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### India

### Food and Agricultural Import Regulations and Standards -Narrative

## **FAIRS Country Report**

Approved By: Jonn Slette Prepared By: FAS New Delhi Staff

#### **Report Highlights:**

The Food Safety and Standards Act, 2006, was implemented in 2011, and the Food Safety and Standards Authority of India (FSSAI) undertook to harmonize food safety regulations with Codex Alimentarius. Multiple amendments to food safety, labeling and packaging regulations were published, as were new draft guidelines on labeling of imported products. Revised guidelines for trade in bovine germplasm and draft health certificates for imported bovine semen and embryos were issued.

#### Disclaimer

This report was prepared by U.S. Embassy New Delhi's Office of Agricultural Affairs (OAA) to serve as reference guide for stakeholders wishing to export food and agricultural products to India. While the OAA makes every effort to describe existing regulations accurately, exporters are strongly advised always to verify import requirements with their customers prior to shipment. THIS REPORT HAS NOT BEEN OFFICIALLY ENDORSED BY THE GOVERNMENT OF INDIA (GOI). IMPORT APPROVAL FOR ANY PRODUCT IS SUBJECT TO LOCAL RULES AND REGULATIONS AS INTERPRETED BY INDIAN BORDER OFFICIALS AT THE TIME OF ENTRY.

#### **Executive Summary:**

Laws pertaining to food and agricultural product imports into India are under the jurisdiction of multiple Government of India authorities: the Food Safety and Standards Authority of India (FSSAI) of the Ministry of Health; the Office of Legal Metrology of the Ministry of Consumer Affairs, Food, and Public Distribution; the Directorate General of Foreign Trade of the Ministry of Commerce and Industry; and two departments of the Ministry of Agriculture, the Department of Animal Husbandry, Dairying and Fisheries and the Department of Agriculture and Cooperation. Exporters are advised to research thoroughly the relevant laws and regulations applicable to their products across all of these regulatory agencies. The Food Safety and Standards Act, 2006, was fully implemented in 2011, and FSSAI undertook to harmonize food safety regulations with Codex Alimentarius. Multiple amendments to food safety, labeling and packaging regulations were published, as were new draft guidelines on labeling of imported products. Revised guidelines for trade in bovine germplasm and draft health certificates for imported bovine semen and embryos were issued.

#### Section I. Food Laws

#### A. Food Safety and Standards Authority of India (FSSAI), Its Law, Rules and Regulations

Food safety in India is governed by law, rules and regulations. The Food Safety and Standards Act, 2006 is the parent <u>law</u> related to food safety and standards. <u>Rules</u> are derived from the core objective of the Act for governing certain actions and decisions (e.g., qualifications of staff, fees, laboratory and sampling protocols) of concerned administrative authorities, whereas <u>regulations</u> constitute implementing guidelines of the parent Act for use by officials at the end-user level (e.g., labeling requirements, food additive limitations).

Law: The 2006 Act formally repealed and replaced the prior regulatory framework, consolidating eight different prior food Act/orders into one legal mechanism under the FSSAI. The 2006 Act also adds key provisions to strengthen the implementation of food safety rules.

Rules: The full text of the Food Safety and Standards Rules (FSSR), 2011 can be accessed from the <u>FSSAI website</u>. While useful to know, the Rules are not generally instructive to U.S. food and agricultural product exporters.

Regulations: The 2011 Food Safety and Standards (FSS) Regulations are available on the <u>FSSAI</u> website and should be consulted regularly for updates, which appear periodically and are published in the official gazette. The regulations govern *inter alia* packaging and labeling, food additives, product standards, licensing and registration of food businesses, and maximum residue levels of contaminants.

The Regulations stipulate, "...all food business operators, food processors, manufacturers, exporters, or importers shall ensure that the food s/he handles meets all the standards under the FSS Regulation 2011." All domestic food operators, including importers, are required to have an FSSAI license to conduct business in India. FSSAI does not require licensing of foreign companies to export food products to India. For further information, in addition to the FSSAI website, please use the GAIN search engine to find reports on India containing the term *FSSAI* in "Report Highlights". In 2013, FSSAI began an effort to harmonize its regulations with Codex Alimentarius. FSSAI intends to complete the harmonization process by January 2015 and fully its harmonization implement by July 15, 2015.

#### B. The Legal Metrology Act, 2009, and the Legal Metrology (Packaged Commodities) Rules, 2011

The Legal Metrology (LM) Act, 2009, establishes uniform standards of weights and measures regulating trade in weights, and other goods which are sold and/or distributed by weight, measure or number. As per the LM Packaged Commodities Rules, 2011 (which came into force on April 1, 2011), manufacturing, packing, selling or importing any pre-packaged commodity is prohibited unless it is in a standardized quantity and carries all prescribed declarations (please refer to Section 18(1) of the rules, 2011). The Department of Consumer Affairs, Ministry of Consumer Affairs, Food, and Public Distribution (commonly called simply the Ministry of Food), is the regulatory authority for the LM Act, 2009, and the LM Packaged Commodities Rules, 2011. The full text can be accessed on the website of the Department of Consumer Affairs at Legal Metrology Act, 2009, the Legal Metrology Packaged Commodities Rules, 2011, and the Legal Metrology Packaged Commodities Rules (Amendment) 2011. The Legal Metrology Act, 2009, imposes standard pack sizes for certain commodities as a consumer protection measure (see Section III. Packaging and Container Regulations, below).

#### C. Livestock Importation Act, 1898

Under the Livestock Importation Act, 1898, the GOI has established procedures for the importation of livestock and related products to India, which are implemented by the Department of Animal Husbandry, Dairying, and Fisheries (DADF), Ministry of Agriculture (MinAg). These procedures are available at: <u>http://dahd.nic.in/order/livestockimport.doc.</u>

Procedures for import of various livestock products are available on the website <u>http://dahd.nic.in/</u>. In addition you may use the <u>GAIN search engine</u> to find relevant GAIN FAIRS export certification reports.

