

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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## India

**Post:** New Delhi

### **Draft Food Import Regulations - 2012**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Exporter Guide

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**Report Highlights:**

On July 23, 2013, The Food Safety and Standards Authority of India (FSSAI) published draft 'Food Safety and Standards (Food Import) Regulations' on its website inviting suggestions and comments from stakeholders. This regulation provides the necessary guidelines and requirements that importers should adhere to while importing food items. FSSAI published a similar draft document for comment on July 7, 2011; however, that draft is no longer valid and has been replaced by this draft. We recommend that interested parties, who reviewed the 2011 document, also review this draft including the forms and schedules at the end of the document because it contains a number of revisions.

## **General Information:**

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

## **Introduction:**

On July 23, 2013, The Food Safety and Standards Authority of India (FSSAI) published draft 'Food Safety and Standards (Food Import) Regulations', 2012 on its website inviting suggestions and comments from stakeholders. This regulation provides the necessary guidelines and requirements that importers should adhere to while importing food items. FSSAI published a similar draft document for comment on July 7, 2011; however, that draft is no longer valid and has been replaced by this draft. We recommend that interested parties, who reviewed the 2011 document, also review this draft including the forms and schedules at the end of the document because it is the most current and complete draft and contains a number of revisions. We have highlighted a number of the changes in the body of this report, but this should not be considered a complete listing of the changes from the 2011 document and should not be substituted for a complete reading of the draft.

The complete draft can be found at [Draft Food Safety and Standards \(Food Import\) Regulations, 2012](#) on the FSSAI website.

## **Details on Draft Food Safety and Standards (Food Import) Regulations', 2012**

- **Type of Regulation:** Draft
- **Notification to the WTO:** Not notified to date
- **Final date for comments:** August 22, 2013
- **Date of Implementation:** will be notified by the FSSAI in the Official Gazette of India
- **Products Affected:** Various imported food items
- **Agency in-charge:** Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, GOI

Comments or suggestions from stakeholders should be emailed on or before August 22, 2013 to:

**The Chief Executive Officer**  
**Food Safety and Standards Authority of India**  
**FDA Bhawan, Kotla Road**  
**New Delhi-110002**  
**E-mail:** [importreg.fssai@gmail.com](mailto:importreg.fssai@gmail.com)

The Regulations relate to the following:

- Powers and duties of FSSAI's Authorized Officers at the port of entry
- Licensing of food importers
- Prohibition and regulation of imports
- Food inspection prioritization based on risk
- Import requirements
- Clearance of special categories of imported food:

- (i) Accredited Food Importer Program
  - (ii) Food Export Oriented Units
  - (iii) Imports by Diplomatic Missions
  - (iv) Imports for quality assurance, research and development
  - (v) Imports for international trade fairs and exhibitions
  - (vi) Imports for special sports events
- Inspection of imported food at the port of entry by FSSAI's Authorized Officers
  - Sampling and testing of imported food
  - Clearance of imported food
  - Disposal of rejected food and food samples
  - Uncleared and unclaimed foods
  - Review process in case the importer requires a review of imported food item

In **Chapter 1**, additions have been made to the list of definitions and these are:

- 'Bill of Entry' means the Bill of Entry filed by the Importer under the provisions of Customs Act, 1962;
- 'Custom House Agent (CHA)' means a person licensed under Customs House Agents Licensing Regulations, 2004 to act as agent for the transaction of any business relating to the entry or departure of conveyances or the import or export of goods at any Customs Station;
- 'Customs Area' means the notified area of a customs station and includes any area in which imported goods or exports goods are ordinarily kept before clearance by the Customs Authorities;
- 'Food Authority' means the Food Safety and Standards Authority of India (FSSAI) established under the Food Safety and Standards Act, 2006 as a statutory body;
- 'Inspection Fee' means the fee levied by FSSAI towards direct and indirect cost involved in Inspection Service activities such as examination of pre-arrival documentation, visual inspection, sampling and disposal of application submitted by a Food Importer for Clearance of Food Imports;
- 'Laboratory analysis fee' is the fee payable towards the testing of Food Samples as per FSSAI (Laboratory Analysis and Sampling) Regulations, 2011 and Laboratory Analysis Report per sample of food analyzed as specified and reviewed by Food Authority from time to time;
- 'Packing list' means the itemized list of articles included in each shipping giving the quantity, description, and weight of the individual articles;
- 'Pre Arrival Document Review (PADR)' means the pre arrival examination of declarations and documents, in respect of the particular food article intended for import;
- 'Review application fee' means the fee levied by FSSAI towards disposal of review application submitted by Food Importer against the order of Authorized Officer pertaining to clearance of Food Imports;
- 'Review Officer' means an officer so designated by the Food Authority to review orders passed under these regulations by the Authorized Officer;

