table 3 — Blood-cockles and Oysters

	Pathogen	n	С	m	М
1.	Salmonella spp.	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g
2.	Shigella spp.	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g
3.	Vibrio cholerae	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g
4.	Vibrio parahaemolyticus	5 (except for a small consignment, one)	2 (except for a small consignment, 0)	100 colony forming	1000 colony forming

³ "Non-intact", for a beef product, means a beef product that has been, or will be, subject to a process (for example, injection with a solution, mechanical tenderisation or comminution) that allows pathogens to penetrate below the beef product's exterior surface into the beef product's interior.

				units in	units in
				one g	one g
5.	Vibrio vulnificus	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g

<u>Table 4 — Meat and Meat Products</u>⁴

	Pathogen	n	С	m	M
1.	Salmonella Enteritidis	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g
2.	Salmonella spp. (except for Salmonella Enteritidis, Salmonella Typhi, Salmonella Paratyphi A and Salmonella Paratyphi B)	5 (except for a small consignment, one)	1	Not detected in 25 g	Not detected in 25 g
3.	<i>Salmonella</i> Typhi	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g
4.	<i>Salmonella</i> Paratyphi A	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g
5.	<i>Salmonella</i> Paratyphi B	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g

<u>Table 5 — Pasteurised Poultry Shell Eggs and other Pasteurised Egg Products</u>

Pathogen	n	С	m	М
1. Listeria monocytogenes (for any pasteurised liquid egg product)	5 (except for a small consignment, one)	0	Not detected in 25 g	Not detected in 25 g

⁴ Meat and meat products include poultry, beef, pork, lamb, amphibian, reptile, venison, game.

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2.	Salmonella	5 (except for	0	Not	Not
	spp.	a small		detected	detected
		consignment,		in 25 g	in 25 g
		one)			

<u>Table 6 — Raw Poultry Shell Eggs and other Raw Egg Products</u>

	Pathogen	Pathogen n		m	M
1.	Salmonella	5 (except for	0	Not	Not
	Enteritidis	a small		detected	detected
		consignment,		in 25 g	in 25 g
		one)			

Request for comments

10 SFA invites views and comments on the proposed microbiological standards for non-RTE food in Tables 2 to 6 above. Should you disagree with the proposed microbiological standards for non-RTE food, please propose alternative microbiological standards and provide supporting information for your proposal.

Procedure and timeframe for submitting views and comments

- 11 All submissions should be clearly and concisely written and should provide a reasoned explanation for any proposed revisions.
- 12 Submissions should reach SFA no later than 12:00 p.m. (Singapore time; UTC+8), 18 Apr 2023, through email with the subject title "Proposed Microbiological Standards for Non-RTE Food", to the following address: adeline yong@sfa.gov.sg

Annex A. Detailed Comparison of Existing and Proposed Microbiological Standards

Table A1. Comparison of Existing and Proposed Non-RTE Product Categories

Existing Non-RTE Product Categories	Proposed Non-RTE Product Categories	Proposed Change
Chilled/frozen meat cuts/offals Frozen comminuted meat (including minced meat, paste, pate, patties, burgers, western sausages and similar products) Raw processed meat products (including Chinese sausage, waxed duck, raw ham, Jinhua ham)	Meat and meat products (includes poultry, beef, amphibian, reptile, lamb, pork, venison, game) Non-intact beef products (includes intact beef products intended for non-intact use)	Non-RTE meat and meat products are no longer differentiated by form/state as there may be difficulties in determining end-point usage at the point of import (e.g. raw intact meat may be further processed into non-intact products before retail stage). The exception to this is non-RTE non-intact beef products where a separate category has been proposed for STEC standards, due to the higher level of food safety concern posed by STEC in such products compared to intact raw beef cuts (e.g., STEC is less easily killed by heat as it is embedded within a tissue matrix instead of being exposed on the surface).
Frozen reptile meat (frog legs and crocodile meat)		Extension of microbiological standard to all other non-RTE amphibian and reptile meat and meat products (e.g. turtle meat)
Egg products	Raw poultry shell eggs and other raw egg products (excluding pasteurized egg products)	Extension of microbiological standard to raw shell eggs due to their potential to be consumed raw/undercooked
	Pasteurised poultry shell eggs and other pasteurised egg products	
Frozen oysters, frozen blood-cockle meat	Blood-cockles and oysters	Extension of microbiological standard to all non-RTE oysters and blood-cockles (regardless of whether they are in chilled, frozen, shelled or shucked state) due to their potential to be consumed undercooked in local cuisine. No standards have been proposed for all other non-RTE

	bivalves as they are infrequently associated with gastrointestinal cases, and are typically consumed fully cooked.
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Table A2. Comparison of Existing and Proposed Standards for Non-RTE Meat and Meat Products

