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Date: 12/23/2016 GAIN Report Number: IN6162

India

Food and Agricultural Import Regulations and Standards -Narrative

FAIRS Country Report

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Report Highlights:

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) issued multiple amendments for regulations related to food imports, food additives, standards, contaminants, toxins, labeling, and packaging in calendar year (CY) 2016. Additionally, the Ministry of Agriculture (MinAg) revised the guidelines for Export/Import of Bovine Germplasm and notified a draft veterinary health certificate for dog and cat food (containing animal origin material) imports to the World Trade Organization (WTO).

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. Only updates from CY 2015 and CY 2016 are listed in this report. OAA New Delhi suggests readers use the <u>GAIN search engine</u> to find similar reports for previous years. While OAA New Delhi makes every effort to accurately describe existing regulations, exporters are strongly advised to always verify import requirements with their Indian customers prior to shipment. This report has not been officially endorsed by the 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 products imported into India are under the jurisdiction of multiple GOI authorities: 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 MinAg departments, the Department of Animal Husbandry, Dairying and Fisheries (DAHDF) and the Department of Agriculture and Cooperation (DAC). Exporters are advised to thoroughly research the laws and regulations applicable to their products across all relevant regulatory agencies.

In CY 2016, FSSAI was actively engaged toward harmonizing food safety regulations with Codex Alimentarius. FSSAI also issued multiple draft and final amendments and/or regulations related to food safety for imported and domestic food products. FSSAI published the 2016 Food Import Regulations and proceeded to implement them with immediate effect. DAHDF also published revised guidelines for Export/Import of Bovine Germplasm and notified a draft veterinary health certificate for dog and cat food (containing animal origin material) imports to the WTO.

Section I. Food Laws:

A. FSSAI's 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 (FBOs), 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 <u>GAIN</u> 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 and has since issued multiple draft amendments in regulations pertaining to food safety. FSSAI continues its efforts to harmonize standards and expect most of the standards required to ensure safe food to be set in the forthcoming months.

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 and more simply called 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 DAHDF, MinAg. These procedures are available at: <u>http://dahd.nic.in/sites/default/files/gazette_27June2014%20%201.pdf</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 January 16, 2015, FSSAI published a draft order for domestically produced and imported meat and poultry products which notes that a procedure will be developed to inspect and monitor slaughtering and processing plants before granting market access to trading partners, and requires a country's competent authority to certify to Indian import requirements. Furthermore, the draft order has introduced modified text for some requirements currently included in veterinary import certificates for imported meat and poultry products. On April 23, 2015, the draft order was notified to the WTO for comment. However, FSSAI postponed the earlier

effective date of July 1, 2015 by three months and the new date of implementation of the order was October 1, 2015 or until further orders, whichever is earlier. To date, FSSAI has not notified if the implementation date of October 1, 2015 will be further extended. For additional details, please refer to GAIN <u>IN5035</u>, GAIN <u>IN5078</u> and GAIN <u>IN5086</u>.

