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India

Post: New Delhi

WTO Notified - Draft Amendment on Standards and Additives Regulation

Report Categories:

Sanitary/Phytosanitary/Food Safety

Fishery Products

Food and Agricultural Import Regulations and Standards - Narrative

Exporter Guide

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Report Highlights:

On January 4, 2016, India notified a draft regulation related to microbiological standards for fish and fish products to the World Trade Organization (WTO). The comment period for trading partners expires on March 4, 2016.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the Government of India (GOI) and WTO websites: <http://www.fssai.gov.in/> and www.wto.org. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

On November 23, 2015, GOI's Food Safety and Standards Authority of India (FSSAI) amended the [Food Safety and Standards \(Food Products Standards and Food Additives\) Regulations, 2011](#), to update microbiological standards for fish and fish products. On January 4, 2016, the amended draft regulation was notified to the WTO. The comment period for trading partners expires on March 4, 2016.

In Appendix B of the [Food Safety and Standards \(Food Products Standards and Food Additives\) Regulations, 2011](#), related to "Microbiological Requirements" Table 1 and related entries have been updated.

The full text of the FSSAI notification is attached below and is also available on FSSAI's website: <http://www.fssai.gov.in/>.

Comments should be sent to:

The Chief Executive Officer
Food Safety and Standards Authority of India
3rd Floor, Food and Drug Administration Bhawan, Kotla Road
New Delhi – 110002
Email: baranip@yahoo.com

Type of Regulation: Draft

Publication date on the FSSAI website: November 23, 2015

Date of Implementation: To be determined

WTO Notification Number: SPS/N/IND/126

WTO Notification Date: January 4, 2016

Final date for comments: March 4, 2016

Products Affected: Fish and fish products

Agency in Charge: Food Safety and Standards Authority of India, GOI

**Notice calling for suggestions, views, comments etc from WTO-SPS
Committee Members within a period of 60 days on the proposed
standards for Microbiological Standards for Fish and Fish Products.**

- 2 In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in APPENDIX B relating to “Microbiological Requirements”, for the TABLE 1 and the entries relating thereto, the following Tables and the entries shall respectively be substituted, namely:-

“Microbiological Requirements of Fish and Fishery Products

**Table 1A
Microbiological requirements for Fish and Fishery products -Hygiene Indicator Organisms**

Sr. No.	Product Category*	Aerobic Plate Count				Coagulase positive Staphylococci				Yeast and mold count			
		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits	
		n	c	m	M	n	c	m	M	n	c	m	M
1.	Raw/Chilled/Frozen Finfish	5	3	5x10 ⁵ cfu/g	10 ⁷ cfu/g	-	-	-	-	-	-	-	-
2.	Raw/Chilled/Frozen Crustaceans	5	3	10 ⁶ cfu/g	10 ⁷ cfu/g	-	-	-	-	-	-	-	-
3.	Raw/Chilled/frozen Cephalopods	5	2	10 ⁵ cfu/g	10 ⁶ cfu/g	-	-	-	-	-	-	-	-
4.	Chilled/Frozen Bivalves	5	2	10 ⁵ cfu/g	10 ⁶ cfu/g	-	-	-	-	-	-	-	-
5.	Frozen cooked crustaceans/Frozen heat shucked mollusca	5	2	10 ⁵ cfu/g	10 ⁶ cfu/g	5	2	10 ² cfu/g	10 ³ cfu/g	-	-	-	-
6.	Dried/ Salted and dried fishery products	5	0	10 ⁵ cfu/g		-	-	-	-	5	0	100cfu/g	
7.	Thermally processed fishery products	Commercially Sterile				-	-	-	-	-	-	-	-
8.	Fermented fishery products	-	-	-	-	5	1	10 ² cfu/g	10 ³ cfu/g	5	0	100cfu/g	
9.	Smoked fishery products	5	0	10 ⁵ cfu/g		5	2	10 ² cfu/g	10 ³ cfu/g	-	-	-	-
10.	Accelerated Freeze Dried fishery products	5	0	10 ⁴ cfu/g		5	0	100cfu/g		-	-	-	-
11.	Fish Mince/Surimi and analogues	5	2	10 ⁶ cfu/g	10 ⁶ cfu/g	5	2	10 ² cfu/g	10 ³ cfu/g	-	-	-	-