Product	Existing Parameter	Existing Standards		ds	Comparison to Proposed Microbiological Standards	
		n	С	m	M	
Chilled meat cuts/offals	Total Plate Count		ing p	r to SFA's website ⁵ for detailed g plan for the individual parameters		Removal of microbiological standards for hygiene indicator microorganisms
Frozen meat cuts/offals	Escherichia coli Count	and product categories.			ries.	
Frozen comminuted meat	Coagulase- positive Staphylococcus aureus Count					
	Salmonella spp.	5	1	All Salmonella spp. except SE, ST, SPt A & B	SE, ST, SPt A & B	 No change to microbiological standards for Salmonella. Standardised the number of sampling units (n) to 5, except for small consignments (defined in
		3/1	0	Not detected in 25g		paragraph 9) where 1 sampling unit will be taken.
	Escherichia coli O157:H7, Listeria monocytogenes	5/3/1	0	Not detect	ed in 25g	Removal of microbiological standards for Escherichia coli O157:H7 in all meat except non- intact beef products

⁵ https://www.sfa.gov.sg/regulatory-limits/limits-for-incidental-constituents-in-food

						 Removal of microbiological standards for <i>Listeria monocytogenes</i> (<i>L. monocytogenes</i> is associated with RTE food) Inclusion of new standard on non-O157 Shigatoxin producing <i>Escherichia coli</i> (O26, O45, O10: O111, O121, O145), STEC, for non-intact beef products due to the higher level of food safety concern posed by STEC in such products compared to intact raw beef cuts (e.g., STEC is less easily killed by heat as it is embedded within a tissue matrix instead of being exposed on the surface).
Raw processed meat products	Total Plate Count	Refer to SFA's website for detailed sampling plan for the individual parameters				 Removal of microbiological standards for hygiene indicator microorganisms
(includes Chinese sausage, waxed duck, raw ham,	Escherichia coli Count		а	nd product categories	S.	
Jinhua ham) ´	Coagulase- positive Staphylococcus aureus Count					
	Salmonella spp.	5/3/1	Not detected in 25g		in 25g	Alignment with Salmonella microbiological standards for other meat and meat products
	Escherichia coli O157:H7	5/3/1	0	Not detected in 25g		Removal of microbiological standards for Escherichia coli O157:H7 in all meat except beef (cattle is known to be main reservoir)
	Total Plate Count	5	0	1.0 x 10 ⁷ CFU/g	-	Removal of microbiological standards for hygiene indicator microorganisms

Frozen reptile meat (frog legs and crocodile meat)	Salmonella spp.	5	1	All spp. except SE, ST, SPt A & B	SE, ST, SPt A & B	•	demoval of microbiological standards for <i>Vibrio</i> holerae and <i>Shigella</i> spp. as frozen reptile meat re deemed to be of a low food safety concern
	Vibrio cholerae, Shigella spp.	5	0	Not detected i	in 25g	•	(typically consumed fully cooked and infrequently associated with foodborne outbreaks). Microbiological standards for <i>Salmonella</i> spp. were however retained as there are concerns with relaxing existing <i>Salmonella</i> standards in light of the increasing trend of Salmonellosis in Singapore.

Table A3. Comparison of Existing and Proposed Standards for Non-RTE Eggs and Egg Products

Product	Parameter	Standards				Comparison to Proposed Microbiological Standards
		n	С	m	M	
Shell Eggs	Salmonella Enteritidis	While SFA does not specify microbiological standards for raw shell eggs, the veterinary conditions for import of table eggs requires that shell eggs are to come from farms which are free from Salmonella Enteritidis			ards for raw ry conditions requires that from farms	No change to microbiological standards for Salmonella for raw shell eggs (zero- tolerance against Salmonella Enteritidis) as SE is known to be the major serotype of concern in shell eggs (transmitted vertically from layer hens to the interior of shell eggs)
Egg Products	Total Plate Count	-	-	-	1.0 x 10⁵ CFU/g	Removal of microbiological standards for hygiene indicator microorganisms
		1.0 x 10 ² CFU/g	No change to microbiological standards for Salmonella for pasteurised eggs and egg			