**Chapter 2** dealing with 'Officers of the Food Authority', the clause on 'Authorized Officer' has been rephrased and it now reads as:

- 'The Chief Executive Officer of Food Authority in his capacity of Food Safety Commissioner

shall, by notification, appoint such persons as he thinks fit, as Authorized Officer for as many Points of Entry as the Food Authority may deem necessary, for the purpose of performing functions under the Act, the rules and the regulations.’

A proviso has been added to the Qualifications of the Authorized Officer which states:

- Provided that on the date of commencement of these regulations, a person who has already been appointed as Port Health Officer under the provision of Food Adulteration Act 1954, may perform the duties of the Authorized Officer, if notified by the Central Government, if the Officer fulfills such conditions as may be specified for the post of Authorized Officer.

Clause 2(a) in ‘Powers and duties of the Authorized Officer,’ has been revised and will now read as:

- ‘to carry out inspection of imported food, draw samples of the imported food and transport the same for analysis in appropriate manner wherever required’

Additional clauses have been added to the same section which are:

- To recommend to Customs to allow for re-processing within the customs area for those articles of primary food which have exceeded the permissible limits on extraneous matter:
  - a) Provided that the importers submits an undertaking to achieve the permissible limit through re-processing; and
  - b) Provided further that the necessary infrastructure and equipment is available within the customs area;
  - c) To inform the laboratory immediately on receipt of advance notice of arrival of food imports from the food importer;
  - d) To seek data or information on food imports from the Customs;
  - e) To store the counter sample in appropriate conditions so that they are fit for analysis in case of re-test appeal or to return to the Food Importer or his Agent as appropriate;
  - f) The Authorized Officer shall have the powers to take photographs of any food consignment;

### **Chapter 3: Licensing of Food Importers**

1. The explanation of ‘Licensing of Food Importers’ has been rephrased and it now states:

- (1) Any person engaged in import of food, other than through personal baggage for gifts or for bonafide medicinal use not exceeding the quantities necessary for direct utilization by the persons concerned, shall obtain License from the Central Licensing Authority in conformance with the procedure laid down in Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011:

Provided that the value of such food imports through personal baggage does not exceed the monetary limits assigned by the Central Board of Excise and Customs.

Provide further that the value of such bona fide gifts imported by post or as air-freight does not exceed the monetary limits assigned by the Central Board of Excise and Customs.

(2) In addition to the criteria mentioned in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, the person shall also fulfill the following criteria, namely:

- a) The food importer shall be registered with Directorate General of Foreign Trade (DGFT) and possess valid import-export code;
- b) The applicant shall submit information on form B of FSS (Licensing and Registration of Food Businesses) Regulations, 2011 or through online and furnish copies of documents listed in the Schedule 2 to the Licensing Authority.

2. A new sub-clause(c) has been added to the clause on suspension or cancellation of license. Sub-clause (c) reads as:

- c) If there is sufficient evidence that the food importer did not comply with the undertaking of intended 'end-use'.

