

No. 15-02/GA/2014-15-FSSAI
Food Safety and Standards Authority of India
(A Statutory Regulatory Authority of Govt. of India)
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road
New Delhi-110002.

Dated the 28th August, 2014

SUBJECT:- MINUTES OF THE 14th AUTHORITY MEETING HELD ON 20th JUNE, 2014

The Authority adopted the minutes of the Fourteenth Authority Meeting of the Food Authority held on 20th June, 2014 at FDA Bhawan, Kotla Road, New Delhi-110002 in its fifteenth Authority Meeting held on 20th August, 2014 after amending the minutes with respect to the supplementary agenda no. 1 related to "Use of Lecithin and Sodium Stearoyl-2-lactylate in biscuits" as below:

"The Food Authority considered and approved the recommendation of the Scientific Committee and its subsequent draft amendment notification w.r.t. the use of Lecithin in biscuits".



(Pradip Chakraborty)
Director (Zone/Training)

Encl. Minutes of 14th Authority Meeting

**Food Safety & Standards Authority of India
(Ministry of Health & Family Welfare)**

File No. 15-02/GA/2014-15/FSSAI

Date: 11.07.2014

**Minutes of the 14th meeting of the Food Authority held on June 20, 2014 at 1100 hrs at
FDA Bhawan, New Delhi**

The fourteenth meeting of the Food Safety and Standards Authority of India (FSSAI) was held on June 20, 2014 at 1100 hrs. at FDA Bhavan, Kotla Road, New Delhi under the Chairmanship of Shri K. Chandramouli, Chairperson, FSSAI. The list of participants present in the meeting is as per **Annexure I**. Leave of absence was granted to the members who could not attend.

Chairperson welcomed the members of the Authority to the meeting and mentioned that after the last meeting a number of Scientific Panel and expert group meetings were held so that sufficient number of important scientific matters regarding standard setting could be brought to this meeting. Further, it was informed that the next meeting of the Authority will be held in August 2014 to complete the work w.r.t. the harmonization of Standards.

He drew the attention of the members towards the various Scientific Panel, expert group and Scientific Committee meetings being held on a continuous basis to strengthen the process of standard setting. He placed on record his appreciation for the work being done by all these scientific bodies of the FSSAI. He informed that the number of proposals of standardization going to panels has increased which would ultimately help in effective implementation of the Act and provide safety to the consumer as laid down in section 16 of the FSS Act, 2006. He also stated that the proposed Amendment in the Act as approved by the Union Cabinet for simplification in notification process was introduced in Rajya Sabha February 2014. This would help in simplifying the process so that standard setting is faster.

He hoped that the deliberations in the Authority would be fruitful. Thereafter, Chairperson, FSSAI requested CEO, FSSAI to conduct the proceedings of the meeting.

Item No. I: Disclosure of interest by members

All the members present during the meeting signed the "Specific Declaration of Interest" in respect of the agenda items to be considered in the meeting, before the proceedings of meeting.

Item No. II: Confirmation of the minutes of the last meeting held on 31st January, 2014

The Authority confirmed the minutes of the thirteenth meeting of the Food Authority held on 31st January, 2014. While adopting the minutes, Director (Codex), FSSAI informed that the Papers related to areca nut submitted by two members of the Authority have been forwarded for consideration to the concerned Director. With regard to the Agenda item pertaining to

product approval process, it was informed that issues raised by JS, MOFPI were replied to by FSSAI vide letter May 2014. Regarding the agenda item no. 12 of the thirteenth Authority meeting, it was informed that AGMARK is denotifying their standards & BIS is in the process of adopting those standards. Thereafter, the issue be taken up. Further, it was informed that the comments regarding enzymatic degumming will be referred to the concerned Expert Group for Oils & Fats.

Item No. III: Action Taken Report – 13th Authority Meeting

As decided and recorded in the minutes of the thirteenth meeting of the Food Authority held on 31st January, 2014, the Action Taken Report on the agenda items of the thirteenth meeting of the Food Authority was enclosed as information to the members of the Authority. The ATR of the previous meetings was also circulated as hard copy during the meeting.

Item No. IV: Chief Executive Officer's report

CEO welcomed all the distinguished members and briefed them about the activities undertaken by FSSAI after the last Authority meeting with respect to: enforcement activities including the number of Central licenses and State registration/ licenses issued by the States; surveillance activities; training and Capacity Building; IEC activities; Scientific Committee/ Scientific Panels meetings and the progress in work on the Standard Setting; harmonization of Standards with Codex; Codex activities and finance. It was informed that around 30 meetings of the Scientific Panels, expert groups and Scientific Committee have been held since the last Authority meeting. He also placed on record his thanks to the Chairs and the members of the Committee, Panels and the expert groups. The details of participation in various Codex Committee meetings was given and it was also informed that first meeting of the Codex Committee meeting on Spices and Culinary Herbs being hosted by India was held in February 2014 in Kochi.

CEO also drew attention of all the members towards some important cases going on in the Hon'ble Supreme Court and the Hon'ble High Court of Bombay. In the case of, Virender Kr. Yadav Vs UOI- pending before Hon'ble High Court of Lucknow-on the appointment of whole time designated officers in the State of Uttar Pradesh, FSSAI has initiated the process to amend the Rule 2.1.2 (b) of the FSS Rules, 2011 wherein the period for appointment of Designated Officer has been proposed to be amended from 1 year to 5 years. Further, as per the order dated 25.04.2013 of the Hon'ble High Court FSSAI has approved SIRD, Lucknow as the training institute under the provisions of Rule 2.1.3 of the FSS Regulations, 2011. A communication is also being addressed to all the State/UT Governments for appointment of full –time DOs.

The EFC meetings were held on 3rd January 2014 and 24th March 2014 respectively to discuss the Central Sector and Centrally Sponsored Schemes.

Some of the members placed on record the commendable job done by FSSAI. It was discussed and decided that the Panel and Committee minutes can be shared with the Authority members as was done this time.

AGENDA ITEMS

1. Approval for revised standards for salted fish/dried salted fish

There were a number of Agenda items from the Scientific Panel on Fish and Fisheries Products. Chairperson and CEO, FSSAI placed on record their appreciation for the work being done by the Scientific Panel for Fish & Fisheries Products under the Chairmanship of Dr. S. Ayyappan, DG, ICAR.

The Food Authority considered and approved the recommendations made by Scientific Committee on the revised standards for salted fish/dried salted fish as under.

Revised Title: Dried/ Salted and Dried fishery products

Dried fish/dry salted fish means the product prepared from fresh or wholesome fish 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.

The product shall be free from foreign matter, objectionable odour and flavour. The product may contain food additives permitted in Appendix A. The product shall conform to the microbiological and chemical requirement as laid down in the regulation. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
1.	Water activity (a_w), at 25°C	Less than 0.78
2.	Salt Content (percent Sodium Chloride)*	Not less than 12 %
3.	Histamine** content, max.	200 mg/Kg, max.
4.	Acid Insoluble Ash	Not more than 1%

*Requirement of salt content is only applicable to dry salted fishery products

** Requirement of Histamine content is only applicable for dried/dry-salted fishery products prepared from listed fish species associated with histamine fish poisoning (at annexure –II)

2. Approval of revised list of fish species having potential to cause histamine fish poisoning

The Food Authority considered and approved the recommendations made by Scientific Committee on the revised list of fish species having potential to cause histamine fish poisoning as enclosed at **Annexure II**.

3. Approval for revision of limits of histamine level for fish and fishery products

The Food Authority considered and approved the recommendations made by Scientific Committee on the revised limits of histamine level for fish and fishery products as enclosed at **Annexure III**.

4. Approval for revised pharmacologically active substances prohibited for fish and fishery products

The Food Authority considered and approved the recommendations made by Scientific Committee on 18 pharmacologically active substances prohibited for fish and fishery products namely 1) Nitrofurans including (i) Furaltadone, (ii) Furazolidone, (iii) Nitrofurantoin, (iv) Nitrofurazone; 2) Chloramphenicol; 3) Sulphamethoxazole; 4) Aristolochiaspp and preparations thereof; 5) Chloroform; 6) Chlorpromazine; 7) Colchicine; 8) Dapsone; 9) Dimetridazole; 10) Metronidazole; 11) Ronidazole; 12) Iprnidazole other nitromidazoles; 13) Clenbuterol; 14) Diethylstilbestrol (DES); 15) Glycopeptides; 16) Stilbenes and other steroids; 17) Crystal Violet; and 18) Malachite Green.

5. Approval for revised heavy metals in fish and fishery Products

The Food Authority considered and approved the recommendations made by Scientific Committee on the revised heavy metals in fish and fishery Products as enclosed at **Annexure IV**.

6. Approval for limits of Biotoxins in Fish and Fishery Products

The Food Authority considered and approved the recommendations made by Scientific Committee on limits of Biotoxins in fish and fishery products as under:

Applicable Fishery Product	Biotoxin	Limit
Bivalve Molluscs	Paralytic Shellfish Poison (PSP)	80 µg/100g (Saxitoxin Equivalent)
	Amnesic Shellfish Poison (ASP)	20 µg/g (Domoic acid equivalent)
	Diarrhetic shellfish poison (DSP)	160 µg of Okadaic acid

		equivalent/Kg
	Azaspiracid poison (AZP)	160 µg of azaspiracid equivalent/Kg
	Brevetoxin (BTX)	200 mouse units or equivalent/Kg

7. Approval for limits of contaminants: Polychlorinated biphenyls (PCBs) and Polycyclic aromatic hydrocarbon (PAH) compounds in Fish and Fishery Products

The Food Authority considered and approved the recommendations made by Scientific Committee on limits of contaminants: Polychlorinated biphenyls (PCBs) and Polycyclic aromatic hydrocarbon (PAH) compounds in Fish and Fishery Products as under:

Category of Food Product	Parameter	Limit
Inland and Migratory Fish	Polychlorinated biphenyls (Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180)	2.0 ppm
Marine Fish, Crustaceans and molluscs	Polychlorinated biphenyls (Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180)	0.5 ppm
Smoked Fishery Products	Benzo(a)pyrene	5.0 ppb

Further it was informed that the microbiological, pesticide & antibiotic residues and veterinary drugs for fish & fishery products is under the consideration of the Panel.

8. Approval of microbiological standards for milk and milk products

The Food Authority considered and approved the recommendations made by Scientific Committee on microbiological standards for milk and milk products as enclosed at **Annexure V**.

However a few Authority members had certain technical suggestions to which Chairperson, FSSAI asked them to send their comments in advance to the Authority that will be taken up during the compilation of the comments received on the draft notification of microbiological standards for milk and milk products.

9. Approval of microbial standards for fruits and vegetable products

The Food Authority held up this agenda and further invited comments from the members of the Authority by June 2014 end for consideration by the Scientific Panel for Biological Hazards, the meeting of which is scheduled for July, 2014.

10. Approval of microbial standards for meat and meat products

The Food Authority considered and approved the recommendations made by Scientific Committee on microbiological standards for meat and meat products as enclosed at **Annexure VI**.

11. Approval for standards for water used into food during its manufacture, preparation or treatment (Water as an Ingredient in Food)

The Food Authority considered and approved the recommendations made by Scientific Committee for standards for water used into food during its manufacture, preparation or treatment (Water as an Ingredient in Food) as enclosed at **Annexure VII**.

12. Approval for standards of lactic acid - food grade

The Food Authority considered and approved the recommendations made by Scientific Committee for standards of lactic acid - food grade as enclosed at **Annexure VIII**.

13. Approval for standards of malt extract

The Food Authority considered and approved the recommendations made by Scientific Committee for standards of malt extract as enclosed at **Annexure IX**. One of the Authority member suggested incorporating "malt is generally prepared by the germinating of whole grains, so as such malt or malt extract cannot be prepared from wheat gluten, corn grits, edible starches (such as potato or tapioca) and legume flours" under pt. no. 3.1 of head No. 3 (Requirements).

14. Approval for adoption of ICMR/DBT guidelines for probiotics

The Food Authority considered and approved the recommendations made by Scientific Committee for adoption of ICMR/DBT guidelines for probiotics with a minor modification in the title as 'ICMR/DBT guidelines for evaluation of probiotics in food' as enclosed at **Annexure X**.

15. Adoption of ICMR guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants

The Food Authority noted this agenda item which was for information to the members of the Authority.

- 16. Draft amendment to Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 w.r.t. fixation of MRLs of 24 pesticides recommended by Scientific Panel on Pesticides and Antibiotic Residues of FSSAI and approved by Scientific Committee in its 11th meeting held on 25.03.2014**

The Food Authority considered and approved the amendment in Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 w.r.t. fixation of MRLs of 24 pesticides recommended by Scientific Panel on Pesticides and Antibiotic Residues of FSSAI as enclosed at **Annexure XI**.

- 17. Final approval of following draft notifications:**

- a. **Food Safety and Standards (Food Products Standards & Food Additives) 2nd amendment Regulations, 2013 (No. 1-83/Sci Pan- Noti/FSSAI-2012 dated 16.5.2013)**
- b. **Food Safety and Standards (Packaging and Labelling) 2nd amendment Regulations, 2013 dated 10-09-2013(No 1-83/Sci Pan- Noti/FSSAI-2012 dated 16.5.2013)**

The Food Authority considered the proposed Food Safety and Standards (Food Products Standards & Food Additives) 2nd amendment Regulations, 2013 & Food Safety and Standards (Packaging and Labelling) 2nd amendment Regulations, 2013. It was pointed out by one of the member that milk powder was inadvertently omitted after dairy based drinks under Sub-regulation 2D(iii) related to Trehalose and added in Oligofructose though it was cleared by CCFS and incorporated into GSR 92E dated 14.02.2011 for Trehalose only. Based on the comments received, the Panel has also approved use of Trehalose in milk powders only in its meeting held on 06.12.2013. Hence, milk powder would be incorporated in the Regulation with this addition under Trehalose and removed from under Oligofructose. There were other editorial corrections also suggested by the member. Accordingly, the Authority approved the Regulation as enclosed at **Annexure-XII**.

- 18. Ingredients approved in the meetings of the Scientific Panel on Functional Food, Nutraceuticals and Dietetic Products and Other Similar Products & the Scientific Committee**

The Food Authority considered and approved the inclusion of following ingredients in the Draft Notification on Food/Health supplements and Nutraceuticals:

- 1) Lactase enzyme with their level [i.e. 3000 to 9000 IU (or FCC units) per day] in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements.