- On July 24, 2013, the Government of India updated the <u>Directorate General of Foreign Trade's</u> (<u>DGFT) Import Policy 2012</u> to reflect minor changes in Chapters 5 and 23 of the Harmonized Tariff Schedule (HTS). Policy condition 4 under Chapter 5 notes that a Sanitary Import Permit shall not be applicable to "human hair." Policy condition 1 under chapter 23 now specifies that an import permit is required for import of items of animal origin or products intended for animal feeding containing animal origin materials under IT(HS) Code 2309 "Preparations of a kind used in Animal Feeding" (IN3102).
- The DADF, Ministry of Agriculture, has revised quality guidelines for trade in bovine germplasm. Some industry sources believe the new guidelines are less restrictive, but it is unclear if this will result in increased imports due to other requirements imposed by many Indian

states. Although not notified to the World Trade Organization (WTO), DADF is immediately implementing the new guidelines. Previous iterations were published in February 2011 and March 2013 (IN3154).

• DADF published two draft health certificates for imported bovine semen and embryos. Both drafts provide new or revised information on import requirements, which are different from previous versions. For example, the genetic disease freedom clause has been removed from both certificates. DADF's bovine germplasm certificates were later notified on the WTO SPS website and the comment deadline was August 4, 2014. U.S. Government comments were also submitted for these WTO notifications. For further details, please refer to IN4041

#### D. Plant Quarantine (Regulation of Import into India) Order, 2003

Plant import regulations are governed by the Plant Quarantine (Regulation of Import into India) Order, 2003, under the Destructive Insects and Pests Act, 1914. The Order was published on November 18, 2003, with "the purpose of prohibiting and regulating the imports into India of agricultural articles," and became effective January 1, 2004. The implementing agency is the Directorate of Plant Protection, Quarantine, and Storage, under the MinAg Department of Agriculture and Cooperation. The Order, as amended, is available on India's <u>Plant Quarantine website</u>.

#### Section II. Labeling Requirements:

Three Government of India authorities regulate labeling of food and agricultural products. They are the Food Safety and Standards Authority of India (Ministry of Health and Family Welfare), Office of Legal Metrology (Department of Consumer Affairs, Ministry of Consumer Affairs, Food and Public Distribution), and the Department of Commerce (Ministry of Commerce and Industry).

#### Food Safety and Standards Authority of India:

Exporters are strongly encouraged to read Chapter 2 of the <u>FSS Packaging and Labeling Regulation</u>, <u>2011</u> before designing labels for products to be exported to India. The labeling regulations cover approximately 20 pages, in more detail than can be included in the summary descriptions of this report.

A. General requirements: All labeling declarations must meet the following requirements:

- Product information must be printed on a label securely affixed to the package or printed on the package itself,
- The label must be printed in the English or Hindi languages (Hindi must be in Devanagari script),
- Products exhibiting only a standard U.S. label will not be allowed to enter,
- No false or misleading or deceptive representation shall be made which can create an erroneous impression of the pre-packaged food in any respect, and
- Content of the label shall be clear, prominent, indelible, and readily legible by the consumer.

#### **B.** Labeling requirements for pre-packaged and wholesale foods:

**Pre-packaged Foods**:

According to the FSS Packaging and Labeling Regulation, 2011, "Prepackaged" or "Pre-packed food" means food, which is placed in a package of any nature, in such a manner that the contents cannot be changed without tampering with the package and which is ready for sale to the consumer.

#### Overview:

Pre-packaged food or pre-packed food including multi-piece packages should carry the following mandatory information on the label:

- 1. The name of the food,
- 2. List of ingredients, except for single ingredient foods,
- 3. Nutritional information,
- 4. Declaration regarding vegetarian and non-vegetarian,
- 5. Declaration of food additives,
- 6. Name and address of the manufacturer,
- 7. Net quantity,
- 8. Lot/code/batch identification,
- 9. Date of manufacture or packing,
- 10. Best before date or use by date or date of expiry,
- 11. Country of origin,
- 12. Instructions for use, if applicable.

#### Further detail:

- 1. Name of food: The name of food shall include trade name or description of food contained in the package.
- 2. List of ingredients: Except for single ingredient foods, a list of ingredients shall be declared on the label, in descending order of their composition by weight or volume.
- 3. Nutritional information: All nutritional facts per 100 gram or 100 ml or per serving of the product shall be given on the label containing
  - i. Energy value in Kcal;
  - ii. The amount of protein, carbohydrates (specify quantity of sugar) and fat in grams or milliliters;
  - iii. The amount of any other nutrient for which a nutritional or health claim is made.

Note: Nutritional information for alcoholic beverages is not required.

- 4. Declaration regarding vegetarian or non-vegetarian:
  - i. Vegetarian food must have a symbol consisting of green color-filled circle inside a square with a green outline prominently displayed on the package, contrasting against the background on the principal display panel, in close proximity to name or brand name of the food.
  - ii. Non-vegetarian food (any food which contains whole or part of any animal including birds, marine animals, eggs, or products of any animal origin as an ingredient, excluding milk or milk products), must have a symbol of a brown color-filled circle inside a square with a brown outline prominently displayed on the package, contrasting against the background on the principal display panel, in close proximity to the name or brand name of the food.

Note: Declaration of veg/non-veg logo shall not apply for alcoholic beverages



- 5. Declaration regarding food additives: This declaration shall be made in accordance with FSS (Packaging and Labeling) Regulation, 2011.
- 6. Name and complete address of manufacturer: The label shall carry the name and complete address of the manufacturing or packing or bottling unit and also the name and complete address of the manufacturer or the company for and whose behalf it is manufactured or packed or bottled.
  - i. Where an article of food is imported into India, the package of food shall also carry the name and complete address of the importer in India.
  - ii. Provided further that where any food article manufactured outside India is packed or bottled in India, the package containing such food article shall also bear on the label, the name of the country of origin of the food article and the name and complete address of the importer and the premises of packing or bottling in India.
- 7. Net quantity: By weight or volume or number, shall be declared on every package of food.
- 8. Lot/code/batch identification: A mark of identification by which the food can be traced in the manufacture and identify in the distribution shall be given on the label. FSSAI has advised verbally that this information may be ink jetted or stamped on the product label or carton.
- 9. Date of manufacture or packing: The date, month and year in which the commodity is manufactured, packed or pre-packed, shall be given on the label. FSSAI has advised verbally that this information may be ink jetted or stamped on the product label or carton.
- 10. Best before and use by date: The month and year in capital letters up to which the product is best for consumption. FSSAI has advised verbally that this information may be ink jetted or stamped on the product label or carton.
- 11. Provided further that the declaration of best before date for consumption shall not be applicable to:
  - i. Wines and liquors,
  - ii. Alcoholic beverages containing 10 percent or more by volume of alcohol.
- 12. Country of origin for imported food:
  - i. The country of origin of the food shall be declared on the label of the food imported into India.
  - ii. When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed, shall be considered to be the country of origin for the purposes of labeling.
- 13. Instructions for use: If necessary, shall be included on the label to ensure correct utilization of the food.