- On June 29, 2015, the MinAg issued a draft notification proposing phytosanitary requirements for the import of hay from the United States (see <u>Draft Notification on the Import of Hay from</u> the U.S. for details). This will be implemented when officially published in the Gazette of India.
- On September 28, 2015, DAHDF published a veterinary health certificate for the import of bovine frozen semen into India through an official gazette notification. Previously, DAHDF published a draft certificate in 2014 (GAIN <u>IN4041</u>). The final certificate provides new or revised information including modified import requirements. For example, it specifically mentions that bovine frozen semen imports require a health certificate written in English that is signed by an official veterinarian of the exporting country and includes information contained in the Form section. The final certificate also added additional disease testing options for bovine brucellosis and paratuberculosis, which include the fluorescence polarization assay and fecal culture test. To date, this veterinary health certificate has not been notified to the WTO (GAIN <u>IN5132</u>).
- On September 28, 2015, DAHDF published a veterinary health certificate for the import of in vivo bovine embryos through an official gazette notification. Previously, the DAHDF published a draft health certificate in 2014 (GAIN <u>IN4041</u>). The final certificate provides new or revised information including modified import requirements. For example, it specifically mentions that in vivo bovine embryo imports require a health certificate written in English that is signed by an official veterinarian of the exporting country and includes information contained in the Form section. The final certificate also added additional disease testing options for paratuberculosis, which include a fecal culture test. According to paragraph (II) (10), the embryos can be stored in new or sterilized liquid nitrogen containers (the draft certificate only mentions sterilized containers). Paragraph (II) (11) requires that the straw should be labeled according to the International Embryo Transfer Society manual. To date, this veterinary health certificate has not been notified to the WTO. (GAIN <u>IN5134</u>).
- On September 28, 2015, DAHDF published a veterinary health certificate for the import of live bovines into India through an official gazette notification. The revised certificate provided new or revised information including modified import requirements. For example, it specifically mentions that live bovine imports require a health certificate written in English that is signed by an official veterinarian of the export country and includes information contained in the Form section. The revised certificate added additional disease testing options for paratuberculosis and schmallenberg serology, which include the fecal culture test and virus neutralization. The new certificate also includes a few modifications in the testing protocol for the disease enzootic bovine leucosis. To date, this veterinary health certificate has not been notified to the WTO. For further details, please refer to (GAIN IN5133).
- On November 6, 2015, DAHDF published a final veterinary health certificate for pork and pork product imports on its website. The revised certificate introduces additional requirements as

compared to the draft protocol notified to the WTO on March 16, 2015 (GAIN <u>IN5036</u>). For example, the final certificate introduces new import requirements under para 6 (f) of section IV, which notes that the consignment of pork and pork products should be produced according to the Codex Code of Hygienic Practice for Meat and sourced from pigs that are slaughtered in an approved slaughter house/abattoir. The final certificate also notes requirements for the *taenia solium* and provides procedures for the inactivation of the *taenia solium cysticerci*. To date, this veterinary health certificate has not been notified to the WTO (GAIN <u>IN5144</u>).

- On July 26, 2016, GOI notified requirements for poultry and poultry product imports from countries reporting an outbreak of Highly Pathogenic Avian Influenza or Low Pathogenic Avian Influenza to the WTO (GAIN <u>IN6105</u>). This is subsequent to the notification of draft requirements to WTO on April 21, 2016 (GAIN <u>IN6059</u>). After reviewing comments, on July 8, 2016, the DAHDF published a gazette notification for poultry and poultry product imports from countries reporting avian influenza (GAIN <u>IN6095</u>). The final notification introduces some new language and modifies texts in comparison to the draft notification. For example, the final notification modifies text for the definition of 'poultry products' in paragraph 1 (f) and inserts an additional criteria for determination of avian influenza status in paragraph 2-2(d). The final notification is available online at <u>http://dahd.nic.in/trade</u> or can be directly accessed at <u>Import of Poultry and Poultry Products into India in view of Outbreak of Avian Influenza</u>. On September 21, 2016, GOI further notified amendments to the requirements for poultry and poultry product imports from countries reporting avian influenza to the WTO (GAIN <u>IN6122</u>).
- In April, 2016, DAHDF revised the Guidelines for Export/Import of Bovine Germplasm. The new guidelines modify text and/or revise the import requirements for semen, embryos, young bulls and young heifers. For example, the new guidelines include import requirements for sexed semen from genomically tested sires, embryos from genomically tested heifers and genomically tested young bulls. The revised guidelines also mention additional requirements for the eligibility of importers. Although not notified to the WTO, the new guidelines were published on the DAHDF website (GAIN IN6090).
- On February 4, 2016, the GOI notified a draft veterinary health certificate for dog and cat food (containing animal origin material) imports to the WTO. This revised draft certificate introduces some new language and requirements in comparison to the earlier protocol. Other modifications or additions include new heat treatment processing guidelines, the identification of ports that can accept imported pet food, new testing requirements for sulphite reduced clostridium for canned and moist pet food, and manufacturer/exporter declarations. The new draft certificate removed the earlier requirement that a processing facility needed to be located at least 25 kilometers radius from an avian influenza infected area. More details on the draft veterinary health certificate are provided in GAIN <u>IN5157</u> and GAIN <u>IN6035</u>. The health certificate is accessible online at <u>http://dahd.nic.in/trade</u> or can be directly accessed at <u>Veterinary Certificate for Import of Dog and Cat Foods into India.</u>