- 2) Selenium Yeast in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements.
- 3) Ferrochel Bisglycinate (elemental Ferrous Bisglycinate) in the list of Minerals of the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements.
- 4) CoQ10 (ubiquinone and ubiquinol) from non GM source up to 1000 mg usage level per day with a minimum of 100 mg usage level per day in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements.
- 5) Bilberry extract containing Lutein from *Vaccinium myrstillus* (to be tested for lutein content) up to 600 mg usage per day with a minimum usage level of 50mg/day in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements.
- 6) Citrus Bioflavonoids (*Citrus x paradisi*, *Citrus reticulata x maxima*, *C. x sinensis* and *Citrus limon*) up to 600 mg usage per day with a minimum usage level of 150mg/day in the list of Nutraceuticals under the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements under FSSR and its testing for total polyphenols content.
- 7) Echinacea (*E. angustifolia*, *E. purpurea*, and *E. pallida*) up to 900 mg usage per day in the list of Nutraceuticals under the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements. The extracts may be tested for content of alkamides (0.25 mg/ml) and cichoric acid (2.5 mg/ml), if the extract used is in liquid form. In case of Hydroethanolic Echinacea extract is in a powdered form computation may be done proportionately to the weight/weight dry powder extract based on liquid extract used to obtain a dry powder format.
- 8) Panax ginseng (syn. Korean Ginseng) - Ginseng extract (obtained from 0.6 to 2.0 gm of Ginseng root, (*Panaxginseng*.C A. Meyer, Araliaceae) upto 400 mg per day usage levels, with a minimum of 90mg usage per day in the list of Nutraceuticals under the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements and its testing for Ginsenoside content ranging from 0.7 to 3%.
- 9) Siberian ginseng- Ginseng extract obtained from 0.6 to 2.0 gm of Ginseng root (*Acanthopanaxsenticosus*, belonging to panax type, C A. Meyer, Araliaceae) up to 450 mg per day usage levels, with a minimum of 100 mg usage per day in the list of Nutraceuticals under the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements and its testing for releutherosides.
- 10) Ginkgo biloba extract obtained from dried leaves of Ginkgo (*Ginkgo biloba*.L.) at a usage level of 240 mg per day with a minimum of 120mg usage per day in the list of Nutraceuticals under the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements under FSSR and Ginkgo biloba extract testing for Ginkgo flavone glycosides and Ginkgolides (diterpene lactones).

Total flavonoids content (20.2 to 27% calculated as flavanol glycosides and tested for total terpene lactones (5.4% to 12.0%). Presence of Ginkgolides A, B, C needs to be tested qualitatively.

- 11) Quercetin obtained from extracts of citrus fruits and other vegetables providing Quercetin at the maximum usage level of 100mg/day in the list of Nutraceuticals under the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements.
- 12) Black cohosh extract from dried rhizomes and roots of *Cimicifugaracemosa* (or *Actaearacemosa*)) at a maximum usage level of 200 mg per day and a minimum of 40 mg per day usage level in the list of Nutraceuticals under the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements and Black cohosh extract testing for total triterpene glycosides (minimum 0.4%), calculated as 23-epi-26-deoxyactein.
- 13) Phycocynin Spirulinaplantesis (*Aethrospiraplantesis*) at the range of 50 mg to 250 mg with the composition: Protein -50-70 %, Carbohydrates -20-40%, Minerals (Ash)-5.0 – 15%, Moisture-3.0 – 6.0 % in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional Foods, Novel Food and Food/Health supplements.

19. Draft regulation on Gluten free and low gluten food products

The Food Authority considered and approved the draft regulation on Gluten free and low gluten food products as enclosed at **Annexure XIII**.

20. Status note on Harmonization of India's Food Standards with Codex Standards and other International Best Practices

The Food Authority noted the status of Harmonization of India's Food Standards with Codex Standards and other International Best Practices which was put up as an information agenda item.

21. Manuals on Adjudicating Officer, Designated Officer and Food Safety Officer

The Food Authority considered the Manuals on Adjudicating Officer, Designated Officer and Food Safety Officer which was put up as an information agenda item. However, CII had a few comments which they would send to the Authority for further consideration.

22. Harmonisation of Horizontal Standards for Microbiological Contamination (Mycotoxins) in Food

The Food Authority considered and approved the recommendation of the Scientific Committee and its subsequent draft Food Safety and Standards (Contaminants, Toxins

and Residues) (Amendment) Regulations, 2014 w.r.t. Horizontal Standards for Microbiological Contamination (Mycotoxins) in Food as enclosed at **Annexure XIV**.

23. Harmonisation of Horizontal Standards for Heavy Metals for All Food Product Categories.

The Food Authority considered and approved the recommendation of the Scientific Committee and its subsequent draft Food Safety and Standards (Contaminants, Toxins and Residues) (Amendment) Regulations, 2014 w.r.t. Horizontal Standards for Heavy Metals for All Food Product Categories as enclosed at **Annexure XV**. However, it was informed that the Standards for heavy metals in Fish have not been covered and would be incorporated later from Scientific Panel for Fish & Fisheries Products.

A few Authority members had certain suggestions/comments which they would send in advance to the Authority and that will be taken up during the compilation of the comments received on the said draft notification.

24. Harmonisation of Horizontal Standards for NOTS (Naturally Occurring Toxins) for all Food Products Categories.

The Food Authority considered and approved the recommendation of the Scientific Committee and its subsequent draft Food Safety and Standards (Contaminants, Toxins and Residues) (Amendment) Regulations, 2014 w.r.t. Horizontal Standards for NOTS (Naturally Occurring Toxins) for all Food Products Categories as enclosed at **Annexure XVI**.

One member mentioned that trypsin inhibitor is also a naturally occurring toxic substance and a maximum level for this should also be considered taking into account the recommendation of ICMR with respect to its presence in soybeans. It was decided that this work could be taken up separately.

25. Agenda arises from Authority Meeting held on 31.1.2014

The Food Authority considered the agendas and approved only one agenda related to the draft notification on Phytosterols with revised labelling provisions as enclosed at **Annexure XVII**.

SUPPLEMENTARY AGENDA'S

Supplementary Agenda item 1. Use of Lecithin and Sodium stearoyl-2-lactylate in biscuits

The Food Authority considered and approved the recommendation of the Scientific Committee and its subsequent draft amendment notification w.r.t. the use of Lecithin and Sodium stearoyl-2-lactylate in biscuits as enclosed at **Annexure XVIII**.

It was also agreed to issue clarification in regard to lecithin pending the amendment.

Supplementary Agenda item 2. Use of Synthetic colour in thermally processed bell pepper, okra and spinach

The Food Authority considered and approved the draft amendment notification w.r.t. the removal of provision for use of synthetic colour in thermally processed green beans/ wax beans/ green peas and processed peas from table 7 under C (b) of FSS Regulations (Food Product Standards and Food Additives), 2011 as enclosed at **Annexure XIX**.

Supplementary Agenda item 3. Approval of "Sodium Alginate" as a Food Additive in Ice Cream

The Food Authority considered and approved the recommendation of the Scientific Committee and its subsequent draft notification w.r.t. the use of Sodium Alginate in ice cream as a food additive at GMP as enclosed at **Annexure XX**.

Supplementary Agenda item 4. Finalisation & adoption of Draft FSSAI Manuals on Method of Analysis of Food

The Food Authority considered and approved the draft FSSAI Manuals on Method of Analysis of Food namely 1. Analysis of Metals; 2. Analysis for Food Additives; 3. Beverages, Sugars and Sugar Products and Confectionery; 4. Cereal and Cereal Products; 5. Manual of Methods Spices and Condiments; 6. Meat & Meat Products and Fish & Fish Products; 7. Milk and Milk Products; 8. Mycotoxins; 9. Oils and fats; 10. Pesticide Residues Analysis in Food; 11. Fruits and Vegetables Products; 12. Antibiotics and Hormone Residues; 13. Manual on "General Guideline on Sampling"; and 14. Method of Testing of Alcoholic Drinks.

In the end Chairperson, FSSAI thanked all the Authority members for actively participating in the meeting and it was decided that the next Authority meeting may be convened in the month of August 2014.


Chief Executive Officer

Chairperson

Annexure I

List of participants**Members of the Authority**

1. Shri K. Chandramouli, Chairperson, FSSAI
2. Shri D.K. Samantaray, Member Secretary
3. Dr. Arun Kumar Panda, Joint Secretary, Ministry of Health & Family Welfare, New Delhi.
4. Shri Utpal Kumar Singh, Joint Secretary, DAC, Krishi Bhawan, New Delhi.
5. Ms. Anuradha Prasad, Joint Secretary, Ministry of Food Processing Industries, Panchsheel Bhawan, New Delhi.
6. Dr. (Ms.) Lalitha Ramakrishna Gowda, Chief Scientist, Department of Protein Chemistry and Technology, CSIR, Mysore, Karnataka.
7. Shri Salim A. Veljee, Commissioner, Food Safety, Goa & Director, Food & Drug Administration, State of Goa.
8. Shri K. S. Rana, Designated Officer, Food Safety Cell, Chandigarh
9. Dr. AR Sharma, CMD, M/s Ricelaa Health Foods Ltd. Village Manwala, Saron Road, Dhuri, Sangrur, Punjab.
10. Shri Vasudev K Thakkar, President, 'V' Care Right & Duty NGO. V. Care House Opp. Keval Farm, Karodia Road, Post-Bajwa, Vadodra, Gujarat.
11. Ms Shreya Pandey, All India Food Processors' Association, 206, Aurobindo Place Market, Hauz Khas, New Delhi.
12. Ms. Meetu Kapur, Confederation of Indian Industry (CII), India Habitat Centre, Core 4A, Ground Floor, Lodhi Road, New Delhi.
13. Shri Thanglura, Mizoram Consumers' Union, Lalat Chamber, Temple Square, Tuikual South, Aizawl, Mizoram.
14. Shri Abukalam, Madina Munavara Coffee Estate, Jayapura Koppa Taluk Chikmagalur, Karnataka.

Officers of FSSAI

1. Shri S. Dave, Advisor, FSSAI
2. Ms. Vinod Kotwal, Director (Codex/Estt./FA/IEC), FSSAI

3. Dr. Sandhya Kabra, Director (QA/PA/Imports), FSSAI
4. Dr. Meenakshi Singh, Scientist (Standards), FSSAI
5. Dr. Pradeep Chakraborty, Director (Zone & Training), FSSAI
6. Dr. Bimal Kumar Dubey, Director (Enforcement & Surveillance), FSSAI
7. Shri Rakesh Kulshrestha, JD(M), FSSAI
8. Shri Anil Mehta, DO(Northern Region), FSSAI
9. Shri PK Karthikeyan, AD (Regulation), FSSAI
10. Shri Sanjay Gupta, AD (Enf.), FSSAI
11. Shri BG Pandian, AD (Imports), FSSAI
12. Dr. Rajesh Kumar, Scientist IV (1), FSSAI

Annexure – II

List of fish species having potential to cause histamine fish poisoning:

Sl.No.	Trade Name	Family	Scientific Name
1.	Lesser Eel or Small Sandeel	Ammodytidae	<i>Ammodytes</i> spp
2.	Lesser Eel or Small Sandeel	Ammodytidae	<i>Ammodytes tobianus</i>
3.	Lesser Eel or Small Sandeel	Ammodytidae	<i>Ammodytes personatus</i>
4.	Kahawai/Western Australian Salmon	Arripidae	<i>Arripis</i> spp.
5.	Australian salmon	Arripidae	<i>Arripis trutta</i>
6.	Garfish	Belonidae	<i>Belone belone</i>
7.	Amberjack or Yellowtail	Carangidae	<i>Seriola</i> spp.
8.	Yellowtail Amberjack	Carangidae	<i>Seriola lalandi</i>
9.	Japanese Amberjack	Carangidae	<i>Seriola quinqueradiata</i>
10.	Longfin Yellowtail	Carangidae	<i>Seriola rivoliana</i>
11.	Greater/Japanese Amberjack or Rudder Fish	Carangidae	<i>Seriola dumerili</i>
12.	Jack/Trevally	Carangidae	<i>Caranx</i> spp.
13.	Blue runner	Carangidae	<i>Caranx crysos</i>
14.	White trevally	Carangidae	<i>Pseudocaranx dentex</i>
15.	Yellow Jack	Carangidae	<i>Carangoides bartholomaei</i>
16.	Leather Jacket	Carangidae	<i>Oligoplites saurus</i>
17.	Moonfish	Carangidae	<i>Selene</i> spp.
18.	Cottonmouth jack	Carangidae	<i>Uraspis secunda</i>
19.	Indian Threadfish	Carangidae	<i>Alectis indica</i>
20.	Rainbow Runner	Carangidae	<i>Elagatis bipinnulata</i>
21.	Roosterfish	Carangidae	<i>Nematistius pectoralis</i>
22.	Scad	Carangidae	<i>Decapterus</i> spp.
23.	Koheru	Carangidae	<i>Decapterus koheru</i>
24.	Indian scad	Carangidae	<i>Decapterus russelli</i>
25.	Jack Mackerel/Horse Mackerel	Carangidae	<i>Trachurus</i> spp.
26.	Cape Horse Mackerel	Carangidae	<i>Trachurus capensis</i>
27.	Yellowtail Horse Mackerel	Carangidae	<i>Trachurus novaezelandiae</i>
28.	Japanese Jack Mackerel	Carangidae	<i>Trachurus japonicas</i>
29.	Atlantic Horse Mackerel	Carangidae	<i>Trachurus trachurus</i>
30.	Chilean Jack Mackerel	Carangidae	<i>Trachurus murphyi</i>
31.	Leather Jacket/Queen Fish	Carangidae	<i>Scomberoides</i> spp.
32.	Talang queenfish	Carangidae	<i>Scomberoides commersonnianus</i>
33.	Trevally	Carangidae	<i>Caranx</i> spp.
34.	Horse Mackerel/Torpedo Scad	Carangidae	<i>Megalaspis cordyla</i>
35.	Trevally	Carangidae	<i>Carangoides</i> spp.
36.	Scad	Carangidae	<i>Alepes</i> spp.
37.	Cleftbelly trevally	Carangidae	<i>Atropus atropus</i>
38.	Scad	Carangidae	<i>Decapterus</i> spp.
39.	Milkfish	Chanidae	<i>Chanos chanos</i>

40.	Herring	Clupeidae	<i>Alosa</i> spp.
41.	Alewife	Clupeidae	<i>Alosa pseudoharengus</i>
42.	Red-eye round herring	Clupeidae	<i>Etrumeus sadina</i>
43.	Tardoore	Clupeidae	<i>Opisthopterus tardoore</i>
44.	Pichard/Shad/Herring	Clupeidae	<i>Clupea</i> spp.
45.	Atlantic herring	Clupeidae	<i>Clupea harengus</i>
46.	Araucanian herring	Clupeidae	<i>Clupea bentincki</i>
47.	Pacific herring	Clupeidae	<i>Clupea pallasii pallasii</i>
48.	Thread Herring	Clupeidae	<i>Opisthonema</i> spp
49.	Pacific thread herring	Clupeidae	<i>Opisthonema libertate</i>
50.	Sprat/Herring	Clupeidae	<i>Harengula</i> spp.
51.	Pacific flatiron herring	Clupeidae	<i>Harengula thrissina</i>
52.	Silver-stripe round herring	Clupeidae	<i>Spratelloides gracilis</i>
53.	Menhaden	Clupeidae	<i>Brevoortia</i> spp.
54.	Gulf Menhaden	Clupeidae	<i>Brevoortia patronus</i>
55.	Atlantic Menhaden	Clupeidae	<i>Brevoortia tyrannus</i>
56.	Pacific Menhaden	Clupeidae	<i>Ethmidium maculatum</i>
57.	Sardine	Clupeidae	<i>Sardinella</i> spp.
58.	Round Sardinella	Clupeidae	<i>Sardinella aurita</i>
59.	Indian Oil Sardine	Clupeidae	<i>Sardinella longiceps</i>
60.	Gold stripe Sardinella	Clupeidae	<i>Sardinella gibbosa</i>
61.	Madeiran Sardinella	Clupeidae	<i>Sardinella maderensis</i>
62.	South American Pilchard	Clupeidae	<i>Sardinops</i> spp.
63.	South American Pilchard	Clupeidae	<i>Sardinops sagax</i>
64.	European Pilchard	Clupeidae	<i>Sardina pilchardus</i>
65.	Spotted Sardinella	Clupeidae	<i>Amblygaster sirm</i>
66.	Bonga Shad	Clupeidae	<i>Ethmalosa fimbriata</i>
67.	Gizaard Shad	Clupeidae	<i>Dorosoma</i> spp.
68.	Chacunda gizzard shad	Clupeidae	<i>Anodontostoma chacunda</i>
69.	Gizzard Shad	Clupeidae	<i>Nematolosa</i> spp.
70.	Hilsa shad	Clupeidae	<i>Tenualosa ilisha</i>
71.	Shad	Clupeidae	<i>Hilsa</i> spp.
72.	Shad	Clupeidae	<i>Tenualosa</i> spp.
73.	Mahi-Mahi /Dolphin fish	Coryphaenidae	<i>Coryphaena hippurus</i>
74.	Anchovy	Engraulidae	<i>Anchoa</i> spp.
75.	Anchovy	Engraulidae	<i>Anchoviella</i> spp.
76.	Pacific anchoveta	Engraulidae	<i>Cetengraulis mysticetus</i>
77.	Anchovy	Engraulidae	<i>Engraulis</i> spp.
78.	Peruvian anchovy	Engraulidae	<i>Engraulis ringens</i>
79.	European anchovy	Engraulidae	<i>Engraulis encrasicolus</i>
80.	Southern African anchovy	Engraulidae	<i>Engraulis capensis</i>
81.	Japanese anchovy	Engraulidae	<i>Engraulis japonicus</i>
82.	Anchovy	Engraulidae	<i>Stolephorus</i> spp.
83.	Escolar	Gempylidae	<i>Lepidocybium flavobrunneum</i>
84.	Oil Fish	Gempylidae	<i>Ruvettus prestiosus</i>
85.	Piper	Hemiramphidae	<i>Hyporhamphus ihi</i>
86.	Atka Mackerel	Hexagrammidae	<i>Pleurogrammus monopterygius</i>
87.	Okhotsk Atka Mackerel	Hexagrammidae	<i>Pleurogrammus azonus</i>

