



THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Voluntary Public

Date: 2/25/2013

GAIN Report Number: IN3013

India

Post: New Delhi

FSSAI invites national experts to participate in harmonization of Indian Food Standards

Report Categories:

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Exporter Guide

Product Brief

Approved By:

David Leishman

Prepared By:

Radha Mani

Report Highlights:

On February 18, 2013, the Food Safety and Standards Authority of India (FSSAI) published a notification inviting relevant national experts to participate in an effort to harmonize Indian food standards with Codex standards and other international best practices. Nominations must be submitted to FSSAI by March 20, 2013.

General Information:

Introduction: On February 18, 2013, the Food Safety and Standards Authority of India (FSSAI) published a notification inviting relevant national to participate in an effort to harmonize Indian food standards with Codex standards and other international best practices. FSSAI is seeking expertise in food regulatory affairs, scientific research, food and nutrition, food technology, policy, etc... The FSSAI has also published four Annexures which include the strategy paper for harmonization (Annexure I); the guidance document on vertical standards (Annexure II); guidance on the role of India's food standards development process (Annexure III); and the nomination form (Annexure IV). Nominations must be submitted to FSSAI by March 20, 2013.

The full text of the Notification along with the Annexures is provided below, and can also be accessed on the FSSAI website at: <http://www.fssai.gov.in/>

Nominations should be submitted by March 20, 2013 to:

Food Safety and Standards Authority of India
3rd Floor, Food and Drug Administration Bhawan,
Kotla road, New Delhi. 110002
Email: fssaiharmonisation@gmail.com

DISCLAIMER: The information contained in this report was retrieved from the following Government of India website www.fssai.gov.in . The U.S. Government makes no claim of accuracy or authenticity.

Food Safety and Standards Authority of India (FSSAI)
Ministry of Health & Family Welfare, Govt. of India
FDA Bhawan, Kotla Road,
New Delhi - 110 002

HARMONISATION OF INDIA'S FOOD STANDARDS WITH CODEX STANDARDS AND OTHER INTERNATIONAL BEST PRACTICES

FSSAI was established under Section 4 of the Food Safety and Standards Act, 2006 with the mandate of laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. The Act aims at food safety as a national movement. To meet this objective, it is necessary that FSSAI follows an inclusive approach by utilising the wisdom of all stakeholders in the country, that all relevant issues are discussed through a transparent consultative process and conflicting opinions reconciled on the basis of scientific evidence.

One of the immediate tasks at hand seems to be to review our food safety standards situation. Currently, several standards in Food Safety & Standards Regulations, 2011 have been drawn from provisions of the Prevention of Food Adulteration (PFA) Act. However, there has been an on-going demand for review of these standards taking into account the latest development in food science across the globe, food consumption pattern, new specifications, presence of new contaminants and toxins as well as use of new food additives and ingredients required by the producers and manufacturers in food business. We also need to consider development of new standards and texts, where necessary while taking cognizance of the developments in an environment of open market in India. Needless to say that the WTO encourages harmonization of national food regulatory standards, guidelines and best practices needs with those of the Codex and provide an equal opportunity to all stakeholders in food business.

To address the above, FSSAI has framed a strategy for taking up this work in a time bound manner. A copy of this strategy paper for harmonization is annexed with this letter (please see **Annexure – I**). You might observe from this paper that this is a massive exercise, and would require participation of all relevant experts in the country be they in the field of food regulatory affairs, scientific research, food and nutrition, food technology, policy affairs, academia, etc. It is evident that the process of harmonization cannot be completed with the active contribution and co-operation of all relevant experts in the country. They would, therefore, have to be identified on the basis of their interest in contributing and experience in the subject matter as they would utilize the available scientific and regulatory information for the expected outcome.

To facilitate the process, it is necessary to identify the current areas and volume of work involved explaining the strategy, scope of work, guidelines for working groups, timelines, format and procedure for forwarding nominations, selection criteria, etc. Detailed documents have been prepared and are shown as several icons contained in **Annexure – II** (Guidance Document on Vertical Standards). These icons are numbered as *Attachments 1 to 12* and can be downloaded from the FSSAI website (fssai.gov.in).