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-DAC. The Order, as amended, is available on India's <u>Plant</u> <u>Quarantine website</u>.

Section II. Labeling Requirements:

Three GOI authorities regulate labeling of food and agricultural products. They are the FSSAI (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.
 - 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:
 - **A.** The country of origin of the food shall be declared on the label of the food imported into India.
 - **B.** 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.

On March 23, 2012, FSSAI published "guidelines related to food import clearance process by FSSAI's Authorized Officer," on its website. These guidelines elaborated the labeling requirements of different kinds of packages of food consignments imported into India. The different categories of packages mentioned in the guidelines were: (1) Pre-packaged food or pre-packed food including multi-piece packages; (2) Wholesale packages (including semi-finished/intermediary food products which will be further processed to make final product and packed as pre-packaged or pre-packed food); (3) Primary food like food grains, pulses, fruits, dry fruits, whole spices, etc., imported in package; and (4) Primary food like food grains, pulses, fruits, whole spices, etc. imported in loose in bulk. For more details on the guidelines, please refer to GAIN IN2055.

The new guidelines, as published on FSSAI website on August 9, 2016, modified the labeling requirements for category 3 above. Specifically, the new guidelines state that for all primary food products, such as food grains, pulses, fruits, dry fruits, whole spices, etc. imported in package, the name

and address of the importer can be verified from the documents that accompany the consignment. The labeling requirements for such products have been revised and will now require the following details:

- > Name of Food
- > Name and complete address of the manufacturer/packer
- Date of Manufacture/packing
- > Net weight
- Lot number/Code number/Batch number
- > Best before or use by date or date of expiry
- Country of Origin

➢ FSSAI logo and license number (as a rectifiable label, which can also be applied upon arrival) The new FSSAI guidelines allow a timeline of six months to comply with the modified labeling requirements (GAIN <u>IN6108</u>).

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.

A. 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. Effective December 31, 2015, the compliance on FSSAI logo and license number began. Interested readers may use the GAIN search engine to find reports on India containing the term *FSSAI* in "Report Highlights" to access background details on the extension of compliance date for logo and license number.

Additionally, the <u>Modified 2016 Food Import Regulations</u> (Chapter 3, clause 3.7) also allows an Authorized Officer to issue an order for directing the food importer or his authorized agent to carry out permissible labeling rectifications, within a prescribed time in the Customs bonded area without altering

or masking the original labeling information in any manner. When such a rectification is done by the importer, the Authorized Officer shall re-inspect the food, and if satisfied, draw sample, subject to all other conditions met by the importer.

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" (GAIN IN3003).

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

On May 14, 2015, the GOI, Department of Consumer Affairs published a notification in the Indian official gazette, amending the Legal Metrology (packaged commodities) Rules, 2011. Important highlights of the amendment include: (a) Adopting the definition of retail packages as defined by the FSSAI; and (b) Allow the use of stickers to include all labeling requirement data on imported food packages. The publication was neither WTO notified, nor any reference was made to a specific comment period for domestic stakeholders. With the first amendment of 2015, these rules were called as Legal Metrology (Packaged Commodities) (First Amendment) Rules, 2015 (GAIN <u>IN5076</u>).