Sr. No.	Product Category*	Aerobic Plate Count				Coagulase positive Staphylococci				Yeast & mold count			
		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits	
		n	c	m	M	n	c	m	M	n	c	m	M
12.	Fish Pickle	5	0	10^3 cfu/g		5	1	10^2 cfu/g	10^3 cfu/g	5	0	100cfu/g	
13.	Battered and breaded fishery products	5	0	10^5 cfu/g	10^7 cfu/g	5	1	10^2 cfu/g	10^3 cfu/g	5	0	100cfu/g	
14.	Convenience fishery products	5	2	5×10^3 cfu/g	5×10^4 cfu/g	5	2	10^2 cfu/g	10^3 cfu/g	-	-	-	
15.	Powdered fish based products	5	2	10^4 cfu/g	10^5 cfu/g	5	2	10 cfu/g	10^2 cfu/g	5	0	100 cfu/g	

Table 1B
Microbiological Requirements for Fish and Fishery products –Safety Indicator Organisms

Sr. No.	Product Category*	<i>Escherichiacoli</i>				<i>Salmonella</i>				<i>Vibriocholerae</i> (01 and 0139)				<i>Listeria monocytogenes</i>				<i>Clostridium botulinum</i>			
		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits	
		n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M
1.	Raw/Chilled/Frozen Finfish	5	3	11 MPN/	500 MPN/g	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
2.	Raw/Chilled/Frozen Crustaceans	5	3	11 MPN/	500 MPN/g	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
3.	Raw/Chilled/frozen Cephalopods	5	0	20 cfu/g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
4.	Chilled/Frozen Bivalves	5	0	46 MPN/g		10	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
5.	Frozen cooked crustaceans/Frozen heat shucked mollusca	5	2	1 MPN/g	10 MPN/g	5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g	-	-	-	-	-
6.	Dried/ Salted and dried fishery products	5	0	20 cfu/g		5	0	Absent/25g		-	-	-	-	-	-	-	-	-	-	-	-
7.	Thermally processed fishery products	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Absence of viable spores or vegetative cells of <i>Clostridium botulinum</i> and absence of botulinum toxin			

Sr. No.	Product Category*	<i>Escherichiacoli</i>				<i>Salmonella</i>				<i>Vibriocholerae</i> (O1 and O139)				<i>Listeria monocytogenes</i>				<i>Clostridium botulinum</i>			
		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits	
		n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M
8.	Fermented fishery products	5	2	4 MPN/g	40 MPN/g	10	0	Absent/25g		-	-	-	-	-	-	-	-	Absence of viable spores or vegetative cells of <i>Clostridium botulinum</i> and absence of botulinum			
9.	Smoked fishery products	5	3	11 MPN/g	500 MPN/g	5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
10.	Accelerated Freeze Dried Fishery Products	5	0	20 cfu/g		5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
11.	Fish Mince/Surimi and analogues	5	0	20 cfu/g		5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
12.	Fish Pickle	5	0	20 cfu/g		5	0	Absent/25g		-	-	-	-	-	-	-	-	-	-	-	-
13.	Battered and breaded fishery products	5	2	11 MPN/g	500 MPN/g	5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g					
14.	Convenience fishery products	5	2	1 MPN/g	10 MPN/g	5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g					
15.	Powered Fish based products	-	-	-	-	5	0	Absent/25g		-	-	-	-	-	-	-	-	-	-	-	-

Sampling Guidelines: The sampling for different microbiological parameters specified in **Table-1 A& 1B** shall be ensured aseptically as per the sampling plan given in **Table-1C** by trained person with specialized knowledge in the field of microbiology following guidelines given in IS11427:2001. The samples shall be stored and transported under appropriate temperature conditions and insulations within 24 hrs of sampling to accredited laboratories for analysis as per the approved sampling plan and test methods. A large sample size may be drawn (if desired) according to the tests required and the type of product. Preservatives shall not be added to samples intended for microbiological examination. The desired number of samples as per sampling plan given in Table-1 A and B shall be taken from full production batches and will be submitted to accredited laboratory in original unopened packaging, sealed at the time of sampling maintained in their original physical state. The final decision shall be drawn based on results with no provision for retesting for microbiological parameters.

Sampling plan: The following terms, as used by the International Commission on Microbiological Specifications of Foods (ICMSF) are defined and used in this standard:

n=the number of sample units which must be examined from the batch/lot of food to satisfy the requirements of a particular sampling plan.

m=Represents an acceptable level and values above it are marginally acceptable in terms of the sampling plan

c=the maximum allowable number of defective sample units in 3-class sampling plan applicable at manufacturing units only.

M= A microbiological criterion which indicate unsatisfactory/potentially hazardous quality.

Values above M are unacceptable in terms of the sampling plan and detection of one or more samples exceeding this level would be cause for rejection of the lot and will attract enforcement/ prosecution by the concerned food safety authorities.