Coagulase-positive Staphylococcus aureus Count	-	-	Not detected in 25g in 1g or mL	products, as such products may be used for RTE applications (e.g. mayonnaise, eggbased desserts like cream, tiramisu etc.)
Salmonella spp., Escherichia coli O157:H7	-	-	Not detected in 25g in 25g or mL	 Inclusion of microbiological standards for Listeria monocytogenes as it has demonstrated the ability to grow in refrigerated liquid pasteurized egg products as a result of insufficient pasteurization/recontamination due to poor handling, which is a cause for concern as such products may be used directly by consumers. Removal of microbiological standards for Escherichia coli O157:H7 as cattle are known to be its main reservoir

Table A4. Comparison of Existing and Proposed Standards for Non-RTE Oysters and Blood-Cockles

Product	Parameter			Standards		Comparison to Proposed Microbiological Standards	
		n	ပ	m	М		
Frozen oysters	Total Plate Count	5	2	5.0 x 10 ⁴ CFU/g	5.0 x 10⁵ CFU/g	Removal of microbiological standards for hygiene indicator microorganisms	
	Escherichia coli Count	5	2	20	1.0 x 10 ² CFU/g	 Extension of microbiological standards for frozen blood cockle meat and frozen oyste to all non-RTE oysters and blood cockles (regardless of whether they are in chilled, 	
Frozen blood-cockle meat	Salmonella spp., Shigella spp., Vibrio cholerae	5	0 Not detected in 25g		ted in 25g	frozen, shelled or shucked state), due to their potential to be consumed raw/undercooked in local cuisine. No	
	Vibrio parahaemolyticus	5	2	1.0 x 10 ² CFU/g	1.0 x 10 ³ CFU/g	standards have been proposed for all other non-RTE bivalves as they are infrequently associated with gastrointestinal cases and are typically consumed fully cooked. No change to microbiological standards for Salmonella, Vibrio parahaemolyticus (for frozen oysters), Vibrio cholerae and Shigeli Inclusion of microbiological standards for	
	Total Plate Count	5	0	5.0 x 10⁴ CFU/g	-		
	Escherichia coli Count	5	0	20	-		
	Salmonella spp., Shigella spp., Vibrio cholerae	5	0	Not detected in 25g		Vibrio vulnificus due to severity of disease caused	
	Vibrio parahaemolyticus	5	0	10 ² C	FU/g		

Annex B. Parameters of Sampling Plan Used to Set Microbiological Standards

SFA has adopted a three-class sampling plan for end-product testing, which comprises the following parameters:

- n: The number of sample units comprising the sample
- c: The number of sample units where the bacterial count may be between "m" and "M"
- m: The threshold value for the number of bacteria; the result is considered satisfactory if:
 - o The number of bacteria in all sample units does not exceed this value, or
 - o The number of bacteria in less than or equal to "c" sample units exceeds this value but does not exceed "M"
- M: The maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in any sample unit exceeds this value

Based on the results of laboratory testing, the following decisions are made:

Table B1. Interpretation of Test Results

Result	Decision
All sample units have bacteria count ≤ m	Accept lot
≤ c out of n samples have bacteria count within > m and ≤ M	
> c out of n samples have bacteria count within > m and ≤ M	Reject lot
Any sample units have bacteria count > M	

Annex C. Methodology for Testing Parameters

Note that stakeholders are allowed to employ any analytical method(s) when conducting their own testing, so long as the method has been validated by an independent validation organisation, and/or conducted in laboratories accredited for the analytical method(s).

Table C1. Test Methodology for Testing Parameters

Test	Test Methodology			
Salmonella spp.	FDA/BAM Chapter 5			
Escherichia coli O157:H7	AOAC 2000.14			
Non-O157 STEC (O26, O45, O103,	AOAC PT 091301			
O111, O121, O145)				
Listeria monocytogenes	AOAC 121402			
Vibrio parahaemolyticus count	Practical Food Microbiology, PHLS, Chapter			
	6.15			
Vibrio cholerae, Vibrio vulnificus	FDA/BAM Chapter 9			
Shigella spp.	APHA, CMMEF, Chapter 38			