On December 5, 2016, the Indian Ministry of Consumer Affairs, Food and Public Distribution's Department of Legal Metrology published an advisory to postpone the implementation date of the Legal Metrology (Packaged Commodities) (Amendment) Rules, 2015, until March 31, 2017. The objective of this extension was primarily for Rule 7 (Sub-rule 5 – Principal Display Panel for labeling) of the Legal Metrology (Packaged Commodities) Rules, 2011, as a means to provide commercial stakeholders an adequate adjustment period. For background details on the subject, readers may access GAIN <u>IN6156</u>, GAIN <u>IN5076</u> and the Legal Metrology (Packaged Commodities) (Amendment) Rules, 2015.

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 <u>DGFT</u> website.

Please see following packaged food label samples:



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
- 13. License Number

Commerce requirements:

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

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:

All Subsequent Information Remains Unchanged from 2015 FAIRS Narrative

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>. 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:

FSSAI discontinued its process of product approval after the Supreme Court of India dismissed an appeal by FSSAI and upheld a June 30, 2013, decision by the Bombay High Court which determined that FSSAI did not have the legal authority to unilaterally issue advisories under the Food Safety Act, 2006. As per the Bombay Court's judgment, all earlier advisories of FSSAI, including the May 11, 2013 advisory on product approval for processed food products were void. After a gap of almost a year and half, on October 4, 2016, FSSAI published its new draft Regulation called the <u>"Food Safety and Standards</u> (Approval for Non-Specified Food and Food Ingredients) Regulations, 2016." The draft Regulation outlined new product approval procedures for all food products not already covered under any preexisting Regulations under the Food Safety Act, 2006. These products have been termed by FSSAI as "nonspecified food and food ingredients." Comments are invited from the WTO member countries on the draft Regulation and the timeline to comment expires on December 16, 2016 (GAIN <u>IN6132</u>).

A chronology of FSSAI notifications related to product approval is provided below.

July 23, 2015: FSSAI published new draft regulations pertaining to health supplements, nutraceuticals, and special dietary and medical purpose foods, functional and novel foods. The draft regulations also determined the general conditions for the manufacture and sale of such categories of foods, as previously

there were no specific regulations for the same. The GOI has sought comments from trading partners through September 23, 2015 (GAIN <u>IN5097</u>).

August 19, 2015: The Supreme Court of India dismissed an appeal by FSSAI and upheld a June 30, 2013, decision by the Bombay High Court which determined that FSSAI did not have the legal authority to unilaterally issue advisories under the Food Safety Act, 2006. The principal result of the Bombay Court's judgment was that FSSAI could no longer legally continue to issue advisories, and voided all earlier FSSAI advisories, including its May 11, 2013, advisory on product approval for processed food products.

August 26, 2015: FSSAI published an official notice that it would no longer "continue with the process of product approvals". The notice further stated that "every effort will be made to expedite the regulations governing Section 22". Products designated under Section 22 of the <u>Food Safety and</u> <u>Standards Act, 2006</u>, include foods derived from genetically engineered sources, nutritional supplements, special foods for medical or dietary requirements, traditional Indian *ayurvedic, sidha* and *unani* foods, organic and "novel foods" (<u>GAIN IN5111</u>).

January 15, 2016: FSSAI amended the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011, related to standards for proprietary food and implemented them with immediate effect, and notified the amendment to the WTO. With this amendment, nutraceuticals, health, and dietary supplements were no longer considered as 'proprietary foods' and would be approved under a separate category. The new definition of proprietary food allows the manufacture, sale, distribution, and import of such foods without product approval. However, the onus of ensuring the safety of proprietary food has been shifted to the food business operator. The new definition of proprietary food with this amendment was defined as follows:

- (1) Proprietary food means an article of food that has not been standardized under these regulations, but does not include any novel food, food for special dietary use, functional food, nutraceutical, health supplement and such other articles of food which the Central Government may notify in this behalf.
- (2) Proprietary food shall contain only those ingredients other than additives which are either standardised in these Regulations or permitted for use in the preparation of other standardised food under these Regulations.
- (3) Proprietary food shall use only such additives as specified for the Category to which the food belongs and such category shall be clearly mentioned on the label along with its name, nature and composition.
- (4) Proprietary food product shall comply with the food additives provisions as prescribed in Appendix A and the microbiological specifications as prescribed in Appendix B of these Regulations and all other Regulations made under this Act.
- (5) The Food Business Operator shall be fully responsible for the safety of the proprietary food."