FSSAI invites interested individuals to participate in this harmonization/ standardization process. We suggest that interested experts may please study the **Annexure – III** (Guidance to the Nominees), which explains the contribution involved in the entire process. This will enable one to take a decision on the

role that he/she would like to play in India's food standards development process. Those committed to contribute to this work are invited to forward their nominations to the Food Safety and Standards Authority of India (FSSAI), 3rd Floor, FDA Bhawan, Kotla Road, New Delhi – 110 002, preferably, by e.mail to a specially created ID: fssaiharmonisation@gmail.com by **March 20, 2013** in **Annexure – IV** (Nomination Form).

FSSAI reserves the right to accept or reject any or all of the nominations at any stage of the process without assigning any reason and no claim/dispute in this respect shall be admissible.

New Delhi
February 18, 2013

Sd/-
S. Dave
Advisor

Annexure - I

STRATEGY FOR HARMONISATION OF INDIA'S DOMESTIC FOODSTANDARDS WITH CODEX STANDARDS AND OTHER INTERNATIONAL BEST PRACTICES

Under the Food Safety and Standards Act, 2006 and the ensuing FSS Regulation of 2011, it is the responsibility of FSSAI to frame standards for food products and for food safety and to monitor their implementation in the country. Several standards have been notified and more are required to be framed and notified. The work on the standardisation process has evolved over these years. The standards are, essentially, based on scientific data and other factors relevant to the safety of food products for protecting the health of consumers. Several of the food standards have been drawn from provisions of the Prevention of Food Adulteration Act. However, there is an on-going demand for review of these standards taking into account the latest development in food science, food consumption pattern, new specifications, presence of new contaminants and toxins as well as use of new food additives and ingredients required by the producers and manufacturers. In the recent past, FSSAI also invited suggestions from the industry and a number of these were also received.

Under Section 16(3)(m) of the FSS Act, 2006, it is also the responsibility of FSSAI to promote consistency with the relevant international standards. This would facilitate trade and ensure availability of safe food to the consumers. The standards and other guidance texts adopted by Codex Alimentarius Commission are the relevant international standards and are also the reference point within the framework of WTO. It is incumbent upon member nations to apply the national treatment clause, meaning thereby, all imported foodstuff will be given a treatment equal to those applicable to the domestic producers, manufacturers and the market. The FAO and WHO of the United Nations regularly encourage countries to harmonise their standards with those of the Codex.

In light of the above, it is considered appropriate to review India's standards and harmonise them with the Codex and other international best practices to the extent possible and necessary taking into account our needs. In doing so, it is necessary to review the existing standards and draft new standards and codes of practice for implementation in the country. The process would also require sufficient amount of capacity building among the stakeholders to ensure proper implementation and monitoring. With a view to achieving this objective, the following strategy is proposed to be followed by FSSAI:

1. Scope of Work

The work involved in this respect is expected to be as follows:

- (a) Review of existing FSS standards with respect to Codex standards and standards of other countries and identify areas requiring improvement;
- (b) Harmonization of such national standards with Codex and other international best practices;
- (c) To develop an approach for undertaking the required changes in the existing standards as well as introduction of new standards; and
- (d) On the basis of identified needs, to develop new standards and codes of practice as well as revise existing standards.

2. Process proposed for Harmonisation of Standards

Taking the recently approved categorization of food products (the Indian Food Code) as the basis, the

proposed process comprises of, where necessary, reviewing the Food Safety and Standards (Food Products Standards and food Additives) Regulations, 2011; Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011; and, Food Safety and Standards (Prohibition and Restriction) Regulations, 2011 and other Regulations by following two approaches as given below:

- Revision or Formulation of Vertical Standards for different food products or group of food products;
- Revision or Formulation of Horizontal Standards.

a) Vertical Standards: Vertical Standards would mean quality standards of food products, e.g., fresh and processed fruits and vegetables, milk and milk products, meat and meat products, fish and fish products, poultry products, fats and oils, etc. In this context, category specific and/or product specific food safety standards (additives, contaminants, pesticide residues, hygiene requirements, residues of veterinary drugs, labelling etc.) will be reviewed. The following two-pronged strategy is proposed to be followed in the following hierarchy:

- i) Review the domestic standards under FSSR and initiate the process of revision/harmonisation. In such cases, it is proposed to review the international standards and identify the necessary changes required for harmonisation with the Codex standards; simultaneously, identify the products where we do not have domestic standards under FSSR but a relevant Codex standard is available. In such cases, it is proposed to adopt/adapt such Codex standards based on India's needs;
- ii) There are several products for which there are neither domestic standards under FSSR nor are there Codex standards, e.g., ethnic foods of Indian origin. In such cases, it is proposed to take up identification of products and the process for their standardization in consultation with sector specific experts;

In respect of (i) above, it is also proposed to review the Codex texts and other internationally followed best practices as well as standards adopted by the EU, USFDA, Canada, etc. while framing the proposals for standards.

b) Horizontal Standards: Horizontal Standards are those which apply across all products categories. For instance, food additives, food contaminants (like heavy metals, toxins, etc.), food hygiene (microbiological standards), pesticide residues, residues of veterinary drugs, food labelling, food inspection and certification, methods of sampling and analysis, and nutrition requirements. These would also need to be equipped with Codes of Practice for uniform application across all vertical standards.

With regard to horizontal standards, it is proposed to prioritize the work in such a manner that we take up review of standards and their harmonisation in respect of additives generally recognised as safe. Such additives are listed in the Table 3 of the General Standards for Food Additives (GSFA) under the Codex. Simultaneously, it is proposed to review and harmonise ingredients/nutrients (including Ayurveda and other ingredients as specified under Section 22 of the FSS Act) and which are also generally recognised as safe.

The work will be initiated with the development of vertical standards. While doing so, the horizontal standards will also get developed. With a view to speeding up the harmonization process, the work on development of several horizontal standards will also need to be simultaneously initiated as mentioned in the preceding paragraph under (b) above. In addition, it is proposed to develop and notify Codex of Practice, such as application of GAP, GMP, GHP, GLP, FSMS, ISO standards, etc.

3. Procedure proposed to be followed

After the identification of work referred to above is completed, it is proposed to utilize the knowledge available in the country in terms of experts in FSSAI, food industry (small, medium, large), relevant Govt. institutions, commodity experts, academicians, consumer organisations as well as the representatives of trade bodies (AIFPA, FICCI, CII, etc.). Because of the volume of work involved, several experts are to be identified to carry forward the work in a collaborative spirit. The draft standards and codes of practice will be developed by such expert groups. These documents will then be considered by a working group of FSSAI. It is proposed to follow an iterative process with the expert groups to check for consistency with the intent of FSS Act and Regulations before circulating the draft texts to a large group of stakeholders by placing them on the FSSAI website for comments/suggestions. After receipt of comments, the draft texts will be placed before the relevant scientific panels, where applicable and then before the Scientific Committee for consideration.

Once the Scientific Committee has approved the draft texts and FSSAI has accepted them, these will be notified to the WTO as per obligations under the WTO Agreement. A minimum of 60 days period will have to be provided to the WTO members for comments before the going through the process of adoption and notification of the standards and other texts by the FSSAI.

4) Proposed Time Frame

The work involved is quite substantial. For the purposes of monitoring the progress, it is proposed that efforts should be made to follow the time lines given below in terms of completion of the activities:

15 March 2013: Receipt of nominations of experts;

April 2013: Consideration and acceptance of nominations by FSSAI, and work assignment to expert groups;

July 2013: Receipt of draft standards and codes of practice;

Oct. 2013: Review by FSSAI working group in consultation with the expert groups and invite stakeholder comments/suggestions on the draft texts;

Dec. 2013: Receipt of stakeholder comments/suggestions on the draft texts;

April 2014: Review by relevant Scientific Panels and/or the Scientific Committee;

July 2014: Acceptance of the draft standards/texts by FSSAI and notification to WTO;

Oct. 2014: Receipt of comments from WTO members and from within India;

Nov. 2014: Where necessary, review by the relevant Scientific Panel and/or by the Scientific Committee; and

Dec. 2014: Adoption of the final standards/texts and notification.