88.	Marlin/Sailfish	Istiophoridae	<i>Makaira</i> spp.
89.	Indo-Pacific blue marlin	Istiophoridae	<i>Makaira mazara</i>
90.	Striped Marlin	Istiophoridae	<i>Kajikia audax</i>
91.	Marlin/Spearfish	Istiophoridae	<i>Tetrapturus</i> spp.
92.	Black Marlin	Istiophoridae	<i>Istiompax indica</i>
93.	Atlantic sailfish	Istiophoridae	<i>Istiophorus albicans</i>
94.	Atlantic white marlin	Istiophoridae	<i>Kajikia albida</i>
95.	Spearfish	Istiophoridae	<i>Tetrapturus</i> spp.
96.	Indo-Pacific sailfish	Istiophoridae	<i>Istiophorus platypterus</i>
97.	Flathead Grey Mullet	Mugilidae	<i>Mugil cephalus</i>
98.	Bluefish	Pomatomidae	<i>Pomatomus saltatrix</i>
99.	Ilisha/Pellona	Pristigasteridae	<i>Ilisha</i> spp.
100.	Indian pellona	Pristigasteridae	<i>Pellona ditchella</i>
101.	Salmon/Trout	Salmonidae	<i>Salmo</i> or <i>Oncorhynchus</i> spp.
102.	Atlantic Salmon	Salmonidae	<i>Salmo salar</i>
103.	Chinook salmon	Salmonidae	<i>Oncorhynchus tshawytscha</i>
104.	Chum Salmon	Salmonidae	<i>Oncorhynchus keta</i>
105.	Coho salmon	Salmonidae	<i>Oncorhynchus kisutch</i>
106.	Amago salmon	Salmonidae	<i>Oncorhynchus macrostomus</i>
107.	Cherry salmon	Salmonidae	<i>Oncorhynchus macrostomus</i>
108.	Masu Salmon	Salmonidae	<i>Oncorhynchus masou</i>
109.	Sockeye salmon	Salmonidae	<i>Oncorhynchus nerka</i>
110.	Pink salmon	Salmonidae	<i>Oncorhynchus gorbuscha</i>
111.	Rainbow Trout	Salmonidae	<i>Oncorhynchus mykiss</i>
112.	Pacific Saury	Scomberesocidae	<i>Cololabis saira</i>
113.	Atlantic Saury	Scomberesocidae	<i>Scomberesox saurus saurus</i>
114.	Leaping Bonito	Scombridae	<i>Cybiosarda elegans</i>
115.	Dogtooth tuna	Scombridae	<i>Gymnosarda unicolor</i>
116.	Plain Bonito	Scombridae	<i>Orcynopsis unicolor</i>
117.	Bonito	Scombridae	<i>Sarda</i> spp
118.	Bullet Tuna/Frigate Tuna	Scombridae	<i>Auxis</i> spp.
119.	Butterfly kingfish	Scombridae	<i>Gasterochisma melampus</i>
120.	Short Mackerel	Scombridae	<i>Grammatorcynus</i> spp.
121.	Short Mackerel	Scombridae	<i>Rastrelliger brachysoma</i>
122.	Indian Mackerel	Scombridae	<i>Rastrelliger kanagurta</i>
123.	Mackerel	Scombridae	<i>Scomber</i> spp.
124.	Atlantic mackerel	Scombridae	<i>Scomber scombrus</i>
125.	Chub mackerel	Scombridae	<i>Scomber japonicus</i>
126.	Blue mackerel	Scombridae	<i>Scomber australasicus</i>
127.	Spanish Mackerel	Scombridae	<i>Scomberomorus</i> spp.
128.	Narrow-barred Spanish mackerel	Scombridae	<i>Scomberomorus commerson</i>
129.	King Mackerel	Scombridae	<i>Scomberomorus cavalla</i>
130.	Japanese Spanish mackerel	Scombridae	<i>Scomberomorus niphonius</i>
131.	Indo-Pacific king mackerel/Spotted Spanish Mackerel	Scombridae	<i>Scomberomorus guttatus</i>
132.	Streaked seerfish	Scombridae	<i>Scomeromorus lineolatus</i>
133.	Tuna	Scombridae	<i>Thunnus</i> spp.
134.	Albacore Tuna	Scombridae	<i>Thunnus alalunga</i>

135.	Yellowfin Tuna	Scombridae	<i>Thunnus albacares</i>
136.	Blackfin Tuna	Scombridae	<i>Thunnus atlanticus</i>
137.	Southern bluefin tuna	Scombridae	<i>Thunnus maccoyi</i>
138.	Bigeye Tuna	Scombridae	<i>Thunnus obesus</i>
139.	Pacific bluefin tuna	Scombridae	<i>Thunnus orientalis</i>
140.	Atlantic bluefin tuna	Scombridae	<i>Thunnus thynnus</i>
141.	Longtail Tuna	Scombridae	<i>Thunnus tonggol</i>
142.	Skipjack Tuna	Scombridae	<i>Katsuwonus pelamis</i>
143.	Little tuna or Kawakawa	Scombridae	<i>Euthynnus affinis</i>
144.	Bonito	Scombridae	<i>Euthynnus</i> spp.
145.	Wahoo	Scombridae	<i>Acanthocybium solandri</i>
146.	Swordfish	Xiphiidae	<i>Xiphias gladius</i>

Annexure – III

Limits of histamine level in fish & fishery products:

Product Category	Applicable to	Histamine Level
1. Raw/Chilled/Frozen Finfish	Species with high amount of free histidine (Listed fish species with potential to cause histamine fish poisoning)	n=9, c=2; m=100 mg/kg, M=200 mg/kg
2. Dried/ Salted and Dried fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
3. Thermally Processed Fishery Products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
4. Fermented Fishery products		n=9, c=2; m=200 mg/kg, M=400 mg/kg
5. Smoked fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
6. Fish Mince/Surimi and analogues		n=9, c=2; m=100 mg/kg, M=200 mg/kg
7. Fish Pickle		n=9, c=2; m=200 mg/kg, M=400 mg/kg
8. Battered and breaded fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
9. Other Ready to Eat fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
10. Other value added fishery products		n=9, c=2; m=100 mg/kg, M=200 mg/kg
11. Other fish based products		n=9, c=2; m=100 mg/kg, M=200 mg/kg

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 exceed 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 $>M$

Annexure – IV

Revised heavy metals in fish and fishery products:**(i) Arsenic**

Category	Limits (Total Arsenic)
Fish and Crustaceans:	76 ppm
Molluscs:	86 ppm

(ii) Cadmium

Category	Limits
Fish:	0.3 ppm
Crustaceans:	0.5 ppm
Cephalopods:	2.0 ppm
Bivalve Molluscs:	2.0 ppm

(iii) Mercury

Category Speciation ^{II}	Limit (Total)
Non-predatory Fish, crustaceans, cephalopods, molluscs	0.5 ppm
Predatory Fish (Tuna, Marlin, Sword Fish, Elasmobranch)	1.0 ppm

*Methyl Mercury to be analyzed if total mercury value exceeds MRL

(iv) Lead

Category	Limits
Fish:	0.3 ppm
Crustacean:	0.5 ppm
Cephalopods:	1.0 ppm
Bivalve Molluscs:	1.5 ppm

(v) Chromium (approved limits)

Chromium: 12 ppm (all Fishery Products)

(vi) Tin (approved limits)

Tin: 200 ppm (only for canned fish products)

Product Description	Table-1 Microbiological Requirements for Milk and Milk Products -Hygiene Indicator Organisms																					
	Total Plate Count				Coliform Count				Staph. aureus (Coagulase positive)				Yeast and mold count				Faecal streptococci					
	Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)			
	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M		
Flavored Milk ¹	5(3)	3	30,000/mL	50,000/mL	5(3)	0	Absent/0.1mL		5	0	Methylene blue reduction test (MBRT) applicable at Manufacturing unit shall not decolorized in 5 hrs (M value) when tested in accordance with the IS 1479 (Part III-1977-1992)				-							
Ice Cream	5(3)	3	50,000/g	75,000/g	5(3)	0	10/g		-	-	-				-							
Flavored Milk / Evaporated	5(3)	2	10/mL ²	100/mL ²	-														-			
Ice Cream	-	-	-														-					
Condensed Milk	5(3)	3	500/g	1,000/g	5(3)	0	Absent/0.1g		5(3)	0	10/g		5(3)	0	10/g		-					
Ice Cream Mix powder ³	5(3)	3	25,000/g	50,000/g	5(3)	2	Absent/0.1g	20/g	5(3)	2	10/g	50/g	5(3)	3	20/g	50/g	-					
Ice Cream Mix powder ; Dairy Whitener ; Ice Cream Mix powder ; based powder ; Butter Milk Mix powder ⁴	5(3)	2	30,000/g	50,000/g	5(3)	2	Absent/0.1g	50/g	5(3)	2	10/g	100/g	5(3)	0	5/0.1g ⁴		-					
Infant Formulae, Infant Milk	5(3)	2	500/g	5000/g	10 (10)	0	Absent/0.1g		5(3)	0	Absent/0.1g		5(3)	0	Absent/0.1g		5	0	Absent/0.1g			
Infant Formula			500/g	5000/g																		
Infant Formula			1,000/g	10,000/g																		
Ice Cream Dessert, Milk Lolly, Ice	5(3)	3	100,000/g	200,000/g	5(3)	3	10/g	100/g	5(3)	2	10/g	100/g	-	-	-	-	-					
Cheese/ Cheese Spread (Ready to Eat)	5(3)	2	25,000/g	50,000/g	5(3)	0	10/g		5(3)	0	10/g		-	-	-	-	-					
Cheese Categories Including Fresh Curd /Cottage /Soft /Semi Soft ⁵ To Eat Products)	-	-	-	-	5(3)	3	100/g	500/g	5(3)	3	10/g	100/g	-	-	50/g	250/g	-					
Ice Cream products : Yoghurt, Dahi, and ⁶ etc	-	-	-	-	5(3)	2	10/g	100/g	5(3)	2	10/g	100/g	5(3)	3	50/g	100/g	-					
Ice Cream / Chhana based sweets	5(3)	3	150,000/g	350,000/g	5(3)	3	10/g	100/g	5(3)	3	10/g	100/g	5(3)	3	50/g	150/g	-					
Ice Cream / Sweets	5(3)	3	25,000/g	75,000/g	5(3)	2	50/g	100/g	5(3)	3	10/g	100/g	5(3)	3	10/g	50/g	-					
Method of Analysis	IS 5402				IS 5401, Part 1				IS 5887, Part 8/Sec 1				IS 5403				IS 5887 (Part-2)					

be stored at manufacturing unit and at retail points in such a way that temperature of milk shall not exceed 8°C as recommended in IS 13688: 1999

in sterilized products shall be checked after incubation at 30°C for 15 days following IS: 5402:2002.

ations for ripened butter are the same as for pasteurized butter excluding the requirements of total plate count.

unit of 5/0.1g as specified in dried product categories shall be applicable only to casein powder

units in all other cheese category will be applicable except mold ripened cheeses.

ents of lactic counts of one million c.f.u./g min as specified by BIS (IS:12898:1989) in such products/ or such products containing probiotic organisms shall be applicable

s indicate no of samples required for testing at retail points:

Table-2 Microbiological Requirements For Milk and Milk Products -Safety Indicator Organisms																			
<i>E.coli</i>		Salmonella / Shigella		<i>L. monocytogenes</i>		<i>B. cereus</i>		Sulphite Reducing Clostridia (SRC)				<i>Enterobacter sakazakii</i>							
Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)	
n	c	M		n	c	M		n	c	m	M	n	c	m	M	n	c	m	M
(3)	0	Absent/ 0.1mL		5(3)	0	Absent/25mL		5(3)	0	Phosphatase test shall be negative as per IS 8479 (Parts I - 1977) before release of product in the market ^b						-			
(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	-						-			
5(3)	0	Sterilized milk products shall comply with a test for commercial sterility as per BIS (IS: 4238-1967) where the acidity does not show a difference of more than 0.02 g from the initial acidity and with no sign of physical alteration during incubation at 55 ± 1°C for 7 days will be considered as sterile.																-	
5(3)	0	Sterilized cream product shall comply with a test for commercial sterility as per BIS (IS : 4884:1968) when incubated at 38 ± 1°C for 14 days and does not show any bulge due to positive pressure within and has not curdled or thinned and is free from any objectionable taste or odor, sliminess etc will be considered as clearing the sterility test.																-	
(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	Product shall comply accelerated storage test as per IS :1166-1986						-			
(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	-	-	-	-	-	-	-	-	-	
(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	100/g	1000/g	5 (3)	3	10/g	100/g	-			
10 (5)	0	Absent/0.1g		15 (5)	0	Absent/25g		10 (5)	0	100/g	500/g	5 (3)	0	10/g	100/g	30 (10)	0	Absent/10g	
(3)	0	Absent/g		5(3)	0	Absent/25g		5(3)	0	-	-	-	-	-	-	-			
(3)	0	Absent/g		5(3)	0	Absent/25g		5(3)	0	Canned product shall comply accelerated storage test as per IS :2785:1964						-			
(3)	0	Absent/0.1g		5(3)	0	Absent/g		5(3)	0	-	-	-	-	-	-	-			
(3)	0	Absent/g		5(3)	0	Absent/25g		5(3)	0	-	-	-	-	-	-	-			

*product shall comply accelerated storage test as per IS: 1166-1986 where sample shall be stored at $37 \pm 1^\circ\text{C}$ for 14 days .The test will pass if the cans do not show any bulge due to positive pressure within and the product inside the can is free from any objectionable taste, odor and sliminess.

10 of samples required at retail points: (-) Not applicable

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

which must be examined from the batch/lot of food to satisfy the requirements of a particular sampling plan.

and values above it are marginally acceptable in terms of the sampling plan.

ber of defective sample units in 3-class sampling plan applicable at manufacturing units only.