Table-1C

Sampling plan for compliance of microbiological parameters at manufacturing units and at retail points

Sampling Plan						
2-class			3-class			
N	c	M	n	c	m	M
n=5-10	c=0	Values of M specified for all testing parameters for different products as specified Table-1&2 will be applicable	5-10	c=1-3	Values of m specified for all testing parameters for different products as specified Table-1 & 2 will be applicable	Values of M specified for all testing parameters for different products as specified Table - 1 & 2 will be applicable

Microbiological criteria and the interpretation: Following three categories of microbiological quality have been assigned in standard based on hygiene and safety indicator organisms. These are satisfactory, unsatisfactory and potentially hazardous.

1. **Satisfactory:** If the test values of m/or M or both applicable within the sampling plan are conforming the specified limits, the microbiological quality of product is considered satisfactory and no action is required.
2. **Unsatisfactory:** if the test values of m/or M or both applicable within the sampling plan are not conforming the specified limits of hygiene indicators i.e. Total plate count, Coagulase positive Staphylococci and Yeast & mold count that indicates poor hygiene or poor handling practices, the microbiological quality of product will be considered un-satisfactory. Under these conditions the premises producing such unsatisfactory product(s) shall be investigated for non conformity or non-compliance and legal action on defected products will be notified by the food safety authority. The subsequent release of such product shall be subject to HACCP / GMP audit clearance of the premises/finished products by the food safety authority.
3. **Potentially hazardous:** If the test values of m/or M or both applicable within the sampling plan are not conforming the specified limits of safety indicators i.e. *E. coli*, *Salmonella*, *Vibrio cholerae* and *L. monocytogenes* that indicates serious food safety concern, the microbiological quality of product will be considered as Potentially hazardous. Under these conditions the premises producing such unsatisfactory product(s) shall be stopped and legal actions on potentially hazardous products will be notified by the food safety authority. The recall action on withdrawal of any of such food still available for sale or distribution shall be initiated and release of subsequent batches of such hazardous products will be under hold by the food manufacturers. Failure by an owner to either cease manufacture of product or withdraw/recall product from sale when requested to do so shall result in seizure of that product where the officer has reason to believe that it is contaminated with pathogenic bacteria. A detail risk assessment will be carried out by the food safety authority to investigate the source /cause of the problem so that remedial action can commence and the approval for restart of such products under non-conformity will be allowed only after compliance of manufacturing unit for food safety standards requirements or guidelines set by the Authority.

Reference test methods

Sr. No.	Test Method	References
1.	Aerobic Plate Count	Aerobic Plate Count. Bacteriological Analytical Manual, Chapter 3. USFDA BAM Online January, 2001
2.	<i>Escherichia coli</i>	Enumeration of <i>Escherichia coli</i> and the Coliform Bacteria. Bacteriological Analytical Manual, Chapter 4. USFDA BAM Online September, 2002.
3.	<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i> , Bacteriological Analytical Manual, Chapter 12. USFDA BAM Online January, 2001
4.	<i>Vibrio cholerae</i>	<i>Vibrio</i> , Bacteriological Analytical Manual, Chapter 9. USFDA BAM Online, May, 2004
5.	<i>Salmonella</i>	<i>Salmonella</i> . Bacteriological Analytical Manual, Chapter 5. USFDA BAM Online, November, 2011
6.	<i>Listeria monocytogenes</i>	Detection and Enumeration of <i>Listeria monocytogenes</i> , Bacteriological Analytical Manual, Chapter 10, USFDA BAM Online April 2011
7.	Yeasts, Molds and Mycotoxins	Yeasts, Molds and Mycotoxins, Bacteriological Analytical Manual, Chapter 18, USFDA BAM Online April 2001
8.	<i>Clostridium botulinum</i>	<i>Clostridium botulinum</i> . Bacteriological Analytical Manual, Chapter 17, USFDA BAM Online Jan 2001

Sr. No.	Test Method	References
9.	Preparation of Fish and Fishery Products for microbiological examination	ISO 6887-3:2003: Microbiology of food and animal feeding stuffs -- Preparation of test samples, initial suspension and decimal dilutions for microbiological examination -- Part 3: Specific rules for the preparation of fish and fishery products