Annexure II

GUIDANCE DOCUMENT ON VERTICAL STANDARDS

- I. As may be observed from the Strategy document, it is aimed at starting this work for developing the vertical standards. It is proposed to cover products where we have domestic standards under FSSR but these need a revision/harmonization with those of the Codex and other international

best practices. Further, it also proposed to cover those products where we do not have domestic standards under FSSR but a relevant Codex standard is available.

- II. II. The list of ‘Vertical Standards’ not specifically provided for under FSSR regulations but adopted by FAO/WHO Codex Alimentarius Commission is given below:



Attacement 1-list of vertical standards

The codex standards for these products will be reviewed and new standards be suggested in the following format, for these categories or standards or products mentioned therein.

Introduction

The format indicates the statements which should be included in standards as appropriate under the relevant headings and may be modified to meet the intended objectives:

1. Name of the Standard
2. Scope
3. Description
4. Composition and Quality Factors
5. Food Additives
6. Contaminants, Toxins and Residues
7. Hygiene
8. Packaging, Labeling and Claims
9. Methods of Analysis and Sampling
10. Processing Aids

Notes on the Headings:

1. Name of the Standard

The name of the standard should be clear and as concise as possible.

2. Scope

This section should contain a clear, concise statement as to the food or foods to which the standard is applicable. In the case of a general standard covering more than one specific product, it should be made clear as to which specific products the standard applies.

3. Description

This section should contain a definition of the product or products with an indication, where appropriate, of the raw materials from which it is derived and any necessary references to processes of manufacture. It may also include references to types and styles of product and to type of pack. There may also be additional definitions when these are required to clarify the meaning of the standard.

4. Composition and Quality Factors

This section should contain all quantitative and/or other requirements as to composition including, where necessary, identity characteristics, provisions on packing media and/or requirements as to compulsory and optional ingredients.

It may also include quality factors which are essential for the designation, definition or composition of the product concerned. Such factors may also include the quality of the raw material, quality criteria for the finished products and/or provisions on taste, odour, colour and texture.

The substance(s) which may need to be restricted for this standard and/or products mentioned herein may be provided in this section. The scientific rationale (links/references from expert consultations of WHO&FAO or JECFA/JMPR/JEMRA/JEMNU or other information source from peer reviewed scientific journals or other regulatory agencies) for this restriction should also be provided.

Information specific to these vertical standards as per sections below (Sections 5-10) is to be given in enclosed formats. These will then be later become a part of the relevant horizontal standards.

If an expert working group [referred to in Para No. 3 of the Strategy document (Annexure I)] on a particular standard is of the view that risk assessment is needed for particular parameter(s) like Contaminants, Food Additives or Microbiological Criteria, this may be mentioned in the relevant sections by the expert working group.

5. Food Additives

This section should contain a general reference to the corresponding Codex General Standard for Food Additives (GSFA). The guidance document for providing inputs suitable for this standard or products mentioned herein or category for this section is in Attachment 2 below.



[Attachment 2-Guidance Document](#)

This section needs to be commented on and developed in two parts:

a. In Excel sheets (Attachments 3 and 4) with guidance from Table 2 of the Codex GSFA (Attachment 5). These are based on Indian Food Categories and will require inputs of allowances mainly from Codex or other national/international regulations as per links provided in the sheet. The objective here is to prepare the list of permitted substances.



[Attachment 3-Format for Food Additives](#)



[Attachment 4-Format for Food Additives](#)



[Attachment 5-Table 2 of Codex GSFA](#)

b. In Excel sheet (Attachment 6) based on Table 3 of the Codex GSFA (Attachment 7) in case any modifications are suggested. The objective here is to prepare the list of substances permitted to be used on GMP basis.



Attachment 6-Format for Additives



Attachment 7-Table 2 of Codex GSFA

6. Contaminants, Toxins and Residues

This section should contain a general reference to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011. This section needs to be commented in the Excel sheets(Attachments 8 and 9) provided below and be based on the Codex General Standard for Contaminants and Toxins in Food and Feed (Attachment 10):



Attachment 8-Format for Contaminants



Attachment 9-Format for Contaminants



Attachment 10-Codex General St.