3. Two new clauses have been added to the power of the Licensing Authority to suspend or cancel the food importer license and they are:

- Any change in the information provided by the importer in the importer applicant details through Form B of FSS (Licensing and Registration of Food Businesses) Regulations, 2011 or through online should be informed to the Authorized Officer within a week of such change and any failure to do so may result in suspension or revocation of food importer license.
- The process of suspension and cancellation of food importer license shall be governed by Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011.

4. The earlier regulation of 2011 required the food importer to inform the Authorized Officer of any suspension or cancellation of license granted by DGFT or revocation or suspension of the importer-exporter code within 24 hours from the date of such order of suspension, revocation or cancellation. As per the latest regulation of 2012, the importer should inform within three days.

5. The proviso stating 'Provided that if a return is not filed within the 30<sup>th</sup> day of November of the relevant year, the Licensing Authority may suspend or cancel the relevant license granted' from clause (2) of 'Returns' has been deleted. It now reads as:

- (3) Any delay in filing return shall attract a penalty of one hundred rupees per day of delay.

#### **Chapter 4: Prohibition and Regulation of Imports**

1. Under the heading "Power of the Food Authority to issue orders for regulation and prohibition of specific food imports", additional clauses have been added which are:

- The Food Authority shall have the power to ensure that all Genetically Modified food may be subject to such further and other requirements as the respective agencies of Government may specify from time to time.
- **Storage facilities for food imports:**
  - (i) The port authorities and custodians of freight stations shall ensure adequate and conducive

storage infrastructure meeting the specified food safety standards for safe storage of various types of imported food consignments in the Customs area till the imported food article is cleared by the Customs.

(ii) The Port Authority may accordingly consider setting up 'Exclusive' Container Freight Stations for storage of imported food.

- **Channelization of food imports:** The Food Authority shall publish an indicative list of Points of Import into the country, and the infrastructure capability of such points of import to handle the import from the perspective of storage and laboratory testing facilities available for various kinds of food articles for the benefit of the Food Imports to channelize the imports accordingly.
- **Annual Report on Food Imports:**
  - (i) The Food Authority shall publish a report annually on the food imports allowed into the country
  - (ii) The Customs, Port Authorities or any other agency involved in the clearance, rejection, auction or destruction of imported food articles in the Customs area shall provide all such statistics to the Food Authority on periodic basis.

## **Chapter 5: Food Inspection Prioritization Based on Risk**

1. An additional clause in the sub-regulation 'Risk Based Framework' has been added to state that "The risk classification for food articles are listed in Schedule I.

2. Three new sub-regulations have been added:

- **Alerts:**

- (1) The Food Authority from time to time may issue Food Alert notifications (Including time bound prohibited foods) or recalls based on the risk associated with the food article.
- (2) The Alert notification shall remain in force until the Food Authority is satisfied that the risk is no longer prevailing or that control measures are in place to prevent the continuation of the risk and confirmed by test reports.
- (3) The Alert notification may lead to conditions such as additional tests at the Point of Entry, mandatory certifications from the exporting countries till such time as deemed fit by food authority.

- **Agreement with Exporting Countries:**

- (1) The Food Authority in consultation with Commerce Ministry as deemed fit may enter into Memorandum of Agreement with relevant agencies in exporting countries on reciprocal basis to facilitate accelerated clearance of food imports from such countries
- (2) The Food Authority shall identify laboratories in exporting countries for prior testing of food samples before the food articles are imported into India.

- **Pre-Arrival Notification**

- (1) The Food Authority in order to facilitate faster clearance of import of food at ports of entry, shall

require submission of a pre-arrival notification by the food importer, providing the identity of each of the following, namely:

- a) The name of the food article; the ingredients of the food article;
- b) The manufacturer and exporter of the food article; the country of origin; the exporting country;
- c) The list of transit countries;
- d) The compliance agreement if any;
- e) The anticipated Port of Entry for the import of food article as specified in the Form A

- (2) A notice referred to in sub regulation (1) shall be submitted in advance by a specified period of time, which shall not be less than two days before the arrival of the consignment.