(GAIN <u>IN6016</u> and GAIN <u>IN6026</u>).

March 23, 2016: FSSAI published a set of frequently asked questions (FAQs) pertaining to the recently amended regulations on proprietary foods (GAIN <u>IN6050</u>).

March 30, 2016: FSSAI published an order stating that until the standards for nutraceuticals, food supplements, and health supplements are finalized, activities for FBOs handling these products will include following the status quo as per the requirements provided in the <u>FSSAI order (See GAIN IN5097</u> and GAIN <u>IN5110</u>).

June 16, 2016: FSSAI published a corrigendum on its website to revise clause (iii) of Item 4 in <u>FAQs for</u> <u>Proprietary Food</u>. This clause pertains to the levels of vitamins and minerals in proprietary foods (GAIN <u>IN6082</u>).

August 22, 2016: FSSAI updated the proprietary food standards with immediate effect. The updated standards are based on the comments received from various stakeholders. FSSAI also directed its States and Union Territory enforcement officials to implement the revised standards on proprietary foods. Under the new revision, nutraceuticals, health, and dietary supplements would still be not considered as proprietary foods and will be approved under a separate category (GAIN <u>IN6114</u>).

Product Sampling:

On June 10, 2016, FSSAI published an updated order regarding the applicable fee to test samples for domestic and imported food products. The updated order was published in continuation to <u>Order No.</u> 10/QA/Lab Costing/ FSSAI/ 2016 of April 12, 2016, which listed different testing fees for various products. According to FSSAI, the new fees will help to facilitate the integration of single-window system of imports (GAIN IN6058). The new testing rates for food products were implemented immediately upon publication (GAIN IN6081).

Currently, there are 121 <u>NABL accredited laboratories</u> and the most recent list of notified laboratories is available on the website of FSSAI. For details on the procedure of sampling, please refer to <u>FSS</u> <u>Laboratory and Sampling Analysis Regulation, 2011</u>. In June, 2016, FSSAI published manuals for its requirements on test methods and analysis by laboratories which pertain to a variety of milk and milk products, oils and fats, fruit and vegetable products, cereal and cereal products, food additives, mycotoxins, spices and condiments, metals. Apart from these manuals, FSSAI has also published a manual to provide general guidelines on sampling methodologies (GAIN <u>IN6074</u>).

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: <u>http://delhicustoms.gov.in/pi2014/PunN-280814.pdf</u>

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: <u>Instructions regarding sampling and testing</u>.

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.

FSSAI's 2016 Modified Food Import Regulations mandates that "no food article shall be allowed to be cleared from the Customs unless it has 60% shelf life at the time of its clearance from the Customs."

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 2016 (GAIN <u>IN6161</u>).

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>http://www.cbec.gov.in/</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 <u>IN6157</u>, "Agricultural Biotechnology Annual 2016".

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 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>http://www.cbec.gov.in/htdocs-cbec/customs/cs-act/formatted-htmls/ipr-enforcementrules</u>).

Instructions regarding the implementation of the Rules are available on the CBEC website: <u>http://www.cbec.gov.in/htdocs-cbec/customs/cs-circulars/cs-circulars-2007/circ41-2k7-cus</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:

Effective April 2, 2016, CBEC launched its Single Window Interface for Facilitating Trade (SWIFT) system for quick single-window import clearances. This is an initiative to speed up clearances for inbound consignments and to improve India's 'ease of doing business.' The SWIFT system enables the exporters and importers to file a common electronic 'integrated declaration' on Indian Custom's Electronic Data Interchange (EDI) Gateway known as ICEGATE. The integrated declaration compiles requisite information for Customs, FSSAI, Plant Quarantine, Animal Quarantine, Drug Controller, Wildlife Control Bureau and Textile Committee and has been designed to replace nine separate forms previously required by these Agencies/Customs. Along with SWIFT, CBEC has also introduced an Integrated Risk Management facility for partner government agencies to ensure that consignments are not selected routinely by inspection agencies but on the basis of risk management principles. The SWIFT system is a key component of upgrading trade facilitation for goods clearance at the point of entry and exit in India. The format of integrated declaration form can be accessed by the clearing house agents (CHAs) through the client portal of customs. For more details on the SWIFT and ICEGATE, please refer to GAIN IN6101.

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>Sampling 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: <u>chairperson@fssai.gov.in</u> 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- <u>ca@nic.in</u> 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: <u>chairman@cbec.gov.in</u> 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: <u>cibsecy@nic.in</u> 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: <u>parsheera-mef@nic.in</u> 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: <u>ficci@ficci.com</u> Website: <u>www.ficci.com</u>

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: www.cii.in

Appendix III: Important Commodity-Specific Reports Submitted Since Last Fairs Country Report

IN6169	Gazetted Notification on Standards for Cereals and Cereal Products
IN6161	Food and Agricultural Import Regulations and Standards - Certification
<u>IN6156</u>	Enforcement Date Extension for 2015 Legal Metrology Rules Amendment
<u>IN6149</u>	Table Olives Standards Made Operational
<u>IN6147</u>	FSSAI Allows Imports of Medical and Therapeutic Foods
IN6145	Nutraceuticals and Food Health Supplement Standards Made Operational
IN6132	FSSAI Proposes Draft Regulation on New Product Approval Procedures
<u>IN6130</u>	FSSAI Publishes Draft Regulation on Food Fortification
<u>IN6129</u>	2016 Amendment to the Legal Metrology Rules
<u>IN6124</u>	An Update to GAIN Report IN6119
<u>IN6123</u>	FSSAI Invites Comments on E-Commerce Regulatory Standards
<u>IN6122</u>	GOI Amends Import Requirements for Poultry and Poultry Products
<u>IN6121</u>	FSSAI Publishes FAQs on Food Licensing and Registration Systems
<u>IN6120</u>	WTO Notified – Draft Amendment on Adoption of 46 Standards of BIS
<u>IN6119</u>	Modified 2016 Food Import Regulations
<u>IN6118</u>	Final Amendment for Irradiated Food Standards and Label Requirements
<u>IN6114</u>	Proprietary Food Standards Updated and Made Operational
<u>IN6110</u>	Compliance Date Extended for Limits of Trans Fatty Acids
<u>IN6108</u>	Modified Guidelines on Labeling of Imported Primary Food Packages
<u>IN6107</u>	FSSAI Invites Comments on Cereal and Cereal Products
<u>IN6106</u>	Final Amendment on Food Product Standards and Labeling Regulations