***Definitions:**

- (1) **Raw/Chilled/Frozen Finfish** includes clean and wholesome finfish, which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices. Chilling is the process of cooling fish or fish products to a temperature approaching that of melting ice. Chilling can be achieved either by using ice, chilled water, ice slurries of both seawater and freshwater), and refrigerated seawater (RSW). Similarly, freezing is the process which is sufficient enough to reduce the temperature of the whole product to a level low enough to preserve the inherent quality of the fish and that have been maintained at this low temperature during transportation, storage and distribution up to and including the time of final sale. Freezing process that is carried out in appropriate equipment in such a way that the range of temperature of maximum crystallization is passed quickly. The quick freezing process shall not be regarded as complete unless and until the product temperature has reached -18°C (0°F) or lower at the thermal centre after thermal stabilization.
- (2) **Raw/Chilled/Frozen Crustaceans** includes clean, whole or peeled crustaceans (shrimp/prawn, crabs and lobster) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.
- (3) **Raw/Chilled/Frozen Cephalopods** includes cleaned, whole or de-skinned cephalopods (squid, cuttlefish and octopus) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.
- (4) **Chilled/Frozen Bivalves** includes clean, whole or shucked bivalves, which are either in live, chilled or frozen condition and handled in accordance with good manufacturing practices. This product category includes filter feeding aquatic animals such as oysters, mussels, clams, cockles and scallops.
- (5) **Frozen cooked Crustaceans/Frozen heat shucked Mollusca** means clean, whole or peeled crustaceans, which are cooked at a defined temperature and time and subsequently frozen. Cooking of crustaceans must be designed to eliminate six log reduction of most heat resistant vegetative bacteria i.e. *Listeria monocytogenes*. Frozen heat shucked mollusca includes bivalves where meat is removed from the shell by subjecting the animals to mild heat before shucking to relax the adductor muscle and subsequently frozen.
- (6) **Dried/ Salted and Dried fishery Products** means the product prepared from fresh or wholesome finfish or shellfish after drying with or without addition of salt. The fish shall be bled, gutted, beheaded, split or filleted and washed prior to salting and drying. Salt used to produce salted fish shall be clean, free from foreign matter, show no visible signs of contamination with dirt, oil, bilge or other extraneous materials.
- (7) **Thermally Processed Fishery Products** means the product obtained by application of heat or temperature for sufficient time to achieve commercial sterility in hermetically sealed containers.
- (8) **Fermented Fishery Products** includes any fish product that has undergone degradative changes through enzymatic or microbiological activity either in presence or absence of salt. Non-traditional products manufactured by accelerated fermentation, acid ensilage and chemical hydrolysis also belong to this category.
- (9) **Smoked Fishery Products** means fish or fishery product subjected to a process of treatment with smoke generated from smouldering wood or plant materials. Here the product category refers to hot smoked fish where fish is smoked at an appropriate combination of temperature and time sufficient to cause the complete coagulation of the proteins in the fish flesh.
- (10) **Accelerated Freeze dried Fishery Products** means fish, shrimp or any fishery product subjected to rapid freezing, followed by drying under high vacuum so as to remove the water by sublimation to a final moisture content of less than 2%.
- (11) **Fish Mince/Surimi and analogues** means comminuted, mechanically removed meat which have been separated from and are essentially free from bones, viscera and skin. Surimi is the stabilized myofibrillar proteins obtained from mechanically deboned fish flesh that is washed with water and blended with cryoprotectants. Surimi analogues are variety of imitation products produced from surimi with addition of ingredients and flavor.

- (12) **Fish Pickle** means an oily, semi-solid product with spices and acidic taste obtained from maturation of partially fried fish with vinegar. It is produced by frying edible portions of fish, shrimp or mollusc, followed by partial cooking with spices, salt and oil and maturing for 1-3 days with added organic acids. The product is intended for direct human consumption as a seasoning, or condiment for food.
- (13) **Battered and Breaded Fishery products** include fish portions, fillets or mince coated with batter and/or breading. Batter means liquid preparation from ground cereals, spices, salt, sugar and other ingredients and/or additives for coating. Typical batter types are: non-leavened batter and leavened batter. Breading means dry breadcrumbs or other dry preparations mainly from cereals with colourants and other ingredients used for the final coating of fishery products.
- (14) **Convenience Fishery Products** include the convenience fishery products are tertiary food products which are in ready to eat form. These products can be consumed directly after minimal handling and processing. This category includes Sous-vide cooked products, surimi-based products cooked (in-pack), pasteurized crab meat, pasteurized molluscs which are distributed as refrigerated, but meant for direct human consumption with minimal or no cooking. This category also includes snack based items prepared from fish and fishery products meant for direct human consumption such as extruded fishery products, fried items namely fish wafers, crackers, fish cutlets, fish burgers, etc.
- (15) **Powdered Fish based Products** include the powdered fish based products which are prepared from finfish/shellfish or parts thereof, with or without other edible ingredients in powdered form, suitable for human consumption. These may be consumed directly or as supplements and also after hydration. This category includes powdered and dried fish products generally used as ingredients in food preparations such as fish soup powder, fish chutney powder, ready to use fish-mix etc”.