#### Wholesale food packages:

According to the FSS Packaging and Labeling Regulation, 2011, "Wholesale package" means a package containing

- (a) A number of retail packages, where such first mentioned package is intended for sale, distribution or delivery to an intermediary and is not intended for sale direct to a single consumer; or
- (b) A commodity of food sold to an intermediary in bulk to enable such intermediary to sell, distribute or deliver such commodity of food to the consumer in smaller quantities.

Wholesale food packages (including semi-finished/intermediary food products which will be further processed to make a final product and will be packed as pre-packaged or pre-packed food) should carry the following information on the label.

- 1. Name of food,
- 2. List of ingredients (not required in case of single ingredient),
- 3. Name and complete address of manufacturer,
- 4. Date of manufacture,
- 5. Best before date or use by date or date of expiry,
- 6. Name and address of importer.

India specifies that imported pre-packaged food products must meet India's country of origin food labeling requirements at the port of entry. Imported bulk food items sold in loose or unpackaged form (almonds, apples, grapes, peas and lentils, etc.) must have an accompanying certificate that specifies country of origin. However, there is currently no requirement to label imported loose or unbranded products at the retail point of sale.

Raw agricultural commodities, spice mixes, condiments, non-nutritive products, alcoholic beverages, fruits and vegetables, processed pre-packaged vegetables and fruits are exempted from nutritional labeling requirements.

Original manufacturer's labels on wholesale packages, applied in the country of origin, that fulfill the labeling requirements of FSSAI's regulations may be allowed. However, tampering of labels and pasting of one label over the other are not permitted.

A wholesale package may show the best before date, expiry date, or use by date. In the case of wholesale packages, if both a best before date and an expiry date are given, then the two must be different and must be clearly specified.

#### **B.** Rectifiable and Non-Rectifiable Labeling:

Absences of vegetarian/non-vegetarian logo, name and address of importer, FSSAI logo and license number on the label are considered "rectifiable labeling deficiencies", which may be dealt with via sticker labels in the custom bonded warehouse at the port. However, absence of name and address of manufacturer, list of ingredients, manufacture date, packing date, best-before or expiry date; batch or code or lot number; net weight or volume; or nutritional information, when required, is not rectifiable with sticker labels. All exporters and importers are responsible for ensuring that the food products entering India from the United States are in full compliance with Indian food laws. For detailed information, please refer to <u>IN2055</u>.

FSSAI announced that as of January 1, 2015, labels on any packaged food products destined for retail sale, as defined by Indian law and regulation should bear the FSSAI logo as well as the registration number under which the food business operator (importer in the case of imported foodstuffs) is registered with FSSAI. On December 17, 2014, FSSAI issued a new notification, extending the deadline for compliance with this requirement to January 1, 2015. (see GAIN report <u>IN4050</u> and IN4116.

# Office of Legal Metrology, Department of Consumer Affairs, Ministry of Consumer Affairs, Food and Public Distribution

#### Labeling requirements:

Per Indian law, most food labeling requirements of the Office of Legal Metrology are superseded by FSSAI's regulations. However, two regulations of this office apply, to wit:

- The retail sale price of the package: Provided that for reducing the Maximum Retail Price (MRP), a sticker with the revised lower MRP (inclusive of all taxes) may be affixed and the same shall not cover the MRP declaration on the label of the package.
- 2. If a product is genetically modified, it must include on the label the initials "GM" (for further information, please refer to GAIN report <u>IN3003</u>).

For detailed information and proviso on labeling, please refer to <u>Legal Metrology (Packaged</u> <u>Commodities) Rules, 2011</u>.

The Department of Legal Metrology has also clarified certain labeling requirements for imported food packages and these are highlighted below.

- The Ministry of Commerce and Industry and Department of Legal Metrology, Ministry of Consumer Affairs, Food and Public Distribution will amend regulations to allow maximum retail price to be legally affixed to imported retail packaged foods with a sticker.
- Both the Department of Legal Metrology and the Ministry of Commerce and Industry will defer to FSSAI's regulations to define wholesale versus retail packaging in accordance with the Food Safety and Standards Act, 2006. A notification to this effect shall be issued by FSSAI to the authorized officers at the port of entry.
- Boxes (cartons) of fresh fruit may indicate fruit count rather than net weight. However, a combination of both will NOT be acceptable.

#### Ministry of Commerce and Industry

As per <u>Notification No. 44 (RE-2000)/1997-2002</u>, issued by the Department of Commerce (DC), Ministry of Commerce and Industry, on November 24, 2000, all packaged commodities, including prepackaged food, imported into India must bear the following declarations:

- 1. Name and complete address of the importer in India.
- 2. Generic or common name of the commodity packed.
- 3. Net quantity using standard units of weights and measures. If the net quantity of the imported package is given in any other unit, its equivalent terms of standard units shall be declared by the importer.
- 4. Month and year in which the commodity was manufactured/packed, or imported.

5. The maximum retail price (MRP) at which the commodity, in packaged form, may be sold to the ultimate consumer. This price shall include all taxes, local or otherwise, freight, transport charges, commission payable to dealers, and all charges towards advertising, delivery, packing, forwarding, and any other relevant charges.

The full notification is available on the DGFT website: <u>DGFT Notification</u>. Please see sample packaged food labels on the following two pages.



