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**Date:** 7/24/2015

**GAIN Report Number:** IN5094

## India

**Post:** New Delhi

### **Draft Amendments on the Biotoxins Limit in Fish and Fish Products**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

Fishery Products

Exporter Guide

FAIRS Subject Report

**Approved By:**

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**Report Highlights:**

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) amended the [Food Safety and Standards \(Contaminants, Toxins and Residues\) Regulations, 2011](#), and has set biotoxin limits in fish and fish products. The GOI is currently seeking comments from interested public stakeholders regarding these draft regulations. The deadline for the public comment period is September 4, 2015.

**Executive Summary:**

FSSAI published draft [Food Safety and Standards \(Contaminants, Toxins and Residues\) Amendment Regulations, 2015](#), which primarily focuses on biotoxins limits in fish and fish products. To date, these draft regulations have not been notified to the World Trade Organization (WTO). However, FSSAI is accepting public comments from interested public stakeholders through September 4, 2015.

**General Information:**

**DISCLAIMER:** The information contained in this report was retrieved from FSSAI's website <http://www.fssai.gov.in/>. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

Comments should be formatted as per the example pasted below and sent to:

Chief Executive Officer  
Food Safety and Standards Authority of India  
Food and Drug Administration Bhawan, Kotla Road  
New Delhi – 110002  
Email: [regulation@fssai.gov.in](mailto:regulation@fssai.gov.in)

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

MINISTRY OF HEALTH AND FAMILY WELFARE  
(Food Safety and Standards Authority of India)  
NOTIFICATION

New Delhi, the 12th June, 2015

F.No.1-10(6)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 by sub-section (1) and clause (i) of sub-section (2) of Section 92 read with section 20 and 21 of the Food Safety and Standards Act, 2006 (34 of 2006) is hereby published as required by the sub-section (1) of section 92, 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 sixty 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 with 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;

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

#### Draft Regulations

1. (1) These regulations may be called the Food Safety and Standards (Contaminants, Toxins and Residues) (Amendment) Regulations, 2015.

(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 2.2 relating to "Crop contaminants and naturally occurring toxic substances":—

(a) in sub-regulation 2.2.1, after clause 2 relating to "Naturally Occurring Toxic Substances", the following clause shall be inserted, namely:-

"3. Polychlorinated biphenyls (PCBs) and Polycyclic Aromatic Hydrocarbon (PAH) compounds in Fish and Fishery Products:

Sl.No. (1)	Name of the Contaminants (2)	Article of the food (3)	Limit (4)
1.	Polychlorinated biphenyls (Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180)	Inland and Migratory Fish	2.0 ppm
2.	Polychlorinated biphenyls (Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180)	Marine Fish, Crustaceans and molluscs	0.5 ppm
3.	Benzo(a)pyrene	Smoked Fishery Products	5.0 ppb.

3. After regulation 2.3 relating to "Residues", the following regulation shall be inserted namely:-

"2.4. Limits of biotoxins in fish and fishery products:

Sl. No. (1)	Name of the Contaminants (2)	Article of the food (3)	Limit (µg/kg) (4)
1.	Paralytic Shellfish Poison (PSP)	Bivalve Molluscs	80 µg/100g (Saxitoxin Equivalent)
2.	Amnesic Shellfish Poison (ASP)	Bivalve Molluscs	20 µg/g (Domonic acid equivalent)
3.	Diarrhetic shellfish Poison (DSP)	Bivalve Molluscs	160 µg of Okadaic acid equivalent/Kg
4.	Azaspiracid Poison (AZP)	Bivalve Molluscs	160 µg of azaspiracid equivalent/Kg
5.	Brevetoxin (BTX)	Bivalve Molluscs	200 mouse units or equivalent/Kg."

YUDHIVIR SINGH MALIK, Chief Executive Officer

[ADVT.-III/4/ Exty./187-O/15(104)]

Note. - The principal regulations were published in the Gazette of India, Extraordinary vide notification number F. No. 2-15015/30/2010, dated the 1<sup>st</sup> August, 2011 and subsequently amended vide F.No. 1-12/Sci.panel/ (Notification)/FSSAI/ 2012 dated the 3<sup>rd</sup> December, 2014

Subject: Draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulation, 2015 regarding limit of biotoxins in fish and fish products. [Amendment in the Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011: Regulation 2.2].

FORMAT FOR SENDING THE COMMENTS/ SUGGESTIONS

Sr. no.	Name and address of the organisation/person, contact number and e-mail.	Relevant section in the draft notification on which comments are being provided	Comments/ suggestions	Rationale	Remarks

Date:

Place:

Name and Signature