## **Chapter 6: Import Requirements**

1. A sub-regulation “Standards” has been added to this chapter which states ‘The food importer shall follow the standards laid down by the Food Authority under the Provisions of the Act, rules and regulations made thereunder.
2. Sub-regulation ‘Furnishing of documents by the Food Importer’ has been rephrased to read as: Every food importer shall furnish the requisite documents as listed in Schedule III to the Authorized Officer of the respective Point of Import and make an application for No Objection Certificate (as provided in Form B) for clearance of imported food.
3. An additional clause has been added to read as: In the case of import of rejected exported food articles which are meant for re-export, labeling requirements need not be as specified under the Food Safety and Standards (Packaging and Labeling) Regulations, 2011.

## **Chapter 7: Clearance of Food Imports for Special Purpose**

1. Apart from the already existing sub-regulations ‘Accredited Food Importer Program’ and Food Export Oriented Units’, the following sub-regulations have been added with their corresponding sub-clauses.

- **Imports by Diplomatic Missions:**

- (1) The Clearance of food imports shall be dealt with in the provisions of Vienna Convention on Consular Relations, 1963 (Article 50 of the Vienna Convention on Consular Relations, 1963).
- (2) The food articles intended for the consumption by the mission for official purpose or personal use of diplomats or their dependents shall be allowed after drawing representative samples for laboratory analysis pending the receipt of the laboratory analysis report, unless there are serious grounds for presuming that the consignment contains prohibited food articles or food articles controlled by the quarantine regulations of India.
- (3) The imported food articles by diplomatic mission or their personnel shall not exceed the quantities necessary for direct utilization by the persons concerned.
- (4) The food articles in the personal baggage of the diplomats shall be cleared without inspection: Provided that, where there is a risk potential and identified food safety concerns, the Authorized Officer is empowered to inspect these food articles but only in the presence of the diplomatic

agent or of his authorized representative, authorized by a letter from the Mission.

- **Imports for Quality Assurance, Research and Development:**

- (1) The samples of food are considered to be for quality assurance, research and development purposes, when they are imported in small quantities and the entire sample is used up by the analysis or is destroyed after analysis or a reasonable retention period after analysis.
- (2) The agency or institution shall furnish an undertaking stating that such food shall be used exclusively for the quality assurance, research and development, and shall not be released for re-sale, test marketing or utilized directly or indirectly for human consumption.

- **Imports for International Trade Fairs and Exhibitions:**

- (1) In case of the food samples imported for exclusive purpose of display in international trade fairs and international food exhibitions conducted in India, the food importer shall provide the laboratory analysis report from a recognized agency in the exporting country and an undertaking on end-usage that the food samples are for the sole purpose of display in exhibition, shall not be released for re-sale, test marketing or utilized directly or indirectly for human consumption and that the same shall be re-exported to exporting country after the exhibition is over or destroyed in compliance with the laws.
- (2) The food importer shall submit documentary proof to the Authorized Officer within the period specified in the customs duty exemption notifications availed at the time of import: provided that for imports for which, such customs duty exemptions was not sought by importer, the food importer shall submit documentary proof within thirty days of completion of the exhibitions that all such food samples brought for the exhibition purpose have been destroyed or re-exported out of the country.

- **Imports for Special Sports Events:**

- (1) In case of the food samples imported for exclusive purpose of special international sports events conducted in India, the food importer shall provide the laboratory analysis report from a recognized agency in the exporting country and shall provide an undertaking that the food article shall not be released for re-sale, test marketing and the unused food articles shall be re-exported to exporting country after the event or destroyed in compliance with the laws.
- (2) The quantities of food articles imported shall not exceed the quantities necessary for direct utilization by the persons concerned for the duration of the stay.
- (3) The food importer shall submit documentary proof to the Authorized Officer within thirty days of completion of the special event that all such food articles brought for the purpose have been consumed or unused food articles are re-exported out of the country or destroyed in compliance with the laws.