#### **FSSAI requirements:**

- 1. The name of the food (proprietary chocolate)
- 2. List of ingredients
- 3. Nutritional information
- 4. Vegetarian/non-vegetarian logo
- 5. Declaration of food additives
- 6. Name and address of the manufacturer
- 7. Net quantity
- 8. Lot/code/batch identification
- 9. Date of manufacture or packing
- 10. Best before date or use by date or date of expiry
- 11. Country of origin
- 12. Instructions for use

### **Commerce requirements:**

- 1. Name and address of importer in India
- 2. Name of the commodity packed
- 3. Net quantity
- Month and year of manufacture, packing, or import.
- 5. The maximum retail price (MRP)

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Instructions for use are not necessary for a product ready to eat from the package.





Importer information is not applicable to domestically produced products.

#### Section III. Packaging and Container Regulations:

Two legal authorities govern food packaging, FSSAI and the Office of Legal Metrology. In addition, the High Court of Himachal Pradesh has issued a legal ruling binding on certain food products in that state.

Chapter 2 of the <u>Food Safety and Standards (packaging and labeling) Regulations, 2011</u> includes specifications for certain types of food packaging. These include specifications for plastic and polymer packaging materials, and requirements for packaging of milk and dairy products, edible oils and fats, fruit and vegetable products, canned meat products, and packaged drinking water. These should be consulted before packaging for such products is designed for export to India (Note: As of the date of this report, the United States does not enjoy access to the Indian market for dairy or meat products.)

Standard size packs for commodities listed under Schedule II of the LM packaged commodities rules, 2011 became mandatory as of July 1, 2012. The affected products include baby food, weaning food, "biscuits" (cookies), bread, un-canned packages of butter and margarine, cereals and pulses, tea, and materials which may be constituted or reconstituted as beverages. For detailed information, please refer to GAIN report IN2038. This amendment to the rules has raised some significant concerns about its potential as a technical barrier to trade. The United States, European Union, Canada, and Australia do not use specific standard pack sizes. For more information, please refer to GAIN Reports IN2038, IN2046, IN2077, IN2085, and IN2150. On June 6, 2013, the Department of Consumer Affairs published a notification amending the rules such that permissible units of weight, measure or number of specific products and product groups have been expanded, i.e., the list of quantities in which products may be packed is now broader (IN3067).

The Legal Metrology rules were amended in 2013, such that permissible units of weight, measure or number of specific products and product groups have been expanded, i.e., the list of quantities in which certain consumer-ready products may be packed is now broader:

- Weaning food may now be packed in 75-, 100-, 125-, 150-, 200-, 250-, 300-, 400-, 500-, 600-, 700-, 800-, 900-gram and 1-, 2-, 5- and 10-kilogram packages.
- Biscuits (cookies in American English) may now be packed in 25-, 50-, 75-, 100-, 150-, 200-, 250-, 300-, 350-, and 400-gram packages and thereafter in multiples of 100 grams up to 1 kilogram.
- Coffee may now be packed in 25-, 50-, 100-, 200-, 250-, 500-, and 750-gram and in 1-kilogram or multiples of 1-kilogram packs.
- Tea is now permitted to be packed in units smaller than 25 grams with no restriction, and in sizes of 25-, 50-, 75-, 100-, 125-, 150-, 200-, 250-, 500-, 750 grams, as well as 1-, 1.5-, 2-kilogram and larger in multiples of 1 kg.
- Materials which may be constituted or reconstituted as beverages may now be packed in 25-, 50-, 100-, 125-, 200-, 500-gram packages, and thereafter in 1-kilogram packages or in multiples of 1 kilogram.
- Edible oils, including vegetable oils as well as *vanaspati* (ghee) and butter oil, may now be packed in units smaller than 50 grams without restriction, and in sizes of 50-, 100-, 175-, 200-, 300-, 500-, and 750 grams, as well as 1-, 2-, 3- and 5 kilograms or multiples of 5 kilograms.

• Aerated (carbonated) soft drinks and non-alcoholic beverages remain unchanged in terms of pack size i.e. 65 and 125 milliliter (fruit based drinks only),100-, 150-, 200-, 250-, 300-, 500-, 750 milliliter and 1-, 1.5-, 2-, 3-, 4-, and 5 liters , but the restriction "in cans only" for 330-milliliter size containers is deleted.

Please see GAIN report IN3067 for more details.

All weights or measures are to be reported in metric units. For details, please refer to the Legal Metrology Act, 2009, and the Legal Metrology (packaged commodities) Rules, 2011, as above. The use of materials such as polyvinyl chloride (PVC) is not allowed for packaging in most cities, due to environmental concerns and waste disposal problems.

Per Judgment 1732/2010 of the High Court of Himachal Pradesh, non-biodegradable packaging of many food items is prohibited in the state of Himachal Pradesh as of January 26, 2014. Packaging of edible oils sold at retail is compulsory, unless specifically exempted by State governments. This measure was introduced to ensure the availability of safe and high quality edible oils in packed form at pre-determined prices to consumers. Edible oils sold in Himachal Pradesh must be packed in metal containers.

#### Section IV. Food Additives Regulations:

Information regarding permitted food colorings and preservatives is published in various sections of FSS Regulation, 2011. For detailed information, please refer to <u>FSS Food Product Standards and Food</u> <u>Additives Regulation, 2011 - Part-I</u> and <u>FSS Food Product Standards and Food Additives Regulation,</u> <u>2011 - Part II</u>. Amendments related to food product standards and additives published by FSSAI are detailed in the "Chronology of FSSAI Notifications/Regulations" at the end of this report.

#### Section V. Pesticides and Other Contaminants:

FSSAI has set maximum residue levels (MRLs) for pesticides, toxins and other contaminants. Please refer to FSS (Contaminants, Toxins and Residues) Regulation, 2011, Chapter 2, Regulation 2.3, for the complete list.

A list of banned/restricted pesticides/pesticide formulations that have been refused registration or face restricted use in India is available at <u>http://cibrc.nic.in/list\_pest\_bann.htm</u>. MRLs set by Codex Alimentarius may be accepted for imported foodstuffs if the subject pesticides are not on the approved or banned lists of pesticides. The Ministry of Agriculture has discontinued pesticide registration through the Pesticide Registration Committee when no MRLs are established.