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 attract enforcement/prosecution by the concerned food safety authorities.

Sampling Plan

Sampling Plan						
2-Class			3-Class			
n	c	M	n	c	m	M
n=5-30	c=0	Values of M specified for all testing parameters for different products as specified Table-1& 2 will be applicable	5-30	c=2,3	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
n=3-10	c=0	Values of M specified for all testing parameters for different products as specified Table-1& 2 will be applicable	3-10	c=0	Not applicable	Values of M specified for all testing parameters for different products as specified in Table-1& 2 will be applicable

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

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.

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, Coliform count, Coagulase positive *S. aureus*, Faecal Streptococci and which indicates poor hygiene or poor handling practices, the microbiological quality of product will be considered unsatisfactory. Under these conditions the premises producing such unsatisfactory and for nonconformity/ 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 by the food safety authority.

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* / *Shigella*, *B. cereus*, **Sulphite Reducing Clostridia(SRC)**, *mycotoxins* and sterility tests etc which indicates serious food safety concern, the microbiological quality of product will be considered as **Potentially hazardous**. Under these conditions the premises 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 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 : product where the officer has reason to believe that it is contaminated with pathogenic bacteria. A detail risk assessment will be carried out to determine by the food safety authority to investigate the 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 / guidelines set by

ds'

Test reference	References
Microbiology - General guidance for the enumeration of micro-organisms- Colony count technique at 30°C (first revision)	IS 5402:2002/ ISO:4833:1991 Reaffirmed 2007
Microbiology - General guidance for the enumeration of Coliforms: Part 1 Colony count Technique (first revision)	IS 5401(Part 1): 2002/ISO 4832:1991 Reaffirmed 2007
Methods for detection of bacteria responsible for food poisoning: Part 8 Horizontal method for enumeration of Coagulase-positive Staphylococci (<i>Staphylococcus aureus</i> and other species) Section 1 Technique using Baird-Parker Agar Medium	IS 5887(Part 8/Sec 1):2002 / ISO 6888-1 :1999 Reaffirmed 2007
Isolation, identification and enumeration of <i>Staphylococcus aureus</i> and faecal streptococci (first revision)	IS 5887(Part 2) : 1976
Meat and milk products — Detection of <i>Enterobacter sakazakii</i> (First Edition)	ISO/TS 22964: 2006
Method for yeast and mould count of food stuffs and animal feeds(first revision)	IS 5403:1999 Reaffirmed 2005/ ISO 7954:1987 Reaffirmed 2009
Methods for detection of bacteria responsible for food poisoning: Isolation, Identification and Enumeration of <i>Escherichia coli</i> (first revision)	IS 5887(Part 1):1976 Reaffirmed 2009 Part 1
Methods for detection of bacteria responsible for food poisoning: Part 3:General guidance on methods for detection of Salmonella/Shigella (first revision) Methods for detection	IS 5887(Part 3):1999/ ISO 6579:1993 Reaffirmed 2009
Methods for Detection of Bacteria Responsible for Food Poisoning-Part 7: General Guidance on Methods for Isolation and Identification of <i>Salmonella</i>	IS 5887(Part 7):1999/ ISO 6579 : 1993 Reaffirmed 2009
Microbiology of food and animal feeding stuffs – Horizontal method for detection and enumeration of <i>Listeria monocytogenes</i> : Part 1 Detection	IS 14988(Part 1):2001/ ISO 11290-1 :1996 Reaffirmed 2007
Methods for detection of bacteria responsible for food poisoning: Part 6 Identification, Enumeration and Confirmation of <i>B.cereus</i>	IS 5887(Part 6):1999 / ISO 7932:1993 Reaffirmed 2007
Microbiology of food and animal feeding stuffs- Horizontal method for the enumeration of sulfite reducing bacteria growing under anaerobic conditions	ISO 15213: 2003
Methods of test for dairy industry part III bacteriological analysis of milk (first revision)	IS 1479 (Part III-1977- Reaffirmed 1992
Indian Standard Specification for sterilized milk	IS: 4238-1967 Reaffirmed 2010
Specification for sterilized cream	BIS (IS : 4884:1968) Reaffirmed 1999
Unsweetened Sterilized Pasteurized Milk – Specification (First Revision)	IS 13688: 1999
Method for determination of phosphatase activity in milk and milk products:	IS 8479 (Parts I):1977 Reaffirmed 1997
Specification For Condensed Milk, Partly Skimmed And Skimmed Condensed Milk (Second Revision)	IS :1166-1986 Reaffirmed 1997
Cheese, processed cheese and processed cheese spread	IS :2785:1964
Methods of sampling for milk and milk products	IS 11546:1999/ ISO 707:1997 Reaffirmed 2010
Milk products-Yoghurt specification	IS: 12898:1989 Reaffirmed 1994
Methods recent version shall apply.	

Annexure – VI

Microbial Requirements for meat and meat products**Hygiene indicators**

Product Category	Total Plate Count				Yeast and mold count				<i>E. coli</i>				<i>Staph aureus</i> (Coagulase +ve)			
	Sampling Plan		Limits (cfu)		Sampling Plan		Limits (cfu)		Sampling Plan		Limits (cfu)		Sampling Plan		Limits (cfu)	
	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M
Fresh meat	5	3	10 ⁶ /g	5x10 ⁶ /g [†]	5	2	10 ⁴ /g	5x10 ⁴ /g	5	2	50/g	500/g	5	2	10/g	100/g
Chilled meat	5	2	10 ⁵ /g	5x10 ⁶ /g	5	2	10 ³ /g	10 ⁴ /g	5	2	10/g	100/g	5	2	10/g	100/g
Frozen meat	5	2	10 ⁴ /g	10 ⁵ /g	5	2	100/g	10 ³ /g	5	2	Absent/g	10/g	5	2	10/g	100/g
Raw minced/comminuted meat/product	5	2	10 ⁵ /g	5x10 ⁶ /g	5	2	100/g	10 ³ /g	5	2	100/g	10 ³ /g	5	1	100/g	10 ³ /g
Cured/Pickled meat	5	2	500/g	5x10 ³ /g	5	2	100/g	10 ³ /g	5	2	10/g	100/g	5	1	100/g	10 ³ /g
Fermented meat products	5	2	10 ⁶ /g	10 ⁷ /g	5	2	100/g	10 ³ /g	5	2	10/g	100/g	5	1	100/g	10 ³ /g
Dried/dehydrated meat product	5	2	10 ³ /g	10 ⁴ /g	5	2	100/g	10 ³ /g	5	2	10/g	100/g	5	1	10/g	100/g
Cooked/Semi cooked meat/smoked	5	2	10 ³ /g	10 ⁴ /g	5	1	10/g	100/g	5	2	10/g	100/g	5	1	10/g	100/g
Canned/Retort pouch meat	N/A	N/A	NA	NA	N/A	N/A	NA	NA	5	0	Absent/g	NA	5	0	Absent/g	NA
Method of analysis	IS: 5402				IS: 5403				IS: 5887 Part I				IS: 5887 Part 2			

Safety Indicators

Product Category	Salmonella			Listeria monocytogenes			Clostridium perfringens				Clostridium botulinum				Campylobacter Spp*			
	Sampling Plan		Limits (cfu)	Sampling Plan		Limits (cfu)	Sampling Plan		Limits (cfu)		Sampling Plan		Limits (cfu)	Sampling Plan		Limits (cfu)		
	n	c	m M	n	c	m M	n	c	m	M	n	c	m	M	n	c	m	M
Fresh meat	5	0	Absent/25g	5	0	Absent/25g	5	1	10/g	100/g	N A	N A	N A	N A	N A	N A	NA	N A
Chilled meat	5	0	Absent/25g	5	0	Absent/25g	5	1	10/g	100/g	N A	N A	N A	N A	N A	N A	NA	N A
Frozen meat	5	0	Absent/25g	5	0	Absent/25g	5	1	10/g	100/g	N A	N A	N A	N A	N A	N A	NA	N A
Raw minced/commi nuted meat/product	5	0	Absent/25g	5	0	Absent/25g	5	2	500/ g	5X10 ³ /g	N A	N A	N A	N A	N A	N A	NA	N A
Cured/Pickled/ Fermented meat products	5	0	Absent/25g	5	0	Absent/25g	5	2	500 /g	5X10 ³ /g	N A	N A	N A	N A	N A	N A	NA	N A
Dried/dehydrat ed meat product	5	0	Absent/25g	5	0	Absent/25g	5	2	500 /g	5X10 ³ /g	N A	N A	N A	N A	N A	N A	NA	
Cooked/ Semi cooked meat/ smoked meat	5	0	Absent/25g	5	0	Absent/25g	5	1	10/g	100/g	N A	N A	N A	N A	5	0	Absent/g	
Canned/ Retort pouch meat	5	0	Absent/25g	5	0	Absent/25g	5	0	Absent/g		5	0	Absent/ g		5	0	Absent/g	
Method of analysis	IS: 5887 Part 3			IS: 14988, Part 2			IS: 5887, Part 4				IS:5887, Part 4				ISO 10272-1&2			

- † Hygienic indicator, applicable for processing only
- * Applicable for poultry meat
- NA= Not applicable
- n = Number of samples to be tested
- m = Maximum permissible number of relevant bacteria. The values above this are marginally acceptable in 3 class plan or unacceptable in 2 class plan
- M = Level at or above which the lot has to be rejected
- c = Maximum allowable number of sample units having microbiological counts between m and M for three class sampling plan and above m for two class sampling plan
- Analytical unit to be taken for sampling should be 10 g. For *Salmonella* and *Listeria monocytogenes* it should be 25 g (wherever mentioned)
- 3-Class plan at manufacturer's level with TPC to be considered.
- Only 2-class plan is applicable in a specified amount of sample at retail level
- If TPC is to be consider only for hygienic of processing unit at manufacturer's level. TPC is not applicable at retail level.
- Requirement of product for *E. coli* and *Clostridium perfringens* and *Clostridium botulinum* characteristics are per gram as per BIS standards No. (IS 5887, Part 4 :1999).

- For IS Standards recent version shall apply.
- **Meat:** All parts of an animal that are intended for human consumption.
- **Cooked Meat/meat product:** Meat/meat product that is subjected to heat treatment, wherein minimum thermal core temperature of 80°C is achieved.
- **Semi-cooked /smoked meat Product:** Partially heat treated/ smoked meat and meat product, wherein minimum thermal core temperature of 60°C is achieved and the product will require additional heat treatment before consumption.
- **Raw minced/comminuted meat:** Boneless meat which has been reduced to fragments by cutting/grinding/dicing/chopping/milling, etc.
- **Canned meat product:** Meat product packed in hermetically sealed containers which have been heat treated after sealing to such an extent that the product is shelf stable.
- **Fresh meat:** Meat that has not been treated in any way to ensure its preservation.
- **Dried meat/meat products:** Meat/meat products in which part of free water has been removed by evaporation or sublimation.
- **Cured/pickled meat products:** Product prepared after curing/pickling meat in solution containing salt/and/or/ nitrate/nitrite and adjuncts for the purpose of preservation and obtaining desirable colour, flavor and shelf life.
- **Chilled meat:** Fresh meat which has been kept between 0-7°C.
- **Frozen meat:** Fresh meat subjected to freezing in an appropriate equipment in such a way that product attains a temperature of -18°C or colder at the thermal center after thermal stabilization.
- **Carcass:** The (slaughtered) body or any part thereof including viscera of animal and bird which has been slaughtered according to the proper procedure in an approved slaughter house.
- **Slaughter house/ abattoir:** The building, premises or place which is licensed/approved by appropriate authority for the slaughter of animal intended for human consumption.
- **Slaughter:** Means killing of an animal for food employing a human method not inconsistent with the provisions of the prevention of cruelty to Animal act, 1960 (54 of 1960) in an authorized slaughter house or abattoir where the animal is subjected to through ante- mortem and post-mortem examination.
- **Fermented meat product:** Chopped or ground meat products that have under gone ageing process and developed characteristics low pH, unique flavour, taste, texture and long shelf life through action of desirable microorganisms.

Annexure – VII

DRAFT STANDARDS FOR WATER AS AN INGREDIENT OF FOOD**1. Definition:**

The Potable Water used as an ingredient of food means the water (treated or untreated) supplied or sourced from any means by food business operator for use into food for its manufacture, preparation or treatment. The food business operators shall ensure that water used as an ingredient of food meet prescribed minimum standards for protecting public health.

2. Requirements:

The water as defined above shall comply with the requirements given in Table 2.1, Table 2.2, Table 2.3, Table 2.4 and Table 2.5. All the water analysis parameters need to be analysed by the food business operator periodically as per the prescribed monitoring requirements for parameters to ensure water potability. The water analysis to be done from a recognized/ public health laboratory while adopting prescribed sampling method.

The method of analysis for different parameters mentioned in table 2.1 to 2.5 may be referred by the laboratories as per IS, AOAC, ISO, USEPA etc.

Record of water analysis reports shall be maintained by the food business operator for monitoring and audit purpose.

Table 2.1: Bacteriological quality of water

Sl. No.	Name of Contaminant	Maximum Contaminant Level (MCL) acceptable
1.	Coliform bacteria, MPN index Per 100 ml	Less than 1
2.	Standard plate count, per ml Max	50 (Note 1)
3.	Proteolytic and lipolytic organisms, combined count per ml, Max	5 (Note 2)
4.	<i>Salmonella typhi</i> per 250 ml	Absent
5.	<i>Vibrio cholera</i> per 250 ml	Absent

Note1: Not applicable in case of cooling water and of hot water used in dairy industry.

Note 2: Not applicable in case of cooling water, hot water and for water used for general purposes in dairy industry.

Table 2.2 : Physical and Chemical Parameters

Sl. No.	Name of Contaminant	Maximum Contaminant Level (MCL) acceptable
i)	Colour (Hazen units), Max	20
ii)	Turbidity (units), Max	10
iii)	Odour	None

iv)	pH	6.5-9.2
v)	Total solids mg/l, Max	1000.0
vi)	Total hardness (as CaCO ₃),mg/l Max	600.0
vii)	Sulphate (as SO ₄),mg/l, Max	200.0
viii)	Fluoride (as F), mg/l, Max	1.5
ix)	Chloride (as Cl),mg/l, Max	250.0
x)	Cyanide (as CN), mg/l, Max	0.01
xi)	Selenium (as Se) mg/l, Max	0.05
xii)	Iron (as Fe), mg/l, Max	0.3
xiii)	Magnesium(as Mg),mg/l, Max	75.0
xiv)	Manganese (as Mn), mg/l, Max	0.2
xv)	Copper (as Cu), mg/l, Max	1.0
xvi)	Lead (as Pb), mg/l, Max	0.1
xvii)	Chromium (as Cr ⁶⁺) mg/l, Max	0.05
xviii)	Zinc (as Zn), mg/l, Max	15.0
xix)	Arsenic (as As) mg/l, Max	0.2
xx)	Nitrate (as N) mg/l, Max	20.0
xxi)	Phenolic substances (as C ₆ H ₅ OH) mg/l, Max	0.001

Table 2.3: Parameters concerning Radioactive Substances

Sl. No.	Name of Contaminant	Maximum Contaminant Level (MCL) acceptable
i)	Alpha emitters, µc/ml, Max	10 ⁻⁹
ii)	Beta emitters, µc/ml, Max	10 ⁻⁸

TABLE 2.4: Additional Parameters for Specific Operations

Sl. NO.	Name of Contaminant	Maximum Contaminant Level (MCL) acceptable		
		Cooling	Washing Flushing and General Purposes	Processing
i)	Total hardness (as CaCO ₃),mg/l Max	30 (Note1)	30 (Note2)	-
ii)	Iron (as Fe), mg/l, Max	-	0.1	0.1
iii)	Manganese (as Mn), mg/l, Max	-	0.1	0.1
iv)	Slime-forming organisms	Absent	-	-

Note 1: For waters which are recirculated and used .In once through and run to waste systems, carbonate hardness should be absent .The Langelier index is of value in finding out the suitability of water for cooling and degree of treatment required, but in applying it, it should be kept in mind that the free carbon di oxide content of the make up water is practically all lost in the first pass.