- **Accelerated clearance:**

- (1) The food importer for quality assurance, research and development by recognized scientific agencies or institutions, for display in international trade fairs and exhibitions and for



consumption by the participating teams in special international sports events, shall be released expeditiously without sampling and laboratory analysis, provided that

- (2) The food imported by food export oriented units, accredited food importer shall be allowed for accelerated clearance by the Authorized Officer after drawing representative samples for laboratory analysis, pending the receipt of the laboratory analysis report subject to production of:
  - a) The laboratory analysis report from exporting country (only in English);
  - b) A bond that the food article will be completely recalled as per the Recall procedures and guidelines of Food Authority, if the laboratory analysis report from the notified laboratory is non-confirmatory; and
  - c) In the case of food requiring cold chain during transport and storage, the temperature profile report showing that the temperature requirements have been fulfilled as required/prescribed.
- (3) The import of food articles of perishable nature like fruits and vegetables, which are prone to quick spoilage, if not kept in refrigerated conditions are also entitled to the Accelerated Clearance as mentioned in sub-regulation (2).
- (4) The enforcement of this regulation shall be applicable:
  - a) If the food article is not in the list of prohibited food article or prohibited exporting source;
  - b) If the previous food imports by the food importer, or food articles from the same manufacturer, have not been cleared for imports over the preceding six months;
  - c) If food articles with certificate of analysis from the same laboratory of the exporting country have not failed in notified or referral laboratory analysis over the preceding six consignments or six months, whichever is earlier; and
  - d) Where special tests are required, the clearance shall be allowed only after the food samples successfully pass through the required tests.

## **Chapter 8 – Inspection by Authorized Officer**

1. An additional clause has been added to sub-regulation ‘Application for Inspection by Authorized Officer’ and it states that:

- Make an application for No Objection Certificate (NOC) to the Authorized Officer of the respective point of entry as specified in regulation 25 in Form B.

2. The following clauses have been added to sub-regulation ‘Verification of documentation furnished by Food Importer’

- a) Whether to prioritize the inspection based on risk framework
- b) Whether the food article intended for import needs a new product approval, and if so, the Authorized Officer shall refer the same to the Food Authority
- c) The Authorized Officer may refuse the inspection and intimate the customs accordingly, if the articles of import are misclassified as food.

3. In addition to the above clauses, a sub clause has been added to the clause on ‘NOC Documentation Review’ which states that:

- b) The Authorized Officer shall ascertain whether the food articles intended for import under clearance of food imports for special purpose covered in Chapter 7 of these regulations.

4. A new sub-regulation on 'Inspection Fee' has been added which states:

- (1) The Food Safety and Standards Authority of India shall collect inspection fee as prescribed in Schedule V from the food importer for providing inspection, documentation review, sampling and analysis thereof, for disposal of application for clearance of food imports submitted by food importer.
- (2) Where a single Bill of Entry is made up of food article consignment consisting of multiple category of food articles, Inspection fee shall be applicable for each food article proposed for inspection.
- (3) The Food Authority shall specify and review the inspection fee from time to time.

### **Chapter 9: Sampling of Imported Food**

1. The sub-regulation 'Sampling of Food Imports' has been rephrased and it now reads as:

If the Authorized Officer is satisfied on inspection that the food proposed for import is not in contravention of labeling, shelf life requirement is not having visible insect or fungal infestation to a greater extent, he shall draw two representative samples of each variety or category of food articles sought to be imported, of sufficient quantity as specified in Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011, and seal the samples as per the provisions of Food Safety and Standards (FSS) Rule 2.4.1 except the rules 2.4.1 (9) (i, iv), 10(ii, iii), 11 and 16 and with the modification that the samples shall be divided into two parts or two already sealed packages shall be taken each of which will be marked and sealed or fastened up in such a manner as its nature permits.

2. An additional requirement of 'Food Safety and Standards (FSS) code of the product category' has been added to the label on any sample of imported food article.

3. The clause on the notifying of sample to the lab for analysis has been rephrased and it now reads as:

One such sample shall be sent to the notified lab for analysis, and the second sample shall be kept in safe custody of the Authorized Officer in his office or any designated place notified by the Food Authority for re-testing purpose.