For additional information on approved pesticides and the procedures for registration of new pesticides, please refer to the Central Insecticide Board and Registration Committee website: http://cibrc.nic.in/. Section VI. Other Regulations and Requirements:

#### **Product Approval:**

For "non-standardized foods", the importer must seek formal product approval from the Product Approval Division of FSSAI. On May 11, 2013, FSSAI issued an advisory for new guidelines on product approval procedures, which were immediately implemented. These guidelines were developed based on feedback from various stakeholders regarding the complexity and long timelines for product approvals. These guidelines supersede all advisories issued earlier and the food products for which the standards are not specified under FSS Act, 2006, will be granted product approval. A summary of guidelines is given below:

1(a) Product approval will be granted to all food products that are known for safety of its ingredients and are permitted under FSS Regulation, 2011, Codex and other regulatory bodies like EU/FSANZ/USFDA etc. and the food product does not contain plants or botanicals or substances from animal origin. The Food Business Operator (FBO) shall submit the application in form 1(a) along with the supporting documents.

1(b) Product approval will be granted only after the completion of safety assessment to all food products that are known for safety of its ingredients and are permitted under FSS Regulation, 2011, Codex and other regulatory bodies like EU/FSANZ/USFDA etc. and the food products contains ingredients including plants or botanicals or substances from animal origin. No-Objection-Certificate (NOC) will be granted to food products in market where license has been granted under previous Act/Orders. The FBO shall submit the application in form 1(b) along with the supporting documents.

1(c) Food products that fall under category 1(b), but, safety of the ingredients is not established, it would be referred to the scientific panel and product approval shall be granted/denied on the basis of risk assessment.

1(d) Food products for which safety of the ingredients is established or products whose ingredients are standardized or permitted under FSSR, 2011, will not require further safety assessment except for authorization of the ingredients contained in the product. The FBO shall submit the application in form 1(d) along with the supporting documents.

A non-refundable application fee of INR 25,000 is payable for each application. If the product requires an assessment by the scientific panel, an additional fee of INR 25,000 is to be remitted by the FBO. For more details on the new product approval guidelines, please see GAIN Report <u>IN3051</u>.

On September 9, 2014, FSSAI launched the online FPAS, which allows FBOs to apply online for a no objection certificate or seek product approval for new food product imports. Based on user feedback, FSSAI may eventually develop an ingredient-based approval system. Please see GAIN Report <u>IN4082</u> for more details.

On October 14, 2014, FSSAI published a detailed fact sheet on the food product approval process. This initiative may help reduce confusion on process, especially on the necessity to apply for approval for domestic or imported products. Please see GAIN Report <u>IN4099</u> for more details.

#### **Product Sampling:**

A sample of any imported article will be sent by the Authorized Officer for analysis to the food analyst of any notified laboratories. The required sampling fee charged by FSSAI for imported products is INR 3,000, excluding the service tax and education cess (surtax), and the sampling process will begin only after receipt of this fee. For details on the list of notified laboratories and procedure of sampling, please refer to FSS Laboratory and Sampling Analysis Regulation, 2011 and the Draft Manual on Food Import Clearance System.

On February 6, 2014, FSSAI published 'General Guidelines' for of the FSSAI Food Import Clearance System (FICS). This guideline document was published to further clarify the FICS for officials working at the port of entry. The new guidelines clarified:

(a) use of stickers for the FSSAI license number as a "rectifiable label". Initially this requirement was to be enforced as of January 1, 2015, although in late December 2014, FSSAI extended the deadline until July 1, 2015.

(b) Outlined procedures for importing intermediary food products that have not received product approval; and

(c) For food products exhibited at trade fairs or similar marketing functions that have not been approved by Indian authorities, at the port of entry an affidavit must be presented that states the product will be destroyed or re-exported after the event. Please see GAIN Report IN4024 for more details.

All imported foods are randomly sampled at the port of entry for conformity with India's FSS Regulations, 2011. On June 16, 2004, the Ministry of Commerce and Industry published a list of "high risk" food items, imports of which are subject to 100 percent sampling. This list includes edible oils and fats, pulses and pulse products, cereal and cereal products, milk powder, condensed milk, food colors, and food additives, among other items. The complete list as given in the policy circular 37 (RE-2003)/2002-2007 issued by the Department of Commerce is available at: List of High Risk Food Items.

Perishable food products like fruits, vegetables, meat, fish, cheese, etc., are subject to routine sampling and testing prior to clearance. Such items shall be cleared after conducting general checks and on the basis of certificates from the internationally known testing laboratories or government laboratories that these products confirm the food safety and quality of such products. A random sampling will also be done in such cases.

For food items not covered under "High Risk" and "Perishable" the following procedure shall be adopted in addition to the general checks by the customs office.

(A) Before the consignment is taken up for sampling, the importer/CHA shall make declaration in writing and provide the complete packing list including the brand name and packing (weights, etc.) particulars of the food product for clearance. The importer shall also declare whether the individual consumer packs are duly labeled in English and contains all the relevant information.

(B) Samples would be drawn from the first five consecutive consignments of each food product imported (preferably complete consumer pack including its label), and referred to the laboratory to ascertain the quality and health safety standards of the consignment.

(C) In case the samples conform to the prescribed standards, the customs officials would switch to a system of checking 5 to 20 percent of the consignments of these food products on a random basis to check for conformity of standards. The selection of food products for random testing would be done by the customs officials based on factors such as the nature of food products, its source of origin as well as track record of the importers and information received from FSSAi from time to time.

(D) Where a product of SAME brand and SAME manufacture imported has been tested and allowed clearance, the same test result shall be taken into consideration for clearance of another consignment by another importer if it fulfils all other criteria such as labeling residual shelf life, etc. This criterion however, shall not be applied to clear similar products.

(E) In case the sample fails to meet the prescribed standards, the customs officials would place the import of the said consignment on alert, discontinue random checking and revert to the procedure of 100 percent sampling. The system of random sampling will be restored only if the test results of the samples drawn from five consecutive consignments re-establish that the food products are in conformity with the prescribed standards.