While commenting on this sheet the relevant Codex standards or Guidelines and/or other national/international regulations may be taken into account.

7. Hygiene

This section should provide Specific requirements for the product based on Recommended Code of Practice given by Codex or International Commission for Microbiological Specifications for Foods (ICMSF). Working groups may refer to Codex Standards, Guidelines or limits for any microbial contaminants for filling up this section. A comparative statement for these limits with national/international regulations shall also be given.

8. Packaging, Labeling and Claims

Any specific labeling requirements for the product or changes in the existing labeling requirements may be given under this section. Suggestions for claims may be given as per the Excel sheet (Attachment 11) given below and these suggestions must be based on international models for claim regulations and the justifications for the same may also be provided.



Attachment 11-Format for Claims

This section should also include a general reference to Food Safety and Standards (Packaging and Labeling) Regulations, 2011.

9. Methods of Analysis and Sampling

Under this section, propose internationally validated reference (like AOAC, ISO, Food Chemical Codex, AACC, AOCS, Codex, IAEA) methods to be used for regulatory/enforcement purposes. The limit of quantification of such methods should be adequate as per the regulatory limits proposed. While filling up this section, care must be taken that the laboratories performing these methods must be complying to ISO/ IEC- 17025. The methods under this section must be given only for those parameters which are specific to this standard. This section may also contain a reference to analysis manual on FSSAI website.

10. Processing Aids:

This section should specify any processing aid(s) suitable for this standard or products mentioned herein or category at Maximum Level of Use in line with Good Manufacturing Practices (GMP).

III. The format for commenting on changes required in vertical standards currently available under FSSR which may need harmonization is given below (please see Excel Sheet in Attachment 12).



Attachment 12-FSSR Standard for review

The expert group working on a standard is expected to prepare a complete draft standard for food products. Further, they may decide to use an alternate template if found more suitable. Reasons for this change of format must be recorded. If the Working Group feels that there is a need to re-write a standard, then the same can be done provided the justification for that is available. This re-written standard shall be as per the format provided in the 'Introduction' para of this document.

Annexure-III

INSTRUCTIONS TO THE NOMINEE

1. STRATEGY FOR THE WORK PROPOSED

The strategy for the harmonisation of national standards with Codex standards including scope of work,

process involved procedure to be followed & time frame has been attached as **Annexure I** with the document.

2. GUIDANCE DOCUMENT ON VERTICAL STANDARDS

The guidance document on Vertical standards indicating the formats to be used for the harmonisation work has been attached as **Annexure II**.

3. GUIDELINES FOR WORKING GROUP

The members of the formed working groups need to follow certain guidelines/ procedure during the harmonisation process & the individual expert would be required to carry out the following activities indicated below:

- (a) Study the existing domestic standards (FSS Regulations, 2011) and identify the necessary changes required in the standards for harmonisation with the Codex and other international standards.
- (b) To utilise the facts, data and information available and formulate new national standards/ guidelines/ codes of practices for final consultation by stakeholders and scientific panels/ FSSAI. In addition, provide scientific substantiation/ evidences, trade data, etc, wherever applicable
- (c) To examine and review the internationally followed best practices as well as standards adopted by Codex first and then by the EU, USFDA, Canada, etc., while framing the proposals for standards.
- (d) To work in collaboration with experts in FSSAI, food industry (small, medium, large), relevant Govt. institutions, commodity experts, academicians, consumer organisations as well as the representatives of trade bodies (AIFPA, FICCI, CII, etc.) to carry forward the work in a collaborative spirit.
- (e) With the role mentioned above, to draft the allotted vertical and horizontal standards and/or Code of Practices/Guidelines for draft notification by FSSAI for stakeholders review/ comments as per timelines indicated in the strategy document.
- (f) To participate dedicatedly in the harmonisation process and provide inputs electronically. Further, as and when required, participate physically in the working group meetings.
- (g) To provide the inputs in given formats on suggested changes, for wider consultation by stakeholders.
- (h) Associations like FICCI, AIFPA, CII, ILSI, PFNDIAI, etc will support for final compilation, modifications and notification of the harmonisation documents in close collaboration with FSSAI and other institutions, so that associations can be contacted in case of clarifications at any stage of process.