Note 2: Especially if used for washing with soap or other alkaline detergents.

Table 2.5: Additional Parameters for Individual Food Industries

Sl. No.	Industry	Name of Contaminant	Maximum Contaminant Level (MCL) acceptable
1.	Bakery: i) Bread manufacture	a) Calcium	Uniformly high
		b) pH	Controlled to optimum
		c) Magnesium	Low
		d) Water of uniform quality preferred	-
	ii) Cracker and cake making	Total hardness (as CaCO_3) mg/l	Preferably below 30
	iii) Cleansing	Total hardness (as CaCO_3) mg/l	Preferably below 30
2.	Canning: i) Legumes (Peas, beans, lentils etc.)	a) Hardness (as CaCO_3), mg/l, Max	75
		b) Alkalinity (as CaCO_3), mg/l, Max	50
		c) Iron (as Fe), mg/l, Max	0.2
	ii) Cooker	a) Carbonate hardness	0.00
		b) Alkalinity (as CaCO_3), mg/l, Max	50
	iii) Cleansing	Total hardness (as CaCO_3) mg/l	Preferably below 30
	vi) General	Iron (as Fe) mg/l, Max	0.2
3.	Citrus fruit:		
	i) Washing citrus fruits	Soft water	-
	ii) Pectin, citric acid and syrup making	Total hardness (as CaCO_3), mg/l	Preferably below 30
4.	Confectionery:	a) Total solids, mg/l, Max	100
		b) Iron (as Fe) mg/l, Max	0.2
		c) pH	Appropriate adjustment
5.	Dairy:		
	i) Processing	Thermophilic bacteria	Absent
	ii) Hot Water	a) Slime forming organism	Absent

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		b) Total hardness (as CaCO_3), mg/l	30
6.	Edible oil refining: Process water	Iron (as Fe), mg/l, Max	0.2
7.	Geletin manufacture: Process water	Demineralized water preferred so that ash content of geletin is kept low.	-
8.	Meat Packing: Cleansing and washing of meat for pickling	a) Soft water preferred to obtain better colour	-
		b) Iron (as Fe), mg/l, Max	0.2
9.	Starch and corn products manufacture: Process water	a) Soft water preferred as hard water increases the ash content of starch and high magnesium content leads to cloudiness in corn.	-
		b) Iron (as Fe) mg/l, Max	0.2
10.	Sugar refining	a) Iron (as Fe), mg/l, Max	0.2
		b) Total Solids	Less than 500 mg/l preferred as electrolytes cause inversion of sugar and yield of sucrose is decreased.

Annexure – VIII

LACTIC ACID, FOOD GRADE

1. **SCOPE:** This standard prescribes the requirement for Lactic acid, Food Grade.

2. **REQUIREMENTS**

2.1 Description:

Lactic acid shall be yellowish to colourless syrupy liquid with an acidic taste and no odour. It consists of a mixture of lactic acid ($C_3H_4O_3$) and lactic acid lactate ($C_1H_{10}O_5$). It is obtained by lactic fermentation of sugars or is prepared synthetically. Purity of common products of commerce is 50 to 90 percent.

Note – Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid lactate, which on dilution and heating hydrolyzes to lactic acid.

2.2 Identification

2.2.1 Solubility – Lactic acid is miscible in water and ethanol; for solids sparingly soluble in water, soluble in acetone.

2.2.2 Test for Acid – One in ten solution of the sample shall be acidic to litmus paper.

2.2.3 Test for Lactate – The material shall give positive test for lactate.

The material shall also comply with the requirements given in sub clause (3)

3. **QUALITY CHARACTERISTICS**

Sl.No.	Characteristic	Requirement
(1)	(2)	(3)
i)	Purity ($C_3H_4O_3$), percent by mass of the labeled concentration	95.0 to 105.0
ii)	Sulphated ash, percent by mass, Max	0.1
iii)	Chlorides, percent by mass, Max	0.2
iv)	Sulphates (as SO_4), percent by mass, Max	0.25
v)	Citric, oxalic, phosphoric and tartaric acids	Conform to test
vi)	Sugars	Conform to test
vii)	Readily carbonizable substances	do
viii)	Cyanide	do
ix)	Methanol, percent by mass, Max	0.2
x)	Iron(as Fe), mg/kg, Max	10
xi)	Heavy metals (as Pb), mg/kg, Max	10
xii)	Arsenic (as As), mg/kg, Max	3

4. FOOD ADDITIVES

Only those additives permitted as per Food Safety and Standards (Food Products Standards and Food Additives), Regulations, 2011 should be used.

5. HYGIENE

The material shall be filled in containers with as little air space as possible. The containers shall be such as to preclude air contamination of the contents with metals or other impurities. The material shall be stored in as cool and dry place so as to avoid excessive exposure to heat.

6. CONTAMINANTS

The products covered by this standard shall comply with the Maximum Levels for contaminants specified in the Regulation Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

7. PACKAGING, LABELING and CLAIMS

The products covered by this standard shall comply with the Food Safety and Standards (Packaging and Labeling) Regulations, 2011.

MALT EXTRACT

1. **SCOPE:** This standard prescribes the requirement for Malt extract.

2. **TYPES**

Malt Extract shall be of the following three types:

Type 1- Diastatic Malt Extract

Type 2- Non Diastatic Malt Extract

Type 3- Brewery Grade Malt Extract

3. **REQUIREMENTS**

3.1 Malt extract shall be prepared by digesting with water sound malted grains of cereals (such as barley, wheat and millets that is *cholam* or ragi at a suitable temperature with or without adding enzymes. The water extract is then strained and evaporated into a viscous product.

3.2 **Description**

Malt extract shall be a viscous liquid, amber or yellowish brown in colour and shall possess a characteristic odour and sweet taste. The material shall be free from any adulterants, off-odour, foreign flavour and impurities.

The material shall also comply with the requirements given in sub clause (4)

4. **QUALITY CHARACTERISTICS**

Table 1 Requirement for Malt Extract

S. No (1)	Characteristic (2)	Requirements		
		(3) Type 1	(4) Type 2	(5) Type 3
i)	Density at 20 ⁰ C Min	1.39	1.39	1.39
ii)	Refractive Index at 20 ⁰ C, Min	1.489	1.489	1.489
iii)	Total solids (as is basis), percent by mass, Min	77	77	77
iv)	Reducing sugar, on dry basis, (calculated as anhydrous maltose), per cent by mass, Min	55-65	55-65	55-65
v)	Crude protein (on dry basis), percent by mass, Min	35-5.5	3.5-5.5	2.5
vi)	Test for starch	Negative	Negative	Negative

Table 2 Microbiological Requirement for Malt Extract

S. No (1)	Characteristic (2)	Requirement (3)
i)	Total bacterial count per g, Max	10000
ii)	Coliform bacteria	Absent

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iii)	Yeast count, per g, Max	500
iv)	Mould count, per g, Max	500

5. **FOOD ADDITIVES:** Only those additives permitted as per Food Safety and Standards (Food Products Standards and Food Additives), Regulations, 2011 should be used.
6. **HYGIENE**
Malt extract shall be manufactured in premises maintained under hygienic condition.
7. **CONTAMINANTS:** The products covered by this standard shall comply with the Maximum Levels for contaminants specified in the Regulation Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.
8. **PACKAGING, LABELING and CLAIMS:** The products covered by this standard shall comply with the Food Safety and Standards (Packaging and Labeling) Regulations, 2011.
Malt extract shall be packed and supplied in sealed, clean, sound and air-tight containers made of galvanized iron, stainless steel, HDPE (food grade) or any other suitable material.

ICMR-DBT
GUIDELINES FOR EVALUATION
OF PROBIOTICS IN FOOD



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FOREWORD

Probiotics are bacteria that help maintain the natural balance of microflora in the intestines. The normal human digestive tract contains about 400 types of probiotic bacteria that reduce the growth of harmful bacteria and promote a healthy digestive system. Experiments into the benefits of probiotic therapies suggest a range of potentially beneficial medicinal uses for probiotics. Recent research on the molecular biology and genomics of *Lactobacillus* has focused on the interaction with the immune system, anti-cancer potential, and potential as a biotherapeutic agent in cases of antibiotic-associated diarrhoea, travellers' diarrhea, paediatric diarrhoea, inflammatory bowel disease and irritable bowel syndrome.

The increasing globalization of food trade has resulted in India being a fast emerging market for probiotic products. With the availability of these products increasing exponentially and the multiple claims made regarding the beneficial health effects, there is the need to put in place sufficient safeguards to protect the consumers from any adverse effects, ensure standardization of commercial products and their efficacy.

The present ICMR-DBT guidelines comprehensively address the various concerns regarding safety, efficacy and reliability as well as labeling of probiotic products being sold in India.

I hope the scientific community, the regulatory agencies and the public at large will be benefited by these guidelines.



(M.K. Bhan)

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Secretary to Government of India
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PREFACE

The concept of probiotics was introduced in early 20th century, however they gained importance in recent years with the emerging scientific evidences suggesting their role in digestive and immunological functions.

During the last decade there has been increased influx of probiotic products in Indian market. However, there was no systematic approach for evaluation of probiotics in food to ensure their safety and efficacy.

Being the apex body in India for the formulation, coordination and promotion of biomedical research, Indian Council of Medical Research (ICMR) along with Department of Biotechnology (DBT) took the initiative to formulate the guidelines for evaluation of probiotics in food in India. A Task Force was constituted to examine various guidelines available in different parts of the world and deliberate on the relevant issues keeping in view the local conditions. The guidelines formulated and presented in this document define a set of parameters required for a product/strain to be termed as 'probiotic'. These include identification of stain, *in vitro* screening for probiotic characteristics, animal studies to establish safety and *in vivo* animal and human studies to establish efficacy. These also include requirements for labeling of the probiotic products with strain specification, viable numbers at the end of shelf life, storage conditions etc which would prevent misleading the consumer.

These guidelines have been developed for scientific purpose with the main aim to guide the regulatory authority for evaluating probiotic products in our country. I hope that these will also stimulate thinking among scientists interested in developing this area in India.


(V.M. Katoch)

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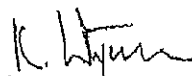
ACKNOWLEDGEMENTS

We gratefully acknowledge the help rendered by all the people involved in the formulation of guidelines.

We are grateful to Dr. N.K. Ganguly, Chairperson of the Task Force on 'Guidelines for evaluation of Probiotics in Food' and Former Director General, Indian Council of Medical Research for identifying the need and significance of guidelines on probiotics in food. The Task force has met thrice to formulate and thoroughly discuss every aspect of the guidelines. Further, Core group and follow up meetings were also held to go over certain technical details of the document. We are grateful to all the Task Force member for their contributions in preparing guidelines and refinement of the manuscript.

We also acknowledge the inputs received from the NGOs/Industry representatives present in the scientific deliberations and the suggestions received from others following posting of draft guidelines on ICMR website.

Efforts of ICMR and DBT secretariat for putting together the available information and co-ordinating the activities of the Task Force is also acknowledged.



(Dr. K. Satyanarayana)

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ABBREVIATIONS

BMS	:	Basic Medical Sciences
CFU	:	Colony Forming Units
DBT	:	Department of Biotechnology
DHR	:	Department of Health Research
DNA	:	Deoxyribonucleic Acid
FAO	:	Food and Agricultural Organization
GCP	:	Good Clinical Practices
GMO	:	Genetically Modified Organisms
GMP	:	Good Manufacturing Practices
GRAS	:	Generally Recognized as Safe
HACCP	:	Hazard Analysis and Critical Control Point
ICMR	:	Indian Council of Medical Research
ICPS	:	International Committee on Systematics of Prokaryotes
JIPMER	:	Jawaharlal Institute of Post Graduate Medical Education and Research
PCR	:	Polymerase Chain Reaction
PFGE	:	Pulsed Field Gel Electrophoresis
PGIMER	:	Postgraduate Institute of Medical Education & Research
PI	:	Publication & Information
RNA	:	Ribonucleic Acid
RHN	:	Reproductive Health & Nutrition
SOPs	:	Standard Operating Procedures
WHO	:	World Health Organization

guidelines and regulations for evaluating the safety and efficacy of probiotics in India which should be in consonance with current international standards.

Keeping in view the above, a Task Force was constituted by ICMR, comprising of experts from varied fields to develop guidelines for evaluation of probiotics in food in India. The Task Force took into consideration the guidelines available in different parts of the world (20, 26-31) and deliberated on the various aspects to be covered (32-36). The guidelines set forth in this document are meant to be followed for a strain or food to be termed as 'probiotic' for marketing in India.

2. GUIDELINES AND REQUIREMENTS FOR PROBIOTIC PRODUCTS

- 2.1. Scope:** The guidelines deal with the use of probiotics in food and provide requirements for assessment of safety and efficacy of the probiotic strain and health claims and labeling of products with probiotics.

Note: These guidelines are not meant for probiotics which by definition would come under drugs, beneficial microorganisms not used in foods or genetically modified microorganisms (GMOs).

- 2.2 Definition of Probiotics:** Probiotics are 'live microorganisms which when administered in adequate amounts confer a health benefit on the host' (FAO/WHO, 2002) (20).

- 2.3 Genus, species and strain identification:** Effects of probiotics are strain specific. Strain identity is important to link a strain to a specific health effect as well as to enable accurate surveillance and epidemiological studies. Both phenotypic and genotypic tests should be done using validated standard methodology. Nomenclature of the bacteria must conform to the current, scientifically recognized names as per the International Committee on Systematics of Prokaryotes (ICPS) (available at <http://www.the-icsp.org/>) (37). A flow diagram indicating various steps for evaluation of candidate probiotic strains is given at figure 1.

The current molecular techniques used for identification include PCR based techniques, 16S rRNA sequencing and DNA finger printing techniques like Ribotyping and Pulsed Field Gel Electrophoresis (PFGE).

It is recommended that probiotic strains in use in India should be deposited in an internationally recognized culture collection/repositories.

- 2.4 In vitro tests to screen potential probiotic strains:** The following *in vitro* tests* with standard methodology are recommended for screening putative probiotic strains:

2.4.1 Resistance to gastric acidity.

2.4.2 Bile acid resistance.

2.4.3 Antimicrobial activity against potentially pathogenic bacteria (acid and bacteriocin production)

* Adherence to mucus and/or human epithelial cells and cell lines has in the past been used to screen candidate probiotics. The Committee debated this and concluded that there are probiotics which are not adherent. Hence this should not be used as a mandatory criterion or to claim superiority of one strain over another in terms of probiotic attributes and functionality.

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ICMR-DBT

GUIDELINES FOR EVALUATION OF PROBIOTICS IN FOOD

1. INTRODUCTION

The concept of probiotics (which means, "for life") was introduced in early 20th century by Elie Metschnikoff (1), it however gained momentum only recently with considerable and significant advances in functional and health food market across the world. India is also fast emerging as a potential market for probiotics in food. The global probiotic market generated US \$15.9 billion in 2008 and is expected to be worth US\$ 32.6 billion by 2014 with a compound annual growth rate of 12.6% from 2009 to 2014 (2). On the other hand the probiotic product industry in India was estimated to be around Rs 20.6 million with a projected annual growth rate of 22.6% until 2015 (3).