The above instructions on the random sampling are available at: http://delhicustoms.gov.in/pi2014/PunN-280814.pdf

Instructions regarding sampling and the clearance of consignments of food articles at ports of entry are available in Policy Circular 25 (RE-2003)/2002-2007 issued by the Department of Commerce and available at: Instructions regarding sampling and testing.

Other important circulars/notifications:

Instructions- regarding clearance of consignments-I Instructions-regarding clearance of consignments-II Instructions-regarding clearance of consignments-III Import of meat and poultry, and other edible and primary agricultural products

#### Shelf Life:

Notification No. 22 (RE-2001) 1997-2002, dated July 30, 2001, issued by the Department of Commerce, Ministry of Commerce and Industry, states:

Imports of all such edible/food products, domestic sale and manufacture of which are governed by the FSSAI shall also be subject to the condition that, at the time of importation, these products are having a valid shelf life of not less than 60 percent of its original shelf life. Shelf life of the product is to be calculated, based on the declaration given on the label of the product, regarding the date of manufacture and the due date of expiry.

http://dgftcom.nic.in/exim/2000/not/not01/not2201.htm.

#### Miscellaneous Requirements:

There is no requirement to register products formally. Export certification requirements for imports of food products in India are summarized in FAIRS Export Certification Report 2014 (IN).

The import of product samples via express mail or parcel post (such as FedEx, UPS, DHL) is allowed, subject to obtaining prior permission from the DGFT. (See <u>www.cbec.gov.in/js-menu/import-</u><u>courier.htm</u>). Mail order imports are not allowed. Contact information to arrange sample shipments is provided in Appendix I. Once the products enter the domestic market, they are subject to random monitoring at the retail and wholesale levels by the relevant regulatory authorities.

The Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests is the decision-making authority for the approval of genetically engineered products. Food ingredients and additives containing bioengineered organisms may not be produced, used, or imported without prior GEAC approval.

Since July 8, 2006, the GOI Foreign Trade Policy (2004-2009) specified that all imports containing products of modern biotechnology must have prior approval from GEAC, Ministry of Environment and Forests. The policy also stipulates a mandatory biotech declaration. The only biotech food product officially permitted for commercial importation is soybean oil derived from Roundup Ready Soybeans. For more information on India's biotech import policy, please refer to GAIN report "Agricultural Biotechnology Annual 2014" (IN4059).

#### Section VII. Other Specific Standards:

Department of Commerce Notification No. 44 (RE-2000)/1997-2002, dated November 24, 2000, requires imports of certain products, including some food products (milk powder, condensed milk, infant milk foods, milk-cereal based weaning foods) and food additives, to comply with mandatory Indian quality standards. All manufacturers and exporters to India of products listed in this notification are required to register with the Bureau of Indian Standards. Please refer to the official <u>DGFT</u> <u>Notification</u> for the list of affected products.

#### Section VIII. Copyright and/or Trademark Laws:

The Indian Copyright Act of 1957 is based on the Bern Convention on Copyrights, to which India is a party. The May 1995 and December 1999 amendments increased protection and introduced stiff mandatory penalties for copyright infringement. On paper, Indian copyright law is now on par with the most modern laws in the world. Trademarks are protected under the Trade Marks Act, 1999 and the Trade Marks Rules, 2002 (in force since September 2003), which repealed the Trade Mark and Merchandise Marks Act, 1958. The changes introduced by the Act include protection of well-known trademarks, as well as service and collective marks; extension of the period of protection from seven to ten years; establishment of an Appellate Board; and increased penalties for infringement of trademarks. GOI enforcement of intellectual property rights has been very weak; however, the situation is slowly improving, as the courts and police are becoming more responsive to domestic stakeholders concerned with the broad effects of piracy.

Foreign firms can register trademarks through a local agent by applying at the Office of the Registrar of Trademarks (www.ipindia.nic.in). However, the registration process can take up to three to five years for the trademark to be officially accepted and notified.

In order to protect the intellectual property of imported products, the Central Board of Excise and Customs (CBEC), Ministry of Finance, has issued the Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007 (<u>CBEC Notification</u> and <u>www.cbec.gov.in/customs/cs-act/notifications/notfns-2k7/csnt49-2k7.htm</u>).

Instructions regarding the implementation of the Rules are available on the CBEC website: <u>http://www.cbec.gov.in/customs/cs-circulars/cs-circulars07/circ41-2k7-cus.htm</u>

#### Section IX. Import Procedures:

**Documentation**: Importers must provide an import declaration in the prescribed Bill of Entry format, disclosing the value of the imported goods. This declaration must be accompanied by the relevant import license and phytosanitary certificate (in the case of agricultural commodities), along with supporting documentation such as sales invoices and freight and insurance certificates. There is no need to translate the import documents into the local language as English is an official language. All consignments are required to be inspected prior to clearance. FSSAI has also authorized its officers at Mumbai, Nhava Sheva, Haldia, Kolkata, Chennai and Cochin seaports, and at the international airports of Mumbai, Kolkata, Chennai, Cochin and New Delhi, to oversee the clearance process of imported food products. FSSAI's authorized officer overseeing import clearance at New Delhi's Indira Gandhi International Airport also oversees the import clearance process at Inland Container Depots in Tuglaqabad and Patparganj areas of New Delhi.

#### **Procedure for Clearance:**

Indian Customs officials inspect incoming consignments, draw samples, and forward the samples to FSSAI port health officers, who verify that the imported food product are in accordance with Indian food law. The FSSAI port health officers take the samples and, based on the regulations, send the samples for testing at FSSAI approved labs. The FSSAI port officers will issue a 'No Objection Certificate' (NOC), as long as lab analysis results show that the imported food product is in compliance with Indian food laws. Customs officers will release the consignment for distribution and sale in India once they have received the NOC from the FSSAI port officer. If the consignment does not comply with the Indian food law, the FSSAI port health officers will inform the customs officers, who will detain, re-export, or destroy the consignment.

Note: FSSAI maintains that there have been no changes in the procedure for sampling, testing, and clearance of imported foods. All the rules and procedures are equivalent to those employed under the PFA Act, as amended.