4. ELIGIBILITY STATUS

The nominee should be an Individual expert from food industry (small, medium, large)/ relevant Govt. institutions/ commodity experts/ academicians etc. Nominee must have extensive experience in similar type of work and meet the qualifying requirements as stipulated below.

- i. The individual or company should have relevant experience in handling matters related to the provisions of Prevention of Food Adulteration Act, 1954 (now repealed) and similar Food laws/ orders including under Essential Commodities Act and have adequate exposure to food safety, quality & standards issues.
- ii. Should be willing as well as capable of working with FSSAI for at least 1 year for successful execution of the work, so assigned.
- iii. Should be aware of the international food laws, rules and regulations, like CODEX, USFDA,

FSANZ, EU, Canada, etc.

5. CRITERIA FOR SHORTLISTING OF NOMINATIONS

Nominations received will be shortlisted by a Committee of FSSAI on the basis of the following criteria:

- i. After receiving the nominations, number of working groups will be constituted for sectors/sub sectors to complete the work proposed. Each working group will consist of one representative each from the small/medium/large industry, academia/research institute and association/trade bodies.
- ii. There will be no process of zonal distribution/selection involved in the shortlisting process.
- iii. Selection process of an individual is based on personal capabilities, knowledge and experience, irrespective of its residing place.
- iv. The person should be willing to contribute his/her time and knowledge for the work to be primarily conducted through electronic means, but be willing to travel as necessary for participating in 1-2 physical meetings for which prior concurrence of FSSAI will be required. TA/DA and honorarium will be paid by FSSAI as per rules.

6. SUBMISSION OF NOMINATION

Nomination form can be downloaded from FSSAI's website at <http://fssai.gov.in> and can be submitted electronically via email to a specially created ID: fssaiharmonisation@gmail.com or by post to Advisor, Food Safety and Standards Authority of India, 3rd Floor, FDA Bhawan, Kotla Road, New Delhi - 110 002 on or before 20th March, 2013 by 5.00 P.M.

NOMINATION FORM

Advisor,
Food Safety and Standards Authority of India
FDA Bhawan, Kotla Road,
New Delhi-110 002

Sub: - Nomination for harmonisation of India's domestic food standards with international standards.

Name	
Designation	
Organisation	
Organisation Address	
Residence Address	
Telephone (Official)	
Telephone (Residence)	
Mobile	
Email 1	
Email 2	

Preference for Working Group (Select any three in each category, basis area of specialization)		
I. Vertical Standards		
Link to IFC: (http://www.fssai.gov.in/Portals/0/Pdf/INDIAN FOOD CODE(25-06-2012).pdf)		
Preference (1, 2 & 3)	Category	Experience in preferred area
	Milk & Milk Products	Preference 1: Preference 2: Preference 3:
	Fats & Oils	
	Fruits & Vegetable Products	
	Cereals & Cereal Products	
	Bakery products	
	Ready-to-eat products	
	Meat & Poultry	
	Fish & fish products	
	Egg & egg products	
	Sweetening agents including honey	
	Sweets & Confectionery	
	Salts, spices & condiments	
	Alcoholic beverages	
	Non-alcoholic Beverages including water	
	Nutrition & Dietary Supplements	
	Food for special dietary uses	
	Foods for infant nutrition	
	Any other (Please specify)	
II. Horizontal standards		
Preference (1, 2 & 3)	Category	Experience in preferred area
	Labelling & Claims	Preference 1: Preference 2: Preference 3:
	Food Additives	
	Processing aids	
	Food Hygiene	
	Pesticide residues	
	Method of analysis & sampling	
	Veterinary drugs	

	Contaminants & Toxins	
	Microbiological contaminants	
	Ingredients	
	Any other (Please specify) (Mycotoxins, NOTS, Heavy Metals, Processing Aids Residues, etc.)	

I have understood the criteria and working procedure. These are acceptable to me and would like to volunteer myself and commit to share my knowledge and dedicate the required time and support for development of India's domestic standards in line with the Codex and other international best practices in a time-bound manner as intended in the strategy document.

Date:

Place:

(Signature)*

*If sent via email, signature is voluntary