Probiotics, especially *Lactobacillus* and *Bifidobacterium* have been suggested to be associated with alleviation of lactose intolerance (4); prevention and cure of viral, bacterial and antibiotic or radiotherapy induced diarrhoeas (5,6,7); immunomodulation (8); antimutagenic (9) and anticarcinogenic effects (10); and even blood cholesterol reduction (11). The optimism associated with probiotics is, however, counter-balanced by skepticism as many "probiotic" products in the market are unreliable in content and unproven clinically (12-15).

Also, *Lactobacilli* and *Bifidobacteria* have been rarely associated with human clinical infections which are likely to be a result of opportunistic infections especially in immunocompromised individuals (16-17). Many probiotic strains in use for several decades have been validated for their safety and efficacy and are therefore, safe to use (18,19). Any new strain used as a probiotic should be evaluated for safety and efficacy.

However, *Enterococcus* is emerging as an important cause of nosocomial infections and isolates are increasingly becoming vancomycin resistant (20). Some side effects, though rare with probiotics are i) systemic infections ii) deleterious metabolic activities iii) excessive immune stimulation in susceptible individuals and iv) gene transfer (21). The absence of pathogenicity and infectivity thus is an essential pre-requisite of probiotic safety (22).

International guidelines (23,24) on probiotics in food broadly specify the kind of tests that may be required to determine the safety and to assess the health claim of a probiotic product in food. Such tests are based on the current understanding of the subject.

The regulatory mechanism for probiotics differs from country to country and also even within a country (23,25).

In India there are no regulatory guidelines for probiotic foods. In the absence of any such standards and guidelines, there is great scope for spurious products with false claims being marketed. It therefore, becomes imperative that these products fulfill some essential prerequisite conditions before being labeled as a 'probiotic product'. A holistic approach is therefore needed for formulating

2.4.4 Ability to reduce pathogen adhesion to surfaces

2.4.5 Bile salt hydrolase activity

These tests are based on the hostile gut environment which they mimic under *in vitro* conditions. The cultures evaluated as probiotics based on these tests should be subjected to preclinical validation in appropriate animal models before clinical trials are conducted in human subjects.

2.5 ***In vivo* safety studies in animal models:** Assessment of the acute, subacute and chronic toxicity of ingestion of extremely large amounts of probiotics should be carried out for all potential strains. Such assessment may not be necessary for strains with established documented use.

2.6 ***In vivo* efficacy studies in animal models:** To substantiate *in vitro* effects, appropriate, validated animal models must be used first, prior to human trials.

2.7 **Evaluation of safety of probiotics for human use:** In recognition of the importance of assuring safety, even among group of bacteria that are Generally Recognized as Safe (GRAS)**, probiotics strains needs to be characterized at a minimum with the following tests:

2.7.1 Determination of antibiotic resistance patterns. It should be ascertained that any given probiotic strain is not at significant risk with regard to transferable antibiotic resistance.

2.7.2 Assessment of undesirable side-effects.

2.7.3 If the strain under evaluation belongs to a species that is a known mammalian toxin producer or of hemolytic potential, it must be tested for toxin production and hemolytic activity respectively.

Assessment of lack of infectivity by a probiotics strain in immunocompromised individuals would be an added measure.

2.8 **Evaluation of efficacy studies in humans:** The principal outcome of efficacy studies on probiotics should be proven with similar benefits in human trials, such as statistically and clinically significant improvement in condition, symptoms, signs, well-being or quality of life, reduced risk of disease or longer time to next occurrence or faster recovery from illness. Each of the parameter should have proven correlation with the probiotics tested.

Probiotics delivered in food may not be tested in Phase 3 studies (effectiveness), unless the product makes a specific health claim wherein it becomes imperative to generate the required evidence necessitating carrying out Phase 3 studies.

If a probiotic food has a record of documented long and safe use outside the country, the data regarding this could be reviewed and deemed as sufficient to allow its marketing within the

** As defined by Food and Drug Administration (FDA), USA (38)

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country. However, labeling of health benefits may require evaluation in a different manner. While taking into account studies done abroad, efficacy studies of probiotics (which are of proven benefit in 'other' populations) should also be conducted on Indian subjects. It is recommended that such 'bridging' human trials should comply with the principles laid down by the Drug Regulatory Authority. Adverse effects, if any, should be monitored and incidents reported to the appropriate authority.

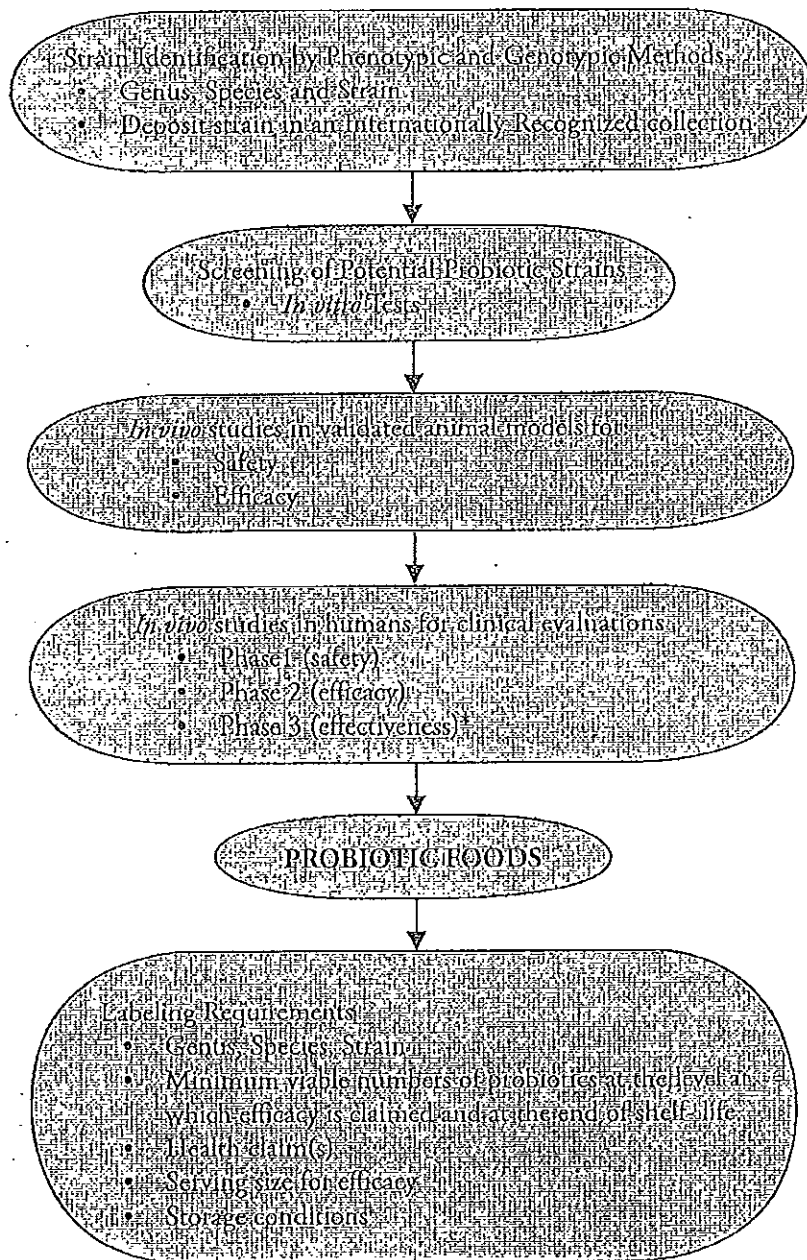
2.9 Effective dosage of probiotic strain / strains: The minimal effective dose or the level of viable cells of the probiotic strain in terms of cfu/ml/day in the carrier food that demonstrates general health promoting functions or well being or specific health claims in target population should be clearly indicated.

2.10 Labeling Requirements: In addition to the general labeling requirements under the food laws, the following information should also be mentioned on the label (23,39):

- Genus, species and strain designation following the standard international nomenclature.
- The minimum viable numbers of each probiotic strain should be specified at the level at which efficacy is claimed and at the end of shelf- life.
- Evidence-based health claim(s) should be clearly stated.
- The suggested serving size to deliver the minimum effective quantity of the probiotic related to the health claim.
- Proper storage conditions to be mentioned.

2.11 Manufacturing and handling procedures: Adequate quality assurance programmes should be in place. Good Manufacturing Practices should be followed in the manufacture of probiotic foods. The Codex General Principles of Food Hygiene and Guidelines for Application of Hazard Analysis and Critical Control Point (HACCP) (40) should be followed.

Figure 1: Guidelines for evaluation of candidate probiotic strains



* Only required if a specific health claim is made

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4. GLOSSARY

Probiotics: Probiotics are 'live microorganisms which when administered in adequate amounts confer a health benefit on the host'

Shelf-life: Survival of sufficient viable organisms ($\geq 10^8$ CFU/gram) to confer health benefits to the host when stored at a specified temperature.

Health Claims: A statement, which characterizes the relationship of any substance to a disease or health-related condition, and these should be based upon well-established, generally accepted knowledge from evidence in the scientific literature and/or recommendations from national or international public health bodies with clinical validation of safety and efficacy.

HACCP: Hazard Analysis and Critical Control Point is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

Codex Alimentarius: The Codex Alimentarius is a collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety. The Codex Alimentarius Commission was created in 1963 by FAO and WHO with the purpose of protecting health of the consumers, ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

GMP: Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

ANNEXURE XI

[TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY, PART III,
SECTION 4]

Government of India
Ministry of Health and Family Welfare
(Food Safety and Standards Authority of India)

New Delhi, the2014

NOTIFICATION

F.No.1-100/SP (PAR)-Notification/Enf/FSSAI/2014.- 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 clause (i) of sub section (2) of section 92 read with section 20 of Food Safety and Standards Act, 2006 (34 of 2006) is hereby published as required by the said subsection (1) of section 92, for the information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulation shall be taken into consideration after the expiry of a period of thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi-110002;

The objections and suggestions which may be received from any person with respect to the said draft regulations before the expiry of the period specified above shall be considered by the Food Safety and Standards Authority of India.

Regulations

1. (1) These regulations may be called the Food Safety and Standards (Contaminants, Toxins and Residues) (Amendment) Regulations, 2014.
- (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 2.3 relating to "residues"
- (A) in sub-regulation 2.3.1 relating to "Restriction on the use of insecticides" in clause 2, in the table,-
- 1) against serial number 2 relating to Carbaryl, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Sesamum	0.05

- 2) against serial number 9 relating to Dichlorovos(content of di-chloroacetaldehyde (D.C.A) be reported where possible), in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Groundnut seeds	0.05
Groundnut Oil	0.20
Mustard seed/oil	0.01

- 3) against serial number 11 relating to Dimethoate (residue to be determined as dimethoate and expressed as dimethoate), in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Mustard	0.01

- 4) against serial number 24 relating to Methyl Parathion (combined residues of parathion methyl and its oxygen analogue to be determined and expressed asparathion methyl), in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Rice	0.01
Black Gram	0.01
Cotton seed oil	0.01
Mustard seed/oil	0.01

- 5) against serial number 42 relating to Carbandazim, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Potato	0.01*
Tea	0.01*

- 6) against serial number 48 relating to Deltamethrin, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)

Brinjal	0.3
Groundnut	0.01*

- 7) against serial number 52 relating to Dithiocarbamates (expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram, zineb), in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Chilli	0.2
Dry chilli	2.0
Onion	4
Turmeric	2

- 8) against serial number 52 (c) relating to Mancozeb under Dithiocarbamate (as CS₂), in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
"Gherkin	0.1*
Tea	0.05**

- 9) after serial number 52 (c) relating to Dithiocarbamate insert "(d) metiram as CS₂", and in columns (3) and (4), the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
"Green chilli	0.05*
Dry chilli	0.5"

- 10) against serial number 54 relating to Phorate, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Cotton seed oil	0.01
Green gram	0.01*

- 11) against serial number 74 relating to Oxydemeton-methyl, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Cotton seed oil	0.01
Chilli	2.0
Dry chilli	20
Mustard oil	0.01

- 12) against serial number 76 relating to Quinalphos, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Cauliflower	0.1
Citrus	0.05
Bengal Gram	0.05
Cotton seed oil	0.05
Mustard seed oil	0.1
Soybean	0.05
Groundnut oil	0.30

- 13) against serial number 95 relating to Carbosulfan, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Chilli	2

- 14) against serial number 101 relating to Metribuzin, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Tomato	0.05*
Sugarcane	0.01*
Potato	0.05*

- 15) against serial number 119 relating to Clodinafop propargyl, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
(3)	(4)
Soyabean	0.05*

- 16) against serial number 136 relating to Buprofezin, in columns (3) and (4), after the existing entries, the following entries shall respectively be inserted, namely:-

Food	Tolerance limit mg/ kg.(ppm)
------	------------------------------

(3)	(4)
Okra	0.01*

17) after serial number 149 relating to Thioclorprid, in column no. (1), (2), (3) and (4) after the entries relating thereto, the following serial numbers and entries shall be inserted, namely:-

(1)	(2)	(3)	(4)
150.	Fenamidone	Gherkin	0.2
151.	Copper Hydroxide	Green chilli	0.1*
		Dry chilli	1
		Rice	0.1*
152.	Pyraclostrobin	Green chilli	0.05*
		Dry chilli	0.5
153.	Difenaconazole	Grapes	0.01*
154.	Penoxuslum	Rice	0.1*
155.	Triasulfuron	Wheat	0.01*
156.	Sodium Aceflourofen	Soyabean	0.05*
157.	Cyantranilipole	Grapes	0.01
		Pomegranate -seed	0.01
		Pomegranate -juice	0.01
		Cabbage	0.01
		Chilli	0.05
		Tomato	0.03
		Gherkin	0.01
158.	Azoxytrobin	Cucumber	0.05*

Note :- * refers to Tolerance limit at Limit of Quantification (LOQ).

(D.K Samantaray)
Chief Executive Officer

Note. - The principal Regulations were published in the Gazette of India, Extraordinary vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011.

Annexure-XII

**[TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY, PART III,
SECTION 4]**

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

Notification

New Delhi, the

No. 1-83F/Sci. Pan- Noti/FSSAI-2012;-Whereas the draft of the Food Safety and Standards of India (Food Products Standards and Food Additives) (Amendment) Regulations, 2012, were published as required under sub- section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India No. 1-83 /Sci. Pan- Noti/FSSAI-2012 dated the 16th May, 2013 in the Gazette of India, Extraordinary, Part III, Section 4, dated the 16th May, 2013, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of Sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 14th July, 2013;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by clause (e) of sub section (2) of section 92 read with section 16 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely:-

1. Short title and commencement- (1) These regulations may be called the Food Safety and Standards (Food Product Standards and Food Additives) (Amendment) Regulations 2013.