4. A new clause has been added to read as:

If the second sample referred for re-testing based on orders of Review Officer, results in non-conformance in lab analysis report, request for re-sampling shall not be allowed.

### **Chapter 10: Laboratory-Analysis of Samples of Imported Food**

1. The proviso under sub-regulation 'Format of Laboratory Analysis Report' has been rephrased to read as:

Provided that if the laboratory is not in a position to provide the results of the tests within this period due to some technical issues relating to testing methods, including cases where the tests prescribed are of a duration of more than five days, it shall immediately provide this information with the justification for the delay to the Authorized Officer.

2. Two new sub-clauses have been added to the sub-regulation 'Lab Analysis Reports' and they are:

(a) Whenever lab analysis of a food sample reveals presence of contaminants and presence of microbiological organisms to an extent of posing significant threat to Public Health, the Laboratory shall provide its finding and recommendations on the follow up action to be taken by the Authorized Officer in the Lab analysis report of the sample.

(b) The Authorized Officer shall suomoto refer the second sample to the Referral Laboratory for retesting to seek the confirmation of the findings of the Notified Laboratory.

### **Chapter 11: Order by the Authorized Officer**

A new sub-regulation 'Communication from Customs' has been added and it reads as:

**Communication from Customs:** Customs shall provide the related information to the Food Authority on status of the Food Article Consignment for which NOC Certificate or Rejection Report or Mandatory Destruction Order has been issued by the Food Authority within a maximum time period of three working days in the case of electronic mode of communication and seven working days in the case of manual mode of communication, from the date of issuance of NOC or Rejection Report or Mandatory Destruction Order.

### **Chapter 12: Disposal of Food Samples and Rejected Food Imports**

1. Clause 1 of sub-regulation 'Rejected Food Consignments' has been rephrased and it now reads as:

(1) Upon receipt of a Rejection Report refusing the clearance of imported food items issued by the Authorized Officer, the Custodian shall dispose of the food consignment and unused samples in the manner indicated in the Rejection Report duly following the rules and guidelines applicable for disposal of goods by the Customs Act, 1962.

2. A new clause has been inserted to the same sub-regulation 'Rejected Food Consignments' which states:

(3) Upon issue of mandatory destruction recommendation for rejected food consignment, no further appeal process shall be entertained and the counter sample shall be destroyed immediately in co-ordination with the concerned authorities.

3. The duration for the food importer to collect the second sample for disposal after the receipt of No Objection Certificate has been reduced from 15 days to 5 days.

### **Chapter 13: Uncleared and Unclaimed Food**

No changes in comparison to the Food Import Regulations 2011

## **Chapter 14: Review Process**

1. Under Clause (a), (b) and (c) of sub-regulation 'Reviewable orders', Regulation number has been updated to 37 and the words 'or visual inspection' has been added after the words 'packing or labeling' in clause (a). They now read as:

- a) Rejection report under regulation 37 rejecting the clearance of the imported food article on the ground of defective storage, packing or labeling or visual inspection.
- b) Any order under regulation 37 directing the food importer to rectify the labeling or packaging of the food article.
- c) Rejection report under regulation 52(2) issued on receipt of a non-conformance lab analysis report.

2. Minor changes have been made to the clauses under sub-regulation 'Format of review application and limitation'. The clauses now read as:

- (1) The review application shall be in the format specified in Form I and shall be accompanied by a non-refundable fees specified in Schedule V.
- (2) The review application shall be presented to the Review Officer along with the required documents and the review application fee within seven days from the date of communication of the Rejection Report to the food importer.
- (3) The Review Officer may admit a review application after the expiry of the said period for an extended period of seven (7) days, if he is satisfied that the food importer had sufficient cause for not presenting it within that period.

3. Under sub-regulation 'Procedure in review', the Review Officer shall now dispose of all review applications within a period of seven days. In the earlier regulation, the duration was 21 days.