The procedures for product sampling and laboratory analysis are described in <u>FSS (Laboratory and</u> <u>Sample Analysis) Regulation, 2011</u>. Prior to sampling a product, the FSSAI port officer will ascertain whether the imported food item is in compliance with the labeling provisions under FSSAI rules so as to

ensure that adequate and accessible information is available to the handler, processor or consumer to enable them to handle, store, process, prepare, and display the food products safely, and that the lot or batch can be easily traced and recalled if necessary. If labeling is found deficient, the product will be rejected without further inspection or sampling. For additional information please contact:

> Office of Agricultural Affairs Embassy of the United States of America Shantipath, Chanakyapuri New Delhi - 110 021, India Ph: (+91-11) 2419-8000, Fax: (+91-11) 2419-8530 E-Mail: agnewdelhi@fas.usda.gov

#### **Appendix I. Government Regulatory Agency Contacts:**

#### A. Overall Food Safety: Food Safety and Standards Regulations, 2011 (as amended)

Chairperson Food Safety and Standards Authority of India FDA Bhavan, Kotla Road New Delhi-110 002 Phone: (91-11) 23220991/92 E-mail: chairperson@fssai.gov.in Website: http://www.fssai.gov.in

#### **B.** The Legal Metrology Act, 2009 (as amended) Department of Consumer Affairs, Ministry of Consumer Affairs, Food, and Public Distribution

Director (Legal Metrology) Department of Consumer Affairs Krishi Bhawan, New Delhi – 110 001 Phone: (91-11) 23389489 Fax: (91-11) 23385322 Email: dirwm- ca@nic.in Website: http://fcamin.nic.in/index.asp

#### C. Phytosanitary Issues Department of Agriculture and Cooperation, Ministry of Agriculture

Joint Secretary - Plant Protection and Quarantine Department of Agriculture and Cooperation Ministry of Agriculture Krishi Bhawan, New Delhi – 110 001 Phone: (91-11) 23070306 Fax: (91-11) 23070306 Website: www.plantquarantineindia.org

#### **D.** Livestock and Products Imports Department of Animal Husbandry, Dairying, and Fisheries, Ministry of Agriculture

Joint Secretary Department of Animal Husbandry and Dairying Ministry of Agriculture Krishi Bhavan, New Delhi - 110 001 Phone: (91-11) 23387804 Fax: (91-11) 23386115 E-mail: jsadd@nic.in Website: http://dahd.nic.in/ E. Foreign Trade Notifications

#### Department of Commerce, Ministry of Commerce and Industries

Director General of Foreign Trade Ministry of Commerce Udyog Bhavan, New Delhi - 110 011 Phone: (91-11)23062777 Fax: (91-11)23061613 E-mail: dgft@nic.in Website: http://dgft.delhi.nic.in/

#### F. Registry of Trademarks Department of Commerce, Ministry of Commerce and Industries

Controller General of Patents, Designs and Trade Marks and Geographical Indication Registry Bhoudhik Sampada Bhavan S.M. Road, Antop Hill, Mumbai – 400 037 Phone: (91-22)24144525/24132735 Fax: (91-22)24132735 E-mail: <u>Mumbai-patent@nic.in</u> Website: www.ipindia.nic.in

# **G.** Central Board of Excise and Customs Ministry of Finance

Chairman Central Board of Excise and Customs Ministry of Finance North Block, New Delhi – 110 001 Phone: (91-11) 23092849 Fax: (91-11) 23092890 E-mail: chairman@cbec.gov.in Website: http://www.cbec.gov.in/

#### H. Pesticide Registration Department of Agriculture and Cooperation, Ministry of Agriculture

Secretary Central Insecticides Board and Registration Committee C.G.O. Complex, N.H. IV Faridabad – 121 001, Haryana Phone: (91-129) 2413002 E-mail: cibsecy@nic.in Website: http://cibrc.gov.in/

#### I. Genetic Engineering Approval Committee (GEAC)

#### **Ministry of Environment and Forests**

Chairman, GEAC Ministry of Environment and Forests Paryavaran Bhawan CGO Complex, Lodi Road New Delhi – 110 003 Phone/Fax: (91-11) 24363967, 24361308 Email: parsheera-mef@nic.in Website: http://envfor.nic.in/

#### **Appendix II. Other Import Specialist Contacts:**

A. Director

Confederation of Indian Food Trade and Industry Federation of Indian Chambers of Commerce and Industry Federation House, Tansen Marg New Delhi – 110 001 Phone: (91-11) 23738760-70 Fax: (91-11) 23311920 E-mail: ficci@ficci.com Website: www.ficci.com

B. Senior Technical Advisor Confederation of Indian Industry The Mantosh Sondhi Center 23, Institutional Area, Lodhi Road New Delhi – 110 003 Phone: (91-11) 2463 3461 Fax: (91-11) 2462 6149 Website: <u>www.cii.in</u>

#### APPENDIX III: IMPORTANT COMMODITY-SPECIFIC REPORTS SUBMITTED SINCE LAST FAIRS COUNTRY REPORT

IN4122	FAIRS Export Certificate
IN4120	Retail Foods
IN4119	Food Processing Ingredients
IN4118	Food Service - Hotel Restaurant Institutional
IN4117	Exporter Guide
<u>IN4114</u>	Draft Amendment on Trans Fatty Acid Levels
<u>IN4115</u>	Draft Amendment on Food Additives Regulations for Pullalan
<u>IN4099</u>	FSSAI publishes FAQs on product approval
<u>IN4093</u>	Clarifications on Labeling of Imported Food Packages
<u>IN4089</u>	Dairy and Products Annual 2014
<u>IN4082</u>	FSSAI Launches the Online Food Product Approval System