(2) They shall come into force on the date of their publication in the Official Gazette

2. In Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011(hereinafter referred to as the said regulations). –

A. in regulation 2.1.9—

(i) after the heading “FOODS FOR INFANT NUTRITION”, the sub-heading “**Infant Milk Substitutes**” shall be inserted;

(ii) in sub regulation 2 relating to infant formula, after the second proviso, the following proviso shall be inserted, namely:

“Provided also that the lactose free or lactose and sucrose free or sucrose free infant milk substitutes shall conform to the following requirements, except the requirements of milk protein and milk fat, in the following manner, namely:—

- (a) total protein, percent. by weight shall not be less than 10.0 per cent and not more than 16 percent;
- (b) total fat, percent by weight shall not be less than 18.0 per cent; and
- (c) the lactose in the product claimed to be lactose free shall not exceed 0.05 percent.”;
- (iii) in sub-regulation 3 relating to milk cereal based complementary food, the heading **“Infant Foods”** shall be inserted;
- (iv) in sub-regulation 4 relating to processed cereal based complementary food, at the end the following proviso shall be inserted, namely:—

‘Provided that the processed cereal based complementary foods for use in specific conditions, where protein needs to be restricted and where other cereals like wheat, soya, legumes and milk cannot be used, such processed cereal based complementary foods shall be prepared with single cereal like rice or ragi, which shall have the minimum protein content of 6-9 per cent. Such products shall be conspicuously labeled, “Processed Mono Cereal Based Complementary Food for use in specific conditions under medical guidance only.”;

B. in regulation 2.4.1, for sub-regulation 2 relating to fortified atta, the following shall be substituted, namely:

“2. Fortified atta means the product obtained by adding one or more of the following nutrients to atta, namely:

S. No	Nutrient	Level of fortification per Kg of atta (Not more than)
1.	Calcium- Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;	1500mg
2.	Iron- (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate, electrolytic iron, ferrous fumarate; (b) Sodium Iron (III) Ethylene Diamine tetra Acetate, Trihydrate (Sodium Feredetate- Na Fe EDTA)	60mg 25mg
3.	Zinc-Zinc Sulphate	30mg
4.	Vitamin A- Retinyl acetate, Retinylpalmitate, Retinylpropionate;	1500 µg RE

S. No	Nutrient	Level of fortification per Kg of atta (Not more than)
5.	Ascorbic Acid (Vitamin C) – Ascorbic acid, sodium ascorbate, calcium ascorbate, ascorbyl- 6-palmitate;	100 mg
6.	Thiamine (Vitamin B1) – Thiamine chloride hydrochloride, Thiamine mononitrate;	3.5mg
7.	Riboflavin (Vitamin B2) – Riboflavin, Riboflavin 5'- Phosphate sodium;	4.0mg
8.	Niacin – Nicotinamide, nicotinic acid;	45mg
9.	Pyridoxine (Vitamin B6) – Pyridoxine hydrochloride;	5mg
10.	Folic acid- Folic acid;	250 µg
11.	Vitamin B12- Cyanocobalamine, hydroxycobalamine;	2.5µg
12	Vitamin D Cholecalciferol Ergocalciferol	1000 IU

It shall be free from any extraneous matter including rodent hair and excreta.”;

C. in regulation 2.4.2, for sub-regulation 2 relating to fortified maida, the following shall be substituted, namely:—

“2. Fortified maida means the product obtained by adding one or more of the following nutrients to maida, namely:—

S. No	Nutrient	Level of fortification per Kg of Maida (Not more than)
1.	Calcium- Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;	1500mg
2.	Iron- (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate, electrolytic iron, ferrous fumarate; (b) Sodium Iron (III) Ethylene Diamine tetra Acetate, Trihydrate (Sodium Feredetate- Na Fe EDTA)	60mg 25mg

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S. No	Nutrient	Level of fortification per Kg of Maida (Not more than)
3.	Zinc-Zinc Sulphate	30mg
4.	Vitamin A- Retinyl acetate, Retinylpalmitate, Retinyl propionate;	1500 µg RE
5.	Ascorbic Acid (Vitamin C) – Ascorbic acid, sodium ascorbate, calcium ascorbate, ascorbyl- 6-palmitate;	100 mg
6.	Thiamine (Vitamin B1) – Thiamine chloride hydrochloride, Thiamine mononitrate;	3.5mg
7.	Riboflavin (Vitamin B2) – Riboflavin, Riboflavin 5'- Phosphate sodium;	4.0mg
8.	Niacin – Nicotinamide, nicotinic acid;	45mg
9.	Pyridoxine (Vitamin B6) – Pyridoxine hydrochloride;	5mg
10.	Folic acid- Folic acid;	250 µg
11.	Vitamin B12- Cyanocobalamine, hydroxycobalamin;	2.5 µg
12	Vitamin D Cholecalciferol Ergocalciferol	1000 IU

It shall be free from any extraneous matter including rodent hair and excreta.”;

D. in regulation 3.1.17 after the table, the following shall be inserted, namely:—“**Use of food ingredients in different foods**

The following food products may contain the food ingredients as specified below in addition to those permitted under these Regulations:

(i)**Oligofructose** may be added at not more than ten per cent of the product, in the following products, subject to label declaration under sub-regulation 43 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011:—

Dairy products like: yoghurt, mousse, spreads, dairy based drinks (milkshakes, yoghurt drink), cheese, pudding, cream and ice-cream; frozen desserts like non dairy ice, sorbet and fruit ice, frozen yoghurt, flakes and ready-to-eat dry breakfast cereals, chocolate and sweets; and carbohydrate based and milk

product based sweets like halwa, 'mysorepak, boondiladdu, jalebi, khoyaburfi, peda, gulabjamun, rasogolla and similar milk product based sweets sold by any name, cooked sausages, ham and meat spreads.

(ii) Phyto or Plant stanol esters may be added to the following products so as to allow users to easily restrict their consumption to maximum 3gm per day through the use of either one portion containing maximum 3 gm or three portions containing 1gm and it shall be added subject to the table declaration under **sub-regulation 48 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011:—**

Fat spread, milk products, milk based fruit drink, fermented milk products, soy and rice drink, cheese products, yoghurt products, spice sauces, salad dressings, juices and nectars.

Products containing Phyto or Plant Stanols be sold in single portions containing either maximum 3 g or 'maximum 1 g of phyto/ plant Stanols, calculated as free phyto or plant Stanols. And if they do not contain so, there should be a clear indication of what constitutes a standard portion of the food, expressed in g or ml, and of the amount of phyto or plant Stanols, calculated as free phyto or plant Stanols, contained in such a portion.

(iii) Trehalose may be added as an ingredient in the following foods, subject to label declaration under **sub-regulation 49 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011:—**

(i)	Biscuits, bread, cakes, Breakfast cereals	0.5-10.0 per cent
(ii)	Carbonated water, thermally processed fruits, Fruit juices, fruit nectars, fruit beverages, fruit Squashes, jam, jelly, fruit cheese, marmalade, Dairy based drinks, Milk powder	0.5-20.0 per cent
(iii)	carbohydrate- based and milk product based sweets like gulabjamun, rasogolla, peda , khoyaburfi	0.5-20.0 per cent
(iv)	Macroni products, noodles, pasta.	0.5-5.0 per cent
(v)	Sweets and confectionery, candies and icings	5.0-7.5 per cent
(vi)	Savories and snacks	0.5-1.0 per cent

(iv) **Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Ferredetate-Na Fe EDTA)** may be added as an ingredient in the following foods:-

Ready to serve beverages, carbonated fruit drink and fruit nectars - Not More than 155ppm”

[F. No. 1-83 /Sci. Pan- Noti/FSSAI-2012]

(D.K.Samantaray)
CEO

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Foot note: The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number 2-15015/30//2010 dated the '1st August, 2011.

- (i) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
- (ii) F.No. 5/15015/30/2012, dated 12th July, 2013.

**[TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY, PART III,
SECTION 4]**

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

Notification

New Delhi, the

No. 1-83L/Sci. Pan- Noti/FSSAI-2012;-Whereas the draft of the Food Safety and Standards of India (Labeling and Packing) (Amendment) Regulations, 2012, were published as required under sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India . No. 1-83 /Sci. Pan- Noti/FSSAI-2012 dated the 16th May, 2013 in the Gazette of India, Extraordinary, Part III, Section 4, dated the 16th May, 2013, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of Sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 22nd August, 2013;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by clause (k) of sub section (2) of section 92 read with section 16 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely:-

1. Short title and commencement ;-(1) These regulations may be called the Food Safety and Standards (Labelling and Packing) (Amendment) Regulations 2013.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In Food Safety and Standards (Labelling and Packing) Regulations, 2011(in regulations 2.4.5).

(A) In sub-regulation 43, after the words "bread and cakes", the following shall be inserted, namely:-

"yoghurt, mousse, spreads, dairy based drinks (milk shakes, yoghurt drink), cheese, pudding, Cream and Ice-Cream, frozen dessert like non dairy ice, Sorbet and Fruit ice, frozen yoghurt, flakes and ready-to-eat dry breakfast cereals, chocolates and sweets and carbohydrate based and milk product based sweets like halwa, mysorepak, boondiladdu, jalebi, khoyaburfi, peda, gulabjamun, rasogolla and similar milk product based sweets sold by any name, cooked sausages, ham and meat spreads".

(B) after sub-regulation(47), the following shall be inserted, namely:-

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“(48) Every package of fat spread, milk products, milk based fruit drink, fermented milk products, soy and rice drink, cheese products, yoghurt products, spice sauces, salad dressings, juices and nectars containing plant stanol esters shall bear the following declarations, namely:-

- Contains Plant Stanol Esters (as Plant Stanols)---gm/100 gm or 100ml.
- Patients on cholesterol lowering medication should use the product under medical supervision
- May not be nutritionally appropriate for pregnant and lactating women and children under the age of five years.
- CONSUMPTION OF MORE THAN 3g. PER DAY, TOTAL OF STEROL, STANOLS OR COMBINATION THEREOF SHALL BE AVOIDED

(49) Every package of biscuits, bread, cakes, breakfast cereals, carbonated water, thermally processed fruits, fruit juices, fruit nectars, fruit beverages, fruit squashes, jam, jelly, fruit cheese, marmalade, dairy based drinks, milk powder, carbohydrate- based and milk product based sweets like gulabjamun, rosogolla, peda, khoyaburfi, Macaroni products, noodles, pasta, sweets and confectionery, candies and icings, savorys and snacks wherever the trehalose is added shall bear the following label, namely shall bear the following label, namely:-

Contains Trehalose”

[F. No. 1-83 /Sci. Pan- Noti/FSSAI-2012]

(D.K.Samantaray)
CEO

Foot note: The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number 2-15015/30//2010 dated the ‘1st August, 2011.

i) F.No. 4/15015/30/2011 dated 7th June, 2013

Annexure-XIII

TO BE PUBLISHED IN PART-III, SECTION 4 OF THE GAZETTE OF INDIA, EXTRAORDINARY]

Government of India
Food Safety and Standards Authority of India
(Ministry of Health and Family Welfare)
New Delhi
Dated:

Notification

F.No. The following draft of certain regulation further to amend Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, with the previous approval of the Central Government, proposes to make, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby publishes as required by the said sub section (2), for information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulation will be taken into consideration after the expiry of a period of sixty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi – 110 002;

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

Draft Regulations

1. (1) These regulations may be called the Food Safety and Standards (Food Product Standards and Food Additives) (Amendment) Regulations 2014.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011(hereinafter referred to as the said regulations), after regulation 2.13 relating to Irradiation of Food, the following shall be inserted, namely:-

2.14 Gluten-free foods:-

These foods consists of or are made from one or more ingredients which may contain rice, rye, barley, oats and millets or ragi, pulses and legumes, where the inherent gluten has been reduced and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer. The product does not contain wheat or any of its ingredients.

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The term "gluten-free" shall be printed in the immediate proximity of the name of the product in the case of products described above.

A food which, by its nature, is suitable for use as part of a gluten-free diet shall not be designated "special dietary", "special dietetic" or any other equivalent term. However, such a food may bear a statement on the label that "this food is by its nature gluten-free" provided that it complies with the essential composition provisions for gluten-free as described above and provided that such a statement does not mislead the consumer.

2.15 . Foods specially processed to reduce gluten content to a level above 20 up to 100mg/kg

These foods consist of one or more ingredients from rice, rye, barley, oats, millets or ragi, pulses and legumes which have been specially processed to reduce the inherent gluten present in them to a level above 20 up to 100 mg/kg in total, based on the food as sold or distributed to the consumer.

The term "Low- gluten" shall be printed in the immediate proximity of the name of the product in the case of products described above.

[F. No. No.-----]

(D.K Samantaray)

CEO

Foot note: The principal regulations were published in the Gazette of India vide F. No. 2-15015/30/2010 dated 1st August, 2011.

- (i) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
- (ii) F.No. 5/15015/30/2012, dated 12th July, 2013.

To,

The Manager,
Govt. of India Press,
New Delhi

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**[TO BE PUBLISHED IN PART-III, SECTION 4 OF THE GAZETTE OF INDIA,
EXTRAORDINARY]**

Government of India
Food Safety and Standards Authority of India
(Ministry of Health and Family Welfare)

New Delhi Dated:

Notification

F.No..... The following draft of certain regulation further to amend Food Safety and Standards (Packaging and labelling) Regulations, 2011, which the Food Safety and Standards Authority of India, with the previous approval of the Central Government, proposes to make, in exercise of the powers conferred by clause (k) of sub-section (2) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby publishes as required by the said sub section (2), for information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulation will be taken into consideration after the expiry of a period of sixty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi – 110 002;

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

Draft Regulations

1. (1) These regulations may be called the Food Safety and Standards (Labelling and Packing) (Amendment) Regulations 2014.

(2) They shall come into force on the date of their final publication in the Official Gazette.

1. In Food Safety and Standards (Labelling and Packing) Regulations, 2011(hereinafter referred to as the said regulations), in regulation 2.4 relating to specific requirement/ Restriction on manner of labelling,-

In sub regulation 2.4.5,- after sub clause (51), the following shall be inserted, namely:-

“(52) The term "gluten-free" shall be printed in the immediate proximity of the name of the product in the case of products described in regulation 2.14:- .

Gluten-Free

(53) The term "Low-Gluten" shall be printed in the immediate proximity of the name of the product in the case of products described in regulation 2.15:-

Low- Gluten

”

[F. No. No.-----]

(D.K Samantaray)
CEO

Foot note: The principal regulations were published in the Gazette of India vide F. No. 2-15015/30/2010 dated 1st August, 2011.

i) F.No. 4/15015/30/2011 dated 7th June, 2013

To,

The Manager,
Govt. of India Press,
New Delhi

Annexure-A

TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY
PART III, SECTION 4]
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)
NOTIFICATION

New Delhi,

Dated, 2014

F.No. P.15025/264/13-PA/FSSAI. 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 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 said sub-section (2), 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 suggestion, if any, 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. Short title and commencement.- (1) These regulations may be called the Food Safety and Standards (contaminants, Toxins and Residues) (Amendment) Regulations, 2014
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", -

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(a) in sub-regulation 2.2.1, in clause (1),-

- (i) for the number "(2)", the number "(3)" shall be substituted.
- (ii) for the number "(1)", the number "(2)" shall be substituted.
- (iii) for the number "(3)", the number "(4)" shall be substituted.
- (iv) for the table, the following table shall be substituted, namely,-

"Table

S.No.	Name of the Contaminants	Article of the food	Limit µg/kg
(1)	(2)	(3)	(4)
1.	Aflatoxin	Cereals and Cereal Products	15
		Pulses	15
		Nuts	
		-Nuts for further processing	15
		-Ready to eat	10
		Dried figs	10
		Oilseeds	
		-Oilseeds for further processing	15
		-Ready to eat	10
		Spices	30
2.	Aflatoxin M ₁	Milk and milk products	0.5
3.	Ochratoxin A	Wheat, barley & rye	20
4.	Patulin	Apple juice & Apple juice ingredients in other beverages	50
5.	Deoxynivalenol (DON)	Wheat	1000

[F.No. P.15025/264/13-PA/FSSAI]

(D. K. Samantaray)
Chief Executive Officer

Note. - The principal regulations were published in the Gazette of India, Extraordinary vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011.

