MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 14th June, 2016

F. No.1-10(2)/Standards/SP(Fish and Fisheries Products)/FSSAI-2013.—The following draft of certain regulations further to amend the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011, which the Food Safety and Standards Authority of India, with previous approval of the Central Government, proposes to make, in exercise of the powers conferred under clause (i) of sub-section (2) of section 92 read with sections 20 and 21 of the Food Safety and Standards Act, 2006 (34 of 2006) is hereby published as required under the sub-section (1)

of section 92 of the said Act for the information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of the period of thirty days from the date on which the copies of the Official Gazette in which this notification is published are made available to the public;

Objections or suggestions, if any, duly supported by scientific evidence, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi-110002 or send it to the email address of Authority at regulation@fssai.gov.in;

The objections and suggestions, which may be received from any person with respect to the said draft regulations before the expiry of the period so specified, will be considered by the Food Authority.

Draft regulations

- **1. Short title and Commencement.-** (1) These regulations may be called the Food Safety and Standards (Contaminants, toxins and Residues) Amendment Regulations, 2016.
 - (2) They shall come into force on the date of their final publication in the official Gazette.
- **2**. In the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011, in regulation 2.5, relating to "Other Contaminants", after sub-regulation 2.5.1, the following sub-regulation shall be inserted, namely:-

"2.5.2 Histamine in Fish and Fishery Products contaminants, toxins and Residues

3. Fish species having potential to cause histamine poisoning

Sl.No.	Family	Scientific Name	Common Name
1.	Carangidae	Alectis indica	Indian Threadfish
		Alepes spp.	Scad
		Atropus atropos	Cleftbelly trevally
		Carangoides bartholomaei	Yellow Jack
		Carangoides spp.	Trevally
		Caranx crysos	Blue runner
		Caranx spp.	Jack/Trevally
		Decapterus koheru	Koheru
		Decapterus russelli	Indian scad
		Decapterus spp.	Scad
		Elagatis bipinnulata	Rainbow Runner
		Megalaspis cordyla	Horse Mackerel/Torpedo Scad
		Nematistius pectoralis	Roosterfish
		Oligoplites saurus	Leather Jacket
		Pseudocaranx dentex	White trevally
		Scomberoides	Talang queenfish

Sl.No.	Family	Scientific Name	Common Name
		commersonnianus	
		Scomberoides spp.	Leather Jacket/Queen Fish
		Selene spp. Moonfish	
		Seriola dumerili	Greater/Japanese Amberjack or Rudder Fish
		Seriola lalandi	Yellowtail Amberjack
		Seriola quinqueradiata	Japanese Amberjack
		Seriola rivoliana	Longfin Yellowtail
		Seriola spp.	Amberjack or Yellowtail
		Trachurus capensis	Cape Horse Mackerel
		Trachurus japonicas	Japanese Jack Mackerel
		Trachurus murphyi	Chilean Jack Mackerel
Trachurus novaezelandiae Trachurus spp. Trachurus trachurus		Trachurus novaezelandiae	Yellowtail Horse Mackerel
		Trachurus spp.	Jack Mackerel/Horse Mackerel
		Trachurus trachurus	Atlantic Horse Mackerel
		Uraspis secunda	Cottonmouth jack
2.	Chanidae	Chanos chanos	Milkfish
3.	Clupeidae	Alosa pseudoharengus	Alewife
		Alosa spp.	Herring
		Amblygaster sirm	Spotted Sardinella
		Anodontostoma chacunda	Chacunda gizzard shad
		Brevoortia patronus	Gulf Menhaden
		Brevoortia spp.	Menhaden
		Brevoortia tyrannus	Atlantic Menhaden
		Clupea bentincki	Araucanian herring
		Clupea harengus	Atlantic herring
		Clupea pallasii pallasii	Pacific herring
		Clupea spp.	Pichard/Shad/Herring

Sl.No.	Family	Scientific Name	Common Name	
		Dorosoma spp.	Gizaard Shad	
		Ethmalosa fimbriata	Bonga Shad	
		Ethmidium maculatum	Pacific Menhaden	
		Etrumeus sadina	Red-eye round herring	
		Harengula spp.	Sprat/Herring	
		Harengula thrissina	Pacific flatiron herring	
		Hilsa spp.	Shad	
		Nematolosa spp.	Gizzard Shad	
		Opisthonema libertate	Pacific thread herring	
		Opisthonema spp	Thread Herring	
		Opisthopterus tardoore	Tardoore	
		Sardina pilchardus	European Pilchard	
		Sardinella aurita	Round Sardinella	
		Sardinella gibbosa	Gold stripe Sardinella	
		Sardinella longiceps	Indian Oil Sardine	
		Sardinella maderensis	Madeiran Sardinella	
		Sardinella spp.	Sardine	
		Sardinops sagax	South American Pilchard	
		Sardinops spp.	South American Pilchard	
		Spratelloides gracilis	Silver-stripe round herring	
	Tenualosa ilisha		Hilsa shad	
		Tenualosa spp.	Shad	
4	Coryphaenidae	Coryphaena hippurus	Mahi-Mahi /Dolphin fish	
5	Engraulidae	Anchoa spp.	Anchovy	
		Anchoviella spp.	Anchovy	
		Cetengraulis mysticetus	Pacific anchoveta	
		Engraulis capensis	Southern African anchovy	
		Engraulis encrasicolus	European anchovy	