<u>IN4073</u>	Import Notification for Livestock
<u>IN4070</u>	FSSAI Extends Deadline on Food Business Operator License
<u>IN4059</u>	Agricultural Biotechnology Annual
<u>IN4057</u>	Draft Amendment on Food Standards and Additives Regulations for Salt
<u>IN4056</u>	Extension of Licensing Timeline for Food Businesses
<u>IN4050</u>	Deadline Extended for Printing FSSAI Logo on Food Labels
<u>IN4048</u>	Retail Foods Sector Update 2014
<u>IN4045</u>	Update on India's Quick Service Restaurant Sector
<u>IN4041</u>	GOI Updates Draft Health Certificates for Bovine Germplasm
<u>IN4024</u>	New FSSAI Guidelines for Labeling and Customs Procedures
<u>IN4017</u>	Updated Guidelines for Importing Trade Shows Samples
<u>IN4014</u>	Livestock and Products Semi-Annual 2014
<u>IN4004</u>	FSSAI extends the timeline to obtain license by six months

#### APPENDIX IV: CHRONOLOGY OF FSSAI REGULATIONS/NOTIFICATIONS (2014)

- On September 9, 2014, FSSAI launched the online FPAS, which allows FBOs to apply online for a no objection certificate or seek product approval for new food product imports. The system was developed by the National Institute for Smart Government with guidance from the Product Approval Screening Committee. Based on user feedback, FSSAI may eventually develop an ingredient-based approval system (<u>IN4082</u>).
- On October 14, 2014, FSSAI published a detailed fact sheet on the food product approval process. This initiative may help reduce confusion on process, especially on the necessity to apply for approval for domestic or imported products. Important highlights include information on (a) food products that have Codex or third country standards but no FSSAI standards; (b) organic products, ingredients, and additives; and (c) specific documentation to obtain product approval (IN4099).

#### Amendments to the Food Products Standards and Food Additives Regulation, 2011

- On June 26, 2014, FSSAI published draft <u>Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2014</u>, which primarily focus on modifying standards and regulations for edible salt. Some changes include adding provisions on food additives and fortifying ingredients (<u>IN4057</u>).
- On December 5, 2014, FSSAI published its draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2014, which primarily focuses on setting maximum limits for trans fatty acids, as well as dates of implementation (IN4114).
- On December 8, 2014, FSSAI published its draft <u>Food Safety and Standards (Food Products</u> <u>Standards and Food Additives) Amendment Regulations, 2014</u> for the inclusion of Pullulan as a food additive. Pullulan has been added to the list of other substances in sub-regulation 3.1.17 (<u>IN4115</u>).

#### Amendments to the Packaging and Labeling Regulation, 2011

- Effective July 1, 2014, the new FSSAI guidelines in respect of the Food Import Clearance System (FICS) allow a sticker for the FSSAI license number and logo to be applied at the port of entry as a "rectifiable label." All other labeling requirements must comply with <u>FSS</u> (<u>Packaging and Labeling</u>) <u>Regulations 2011</u> prior to reaching customs. The new guidelines also outline procedures for importing intermediary food products that have not received product approval (<u>IN4024</u>).
- FSSAI previously announced that as labels on any packages of foodstuffs destined for retail sale as defined by Indian law and regulation should bear the FSSAI logo as well as the registration number under which the food business operator (importer in the case of imported foodstuffs) is registered with FSSAI. On December 17, 2014, FSSAI issued a new notification extending the deadline for compliance with this requirement to July 1, 2015 (IN4050 and IN4116).
- The Government of India has clarified certain labeling requirements for imported food packages. These include: (a) Ministry of Commerce and Industry and Department of Legal Metrology regulations are to be amended to allow the use of a sticker for the maximum retail price on imported retail packaged foods; (b) both the Department of Legal Metrology and the Ministry of Commerce and Industry will defer to the Food Safety and Standards Authority (FSSAI) regulations to define wholesale versus retail packaging; and (c) boxes (cartons) of fresh fruit may indicate fruit count rather than net weight (<u>IN4093)</u>.

#### Amendments to Licensing and Registration of Food Business Regulation, 2011

- On February 4, 2014, FSSAI issued a statutory advisory extending the deadline to obtain a food business operator (FBO) license to August 4, 2014. The previous deadline was February 4, 2014. The Indian media reported that the National Restaurants Association of India (NRAI) requested an extension since FBO licenses were not being issued on a timely basis. Reportedly, vendors were concerned that even by applying before the deadline, without a FBO license they may be forced to close operations. As of February 4, 2014, FSSAI issued 481,964 FBO licenses and recorded 1,910,160 FBO registrations (IN4004).
- On June 10, 2014, FSSAI published Food Safety and Standards (FSS) (Licensing and Registration of Food Business) Regulations, 2014, which includes amendments to the 2011 regulations. Major changes include: (a) Beginning on June 10, 2014, the license registration timeline has been extended to 36 months for food businesses; (b) removing additional fees for businesses renewing licenses within 30 days of license expiration; and (c) amending the annual tax form (IN4056).
- On August 4, 2014, FSSAI extended the timeline to obtain a food business operator (FBO) license to February 4, 2015 (<u>IN4070</u>).

# APPENDIX V: CHRONOLOGY OF MINISTRY OF AGRICULTURE, DIRECTORATE OF PLANT PROTECTION, QUARANTINE AND STORAGE ACTIONS

- In February 2011, the MinAg Directorate of Plant Protection, Quarantine and Storage unveiled the new online Plant Quarantine Information System (PQIS). The PQIS facilitates the application process for import permits and import release orders. Exporters are now also able to apply online for phyto-sanitary certificates. For more information, please refer to GAIN Report "India Launches Online Plant Quarantine Information System" (<u>IN3082</u>).
- On January 3, 2012, MinAg issued a draft notification proposing additional phytosanitary requirements for the import of pome fruits from various countries, including the United States For more information, please refer to GAIN report "Comment Period Extended for Import of Pome Fruits Draft Notification." This is yet to be implemented (IN2035).
- On May 28, 2013, MinAg released a notification amending Schedule VI of the Plant Quarantine Order, 2003 (the regulation for importing plant material into India), allowing import of walnuts (*Juglans spp.*) from the United States. The notification includes "*Juglans spp*. (Walnut)" as "dry fruits for consumption (shelled and unshelled)" from the United States of America, but with an additional declaration and special conditions, specifically fumigation with methyl bromide or other fumigant as approved by the Plant Protection Adviser. For more information, please refer to (<u>IN3082</u>).