Annexure-B

TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY
PART III, SECTION 4]
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)
NOTIFICATION

New Delhi,

Dated, 2014

F.No. P.15025/264/13-PA/FSSAI. 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 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 said sub-section (2), 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 suggestion, if any, 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. Short title and commencement.- (1) These regulations may be called the Food Safety and Standards (Contaminants, Toxins and Residues) (Amendment) Regulations, 2014
2. In the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011, in regulation 2.1 relating to "Metal Contaminants", -
 - (a) in sub-regulation 2.1.1, in clause (2), in the table,-

- 65.
- 1) against serial number 1 relating to Lead, in columns (2) and (3), after the existing entries, the following entries shall respectively be inserted, namely,-

(2)	(3)
Assorted subtropical fruits, edible peel	0.1
Assorted subtropical fruits, inedible peel	0.1
Berries and other small fruits	0.2
Citrus fruits	0.1
Pome fruits	0.1
Stone fruits	0.1
Brassica Vegetables excluding Kale	0.3
Bulb vegetables	0.1
Fruits and vegetables, cucurbits	0.1
Fruiting vegetables other than cucurbits (excluding mushrooms)	0.1
Leafy vegetables (including brassica leafy vegetables but excluding spinach)	0.3
Legume vegetables	0.2
Pulses	0.2
Root and tuber vegetable	0.1
Canned fruit cocktail	1
Canned grapefruit	1
Canned mandarin oranges	1
Canned mangoes	1
Canned pineapple	1
Canned raspberries	1
Canned Strawberries	1
Canned Tropical fruit salad	1
Jam (fruit preserves) & jellies	1
Mango Chutney	1
Table Olives	1
Canned Asparagus	1
Canned Carrots	1
Canned Green beans and Canned wax beans	1
Canned green peas	1

Canned mature processed peas	1
Canned Mushrooms	1
Canned Palmito	1
Canned Sweetcorn	1
Canned Tomatoes	1
Pickled cucumbers (Cucumber pickles)	1
Processed tomato concentrates	1.5
Fruit Juices (including nectars; ready to drink)	0.05
Cereal Grains, except buckwheat, canihua & Quinoa	0.2
Canned Chestnuts and canned chestnut purée	1
Meat of cattle, sheep & pig (also applies to fat from meat)	0.1
Poultry meat	0.1
Cattle, edible offal of	0.5
Pig, edible offal of	0.5
Poultry, edible offal of	0.5
Edible fats and oils (edible fats and oils not covered by individual standards)	0.1
Fish	0.3
Margraïne	0.1
Minarine	0.1
Named animal fats (lard, rendered pork fat, premier jus and edible tallow)	0.1
Olive Oil, refined	0.1
Olive Oil, virgin	0.1
Olive, residue oil (olive pomace oil)	0.1
Poultry fats	0.1

Vegetable Oils, crude (Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter)	0.1
Vegetable Oils, edible (Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter)	0.1
Milks (A concentration factor applies to partially or wholly dehydrated milks.)	0.02
Secondary milk products (as consumed)	0.02
Natural mineral Water, expressed in mg/L	0.01
Infant formula (ready to use)	0.02
Salt, food grade	2
Wine	0.2

- 2) against serial number 3 relating to Arsenic, in columns (2) and (3), after the existing entries, the following entries shall respectively be inserted, namely,-

(2)	(3)
Edible fats and oils (edible fats and oils not covered by individual standards)	0.1
Margarine	0.1
Minarine	0.1
Named animal fats (lard, rendered pork fat, premier jus and edible tallow)	0.1

Olive Oil, refined	0.1
Olive Oil, virgin	0.1
Olive, residue oil (olive pomace oil)	0.1
Vegetable Oils, crude (Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils	0.1
Vegetable Oils, edible (Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils	0.1
Natural mineral Water, expressed in mg/L	0.01
Salt, food grade	0.5

- 3) against serial number 4 relating to Tin, in columns (2) and (3), after the existing entries, the following entries shall respectively be inserted, namely,-

(2)	(3)
Canned foods other than beverages	250
Canned beverages, including fruit juices and vegetable juices	150
Canned citrus fruits	250
Canned stone fruits	250
Canned vegetables	250
Canned fruit cocktail	250
Canned mangoes	250
Canned pineapple	250
Canned raspberries	250
Canned strawberries	250
Canned tropical fruit salad	250

Mango Chutney	250
Table Olives	250
Canned mushrooms	250
Canned tomatoes	250
Pickled cucumber	250
Processed tomato concentrates	250
Canned chestnuts and chestnut purée	250
Cooked cured chopped meat (For products in tins)	250
Cooked cured chopped meat (For products in other containers)	50
Cooked cured ham (For products in other containers)	50
Cooked cured ham (For products in tins)	200
Cooked cured pork shoulder (For products in other containers)	50
Cooked cured pork shoulder (For products in tins)	200
Corned beef (For products in other containers)	50
Corned beef (For products in tins)	200
Luncheon meat (For products in other containers)	50
Luncheon meat (For products in tins)	200

- 4) against serial number 6 relating to Cadmium, in columns (2) and (3), after the existing entries, the following entries shall respectively be inserted, namely,-

(2)	(3)
Brassica Vegetables	0.05
Bulb vegetables	0.05
Fruiting vegetables, cucurbits	0.05
Fruiting vegetables other than cucurbits (excluding tomatoes and edible fungi)	0.05

Leafy vegetables	0.2
Legume vegetables	0.1
Potato, Peeled	0.1
Pulses, excluding soybean dry	0.1
Root and Tuber Vegetables, excluding potato and celeriac	0.1
Stalk and Stem vegetables	0.1
Cereal Grains, except buckwheat, canihua & Quinoa (excluding wheat and rice; and bran and germ	0.1
Rice, polished	0.4
Wheat	0.2
Marine bivalve molluscs, excluding oysters and scallops	2
Cephalopods (without viscera)	2
Natural mineral Water, expressed in mg/L	0.003
Salt, food grade	0.5

- 5) against serial number 7 relating to Mercury, in columns (2) and (3), after the existing entries, the following entries shall respectively be inserted, namely,-

(2)	(3)
Natural mineral Water, expressed in mg/L	0.001
Salt, food grade	0.1

- 6) against serial number 8 relating to Methyl Mercury, in columns (2) and (3), after the existing entries, the following entries shall respectively be inserted, namely,-

(2)	(3)
Fish (except predatory fish), Guidance levels for fresh, processed fish, fish products.	0.5
Predatory Fish (such as shark, sword fish, tuna, pike and others), Guidance levels for fresh, processed fish, fish products.	1

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[F.No. P.15025/264/13-PA/FSSAI]

(D. K. Samantaray)
Chief Executive Officer

Note. - The principal regulations were published in the Gazette of India, Extraordinary vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011.

Annexure-C

TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY
PART III, SECTION 4]
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)
NOTIFICATION

New Delhi,

Dated, 2014

F.No. P.15025/264/13-PA/FSSAI. 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 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 said sub-section (2), 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 suggestion, if any, 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. Short title and commencement.- (1) These regulations may be called the Food Safety and Standards (contaminants, Toxins and Residues) (Amendment) Regulations, 2014
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", -
 - (b) in sub-regulation 2.2.1, in clause (2),-
 - (i) for the number "(1)", the number "(2)" shall be substituted.

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(ii) For the words "any article of food", the words and figures "article of food mentioned in column (3)" shall be substituted.

(iii) for the number "(2)", the number "(4)" shall be substituted.

(iv) for the table, the following table shall be substituted, namely,-

"Table

S.No	Name of Naturally Occurring Toxic Substances (NOTS)	Article of food	Maximum Limits (ppm)
(1)	(2)	(3)	(4)
1	Agaric acid	Food containing mushrooms	100
		Alcoholic beverages	100
2	Hydrocyanic acid	Nougat, marzipan or its substitutes or similar products	5
		Canned stone fruits	5
		Alcoholic beverages	5
		Confectionery	5
		Stone fruit juices	5
3	Hypericine	Alcoholic beverages	1
4	Saffrole	Meat preparations and meat products, including poultry and game	10
		Fish preparations and fish products	10
		Soups and sauces	10
		Non-alcoholic beverages	10
		Food containing mace and nutmeg	10
		Alcoholic beverages	10

[F.No. P.15025/264/13-PA/FSSAI]

(D. K. Samantaray)
Chief Executive Officer

Note. - The principal regulations were published in the Gazette of India, Extraordinary vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011.

Annexure XVII

**[TO BE PUBLISHED IN PART-III, SECTION 4 OF THE GAZETTE OF INDIA,
EXTRAORDINARY]**

Government of India
Food Safety and Standards Authority of India
(Ministry of Health and Family Welfare)

New Delhi Dated:

Notification

No. The following draft of certain regulations to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, with the previous approval of the Central Government, proposes to make, in exercise of the powers conferred by clause(e) of sub-section (2) of section 92 read with sub-section (2) of section 16 of the Food Safety and Standards Act, 2006, is hereby published as required by 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 a 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, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi-I 10 002;

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

Draft Regulations

(1) These regulations may be called the Food Safety and Standards (Food Product Standards and Food Additives) (Amendment) Regulations 2014.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011(hereinafter referred to as the said regulations). –

A. in regulation 3.1.17 related to “Other substance to be used in specified limits” after the sub-regulation (iv) related to Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Ferredetate-Na Fe EDTA), the following shall be inserted, namely

(v) :— “**Use of Plant sterol (Phytosterols) as food ingredients**-Phyto or Plant sterol from non LM source for use in the categories of food products with their use at the level of 0-40mg/kg of body weight. The product should not exceed the ADI for Phytosterols and shall comply with the label declaration under sub-regulation 53 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011:—

Yellow fat spread, milk products, milk based fruit drink, fermented milk products, cheese, salad dressings, juices and nectars, Edible oils, Baked products (Bread).

[F. No.....]

(D.K.Samantaray)
CEO

Foot note: The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number 2-15015/30//2010 dated the ‘1st August, 2011.

**[TO BE PUBLISHED IN PART-III, SECTION 4 OF THE GAZETTE OF INDIA,
EXTRAORDINARY]**

Government of India
Food Safety and Standards Authority of India
(Ministry of Health and Family Welfare)

New Delhi Dated:

Notification

No.—The following draft of certain regulations to amend the Food Safety and Standards (Packaging and labelling) Regulations, 2011, which the Food Safety and Standards Authority of India, with the previous approval of the Central Government, proposes to make, in exercise of the powers conferred by clause(e) of sub-section (2) of section 92 read with sub-section (2) of section 16 of the Food Safety and Standards Act, 2006, is hereby published as required by 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 a 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, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi-I 10 002;

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

Draft Regulations

- (1) These regulations may be called the Food Safety and Standards (Labelling and Packing) (Amendment) Regulations 2014.
- (2) They shall come into force on the date of their final publication in the Official Gazette.
2. In Food Safety and Standards (Labelling and Packing) Regulations, 2011, in regulations 2.4 related to Specific Requirements/ Restrictions on manner of labelling
 - (C) In sub-regulation 2.4.5 relating to Specific Labelling Requirements of other Products, after clause(52), the following shall be inserted, namely:-

“(52) Yellow fat spread, milk products, milk based fruit drink, fermented milk products, cheese, salad dressings, juices and nectars, Edible oils, Baked products (Bread) containing plant sterol shall bear the following declarations, namely:-

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1. "Product is for people who want to lower their blood cholesterol".
 2. "Strict medical supervision for pregnant and lactating women"
 3. CONSUMPTION OF MORE THAN 3g. PER DAY, TOTAL OF STEROL, STANOL OR COMBINATION THEREOF MUST BE AVOIDED

[F. No.....]

(D.K.Samantaray)
CEO

Foot note: The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number 2-15015/30//2010 dated the '1st August, 2011.

Annexure XVIII

**[TO BE PUBLISHED IN THE GAZETTE OF INDIA,
EXTRAORDINARY, PART III, SECTION 4]
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)
NOTIFICATION**

New Delhi, dated, 2014

F.No P.15025/261/2013-PA/FSSAI.- The following draft of certain regulation further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, with previous approval of Central Government, proposes to make, in exercise of the powers conferred by clause (e) of sub- section (2) of section 92 read with section 16 of Food Safety and Standards Act, 2006 (34 of 2006) is hereby publishes as required by the said sub-section (2), 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 suggestion, if any, 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 regulation

1. Short title and commencement. - These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2014
2. in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in Appendix A, relating to list of food additives,-
 - (a) in Table 1 relating to “ List of food Additives for use in bread and biscuits”, in serial number B, against item 7, relating to column number 4, for the symbol “- ”, the words “GMP” shall be substituted.

[F.No. P15025/261/2013-PA/FSSAI]

D. K. Samantaray
Chief Executive Officer

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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, 2010 and subsequently amended vide notification numbers:

- (i) F.No. 4/15015/30/2011, dated 7th June, 2013.
- (ii) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
- (iii) F.No. 5/15015/30/2012, dated 12th July, 2013.

Annexure XIX

**[TO BE PUBLISHED IN THE GAZETTE OF INDIA,
EXTRAORDINARY, PART III, SECTION 4]
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)
NOTIFICATION**

New Delhi, dated, 2014

F.No P.15025/261/2013-PA/FSSAI.- The following draft of certain regulation further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, with previous approval of Central Government, proposes to make, in exercise of the powers conferred by clause (e) of sub- section (2) of section 92 read with section 16 of Food Safety and Standards Act, 2006 (34 of 2006) is hereby publishes as required by the said sub-section (2), 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 suggestion, if any, 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 regulation

1. Short title and commencement. - These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2014
2. in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011,
 - (a) in Appendix A, relating to list of food additives, in Table 7 relating to " List of food Additives in thermally Processed Vegetables", in serial number C, in item (b) against sub-item 1-8, in column no 4, 7 and 12, for the words and numbers "200 ppm maximum" the symbol "-" shall be substituted.

[F.No. P15025/261/2013-PA/FSSAI]

D. K. Samantaray
Chief Executive Officer

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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 1st August, 2010 and subsequently amended vide notification numbers:

- (i) F.No. 4/15015/30/2011, dated 7th June, 2013.
- (ii) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
- (iii) F.No. 5/15015/30/2012, dated 12th July, 2013.

Annexure XX

**[TO BE PUBLISHED IN THE GAZETTE OF INDIA,
EXTRAORDINARY, PART III, SECTION 4]
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)
NOTIFICATION**

New Delhi, dated, 2014

F.No P.15025/855/2012-PA/FSSAI.- The following draft of certain regulation further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, with previous approval of Central Government, proposes to make, in exercise of the powers conferred by clause (e) of sub- section (2) of section 92 read with section 16 of Food Safety and Standards Act, 2006 (34 of 2006) is hereby publishes as required by the said sub-section (2), 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 suggestion, if any, 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 regulation

1. Short title and commencement. - These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2014
2. in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in Appendix A, relating to list of food additives,-
 - (a) in Table 14 relating to " List of food Additives for use in Milk products", in serial number A, against item 3, relating to column number 12, for the symbol "- ", the words "Sodium alginate (GMP) in ice cream only" shall be substituted.

[F.No. P15025/855/2012-PA/FSSAI]

D. K. Samantaray
Chief Executive Officer

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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, 2010 and subsequently amended vide notification numbers:

- (i) F.No. 4/15015/30/2011, dated 7th June, 2013.
- (ii) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
- (iii) F.No. 5/15015/30/2012, dated 12th July, 2013.