Sl.No.	Family	Scientific Name	Common Name
		Engraulis japonicus	Japanese anchovy
		Engraulis ringens	Peruvian anchovy
		Engraulis spp.	Anchovy
		Stolephorus spp.	Anchovy
6	Istiophoridae	Istiompax indica	Black Marlin
		Istiophorus albicans	Atlantic sailfish
		Istiophorus platypterus	Indo-Pacific sailfish
		Kajikia albida	Atlantic white marlin
		Kajikia audax	Striped Marlin
		Makaira mazara	Indo-Pacific blue marlin
		Makaira spp.	Marlin/Sailfish
		Tetrapturus spp.	Marlin/Spearfish
		Tetrapturus spp.	Spearfish
7	Mugilidae	Mugil cephalus	Flathead Grey Mullet
8	Pristigasteridae	Ilisha spp.	Ilisha/Pellona
		Pellona ditchella	Indian pellona
9	Scombridae	Acanthocybium solandri	Wahoo
		Auxis spp.	Bullet Tuna/Frigate Tuna
		Cybiosarda elegans	Leaping Bonito
		Euthynnus affinis	Little tuna or Kawakawa
		Euthynnus spp.	Bonito
		Gasterochisma melampus	Butterfly kingfish
		Grammatorcynus spp.	Short Mackerel
		Gymnosarda unicolor	Dogtooth tuna
		Katsuwonus pelamis	Skipjack Tuna
		Orcynopsis unicolor	Plain Bonito
		Rastrelliger brachysoma	Short Mackerel

Sl.No.	Family	Scientific Name	Common Name
		Rastrelliger kanagurta	Indian Mackerel
		Sarda spp	Bonito
		Scomber australasicus	Blue mackerel
		Scomber japonicas	Chub mackerel
		Scomber scombrus	Atlantic mackerel
		Scomber spp.	Mackerel
		Scomberomorus cavalla	King Mackerel
		Scomberomorus commerson	Narrow-barred Spanish mackerel
		Scomberomorus guttatus	Indo-Pacific king mackerel/Spotted Spanish Mackerel
		Scomberomorus niphonius	Japanese Spanish mackerel
		Scomberomorus spp.	Spanish Mackerel
		Scomeromorus lineolatus	Streaked seerfish
		Thunnus alalunga	Albacore Tuna
		Thunnus albacares	Yellowfin Tuna
		Thunnus atlanticus	Blackfin Tuna
		Thunnus maccoyi	Southern bluefin tuna
		Thunnus obesus	Bigeye Tuna
		Thunnus orientalis	Pacific bluefin tuna
		Thunnus spp.	Tuna
		Thunnus thynnus	Atlantic bluefin tuna
		Thunnus tonggol	Longtail Tuna
10	Xiphiidae	Xiphias gladius	Swordfish

4. Limits of histamine level in fish and fishery products

Product Category		Applicable to	Histamine Level		
12.	Raw/Chilled/Frozen Finfish	Species with high amount of free histidine	n=9, c=2; m=100 mg/kg, M=200 mg/kg		
13.	Dried/ Salted and Dried fishery products	(Listed fish species with potential to cause histamine fish poisoning)	n=9, c=2; m=100 mg/kg, M=200 mg/kg		
14.	Thermally Processed Fishery Products		n=9, c=2; m=100 mg/kg, M=200 mg/kg		

Produ	uct Category	Applicable to	Histamine Level
15.	Smoked fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
16.	Fish Mince/Surimi and analogues		n=9, c=2; m=100 mg/kg, M=200 mg/kg
17.	Battered and breaded fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
18.	Other Ready to Eat fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
19.	Other value added fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
20.	Other fish based products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
21.	Fermented Fishery products		n=9, c=2; m=200 mg/kg, M=400 mg/kg
22.	Fish Pickle		n=9, c=2; m=200 mg/kg, M=400 mg/kg

Where,

- n: Number of units comprising the sample
- c: Maximum allowable number of defective sample units
- m: Acceptable level in a sample
- M: Specified level when exceeded in one or more samples would cause the lot to be rejected
- Satisfactory, if the following requirements are fulfilled:
 - 1. the mean value observed is \leq m
 - 2. a maximum of c/n values observed are between m and M
 - 3. no values observed exceed the limit of M,
- Unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more
 of the values observed are >M."

PAWAN AGARWAL, Chief Executive Officer [ADVT. III/4/Exty./134(187)]

- **Note.** The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011 and subsequently amended vide notification numbers:
- (i) F. No.1-12/Sci.panel/(Notification)/FSSAI/2012, dated 3rd December, 2014;
- (ii) F. No. P. 15025/264/13-PA/FSSAI, dated 4th November, 2015;
- (iii) F.No.1-99/1/SP(Contaminants)/FSSAI/2009, dated 4th November, 2015;
- (iv) F. No. 1-99/4/SP(Contaminants)/FSSAI/2014, dated 4th November, 2015;
- (v) F.No.1-10(6)/Standards/SP(Fish and Fisheries Products)/FSSAI-2013, dated 4th January, 2016 and
- (vi) F.No. P.15025/264/13-PA/FSSAI, dated 5th January, 2016.