<u>IN6105</u>	WTO Notified Import Requirements for Poultry and Poultry Products
IN6101	Indian Government Rolls Out Single Window Import Clearances
IN6097	WTO Notified Draft on Microbial Standards of FnV and their Products
IN6095	GOI Notification for Poultry and Poultry Product Imports
IN6094	FSSAI Proposes Adoption of 46 BIS Standards for Food Additives
IN6093	Draft Amendments Relating to Fats-Oils-Oats and Pasta
IN6092	FSSAI Invite Comments from Stakeholders on Alcoholic Beverages
IN6090	Bovine Germplasm Guidelines for Trade – Revised April 2016
IN6089	Duty-free Shops Repealed from 2016 Food Import Regulations
IN6086	FSSAI Proposes Amendments in the Norms for Carbonated Drinks
IN6084	Draft Standards for Fish and Fish Products
IN6083	FSSAI Publishes the Final List of Food Additives
IN6082	Corrigenda on the FAQs for Proprietary Food
IN6081	FSSAI Publishes Updated Rates for Testing Food Product
IN6075	Timeline for Food Business License Extended for the Last Time
<u>IN6074</u>	FSSAI Publishes Manuals on Test Methods for Various Food Products
IN6071	WTO Notified Plant Quarantine Fifth Amendment 2016
IN6066	GOI Invite Comments from WTO SPS members on Standards for Chocolates
IN6063	FSSAI Notice on Adoption and Operationalization of Codex Standards
IN6059	Draft Requirements for Poultry and Poultry Product Imports
IN6058	FSSAI Publishes Parameters for Testing Various Food Products
IN6055	WTO Notified Draft Standards for Fortified Milk and Edible Lactose
IN6054	WTO Notified – Histamine Level in Fish and Fish Products
<u>IN6052</u>	WTO Notified – GOI Standards for Fruits and Vegetables
<u>IN6050</u>	FSSAI Publishes FAQs for Proprietary Food
<u>IN6049</u>	Enforcement Measures for Nutraceuticals and Food-Health Supplements
<u>IN6048</u>	FSSAI Clarifies Use of Monosodium Glutamate in Noodles and Pasta
<u>IN6042</u>	FSSAI Invites Comments Related to Oats and Pasta
<u>IN6037</u>	Pre-Arrival Document Scrutiny in the Food Import Clearance System
<u>IN6035</u>	WTO Notified Draft Health Certificate for Dog and Cat Food Imports
<u>IN6034</u>	WTO Deadline for Comments on 2016 Food Import Regulations
<u>IN6027</u>	GOI Invites Comments from WTO TBT Members on Food Import Regulations
<u>IN6026</u>	WTO Notified – GOI's New Standards for Proprietary Food
<u>IN6025</u>	3 month Extension of Timeline to Obtain FSSAI Food Business Licenses
<u>IN6019</u>	Final Amendment on Biotoxin Limits in Fish and Fish Products
<u>IN6018</u>	Final Amendment on Standards for Salted and Dried Salted Fish
<u>IN6017</u>	2016 Food Import Regulations
<u>IN6016</u>	GOI Amends Standards for Proprietary Food
<u>IN6015</u>	WTO Notified – Draft Amendment on Standards for Fruits and Vegetables
<u>IN6013</u>	Implementation Begins for Draft Standards on Food Additives
<u>IN6012</u>	WTO Notified – Draft Amendment on Standards and Additives Regulation
<u>IN6011</u>	WTO Notified Draft Amendments on Pharmacologically Active Substances
<u>IN6010</u>	WTO Notified – BIS Proposed Standards for Malt and Malt Based Foods
<u>IN6009</u>	WTO Notified – Removal of Zinc from the Metal Contaminants List
<u>IN6008</u>	Compliance Date for Trans Fat Label Declarations Extended Further
<u>IN6007</u>	Final Amendment on Standards for Melamine in Infant and Other Foods

<u>IN6006</u>	WTO Notified – Irradiated Foods Standards and Labeling Requirements
<u>IN6004</u>	Enforcement Date Extended for 2015 Legal Metrology Rules Amendment
IN6002	WTO Notified Draft Standards for Milk and Dairy Products

Appendix IV: Chronology of FSSAI Regulations/Notifications (2016)

- On November 24, 2016, FSSAI issued new standards for nutritional supplements, nutraceuticals, foods for special dietary requirements, and foods for special medical requirements. Although FSSAI has made the new standards operational, full implementation will not be enforced as of January 1, 2018, thereby giving stakeholders' time to adjust and come into compliance (GAIN IN6145).
- Based on the representations received from various organizations to allow the import of foods required by infants and children suffering from special medical conditions, FSSAI has agreed to allow for imports of these specialty foods. Currently, there are no standards that exist for therapeutic foods. FSSAI expects standards to be finalized within two years or earlier (GAIN IN6147).
- On October 4, 2016, FSSAI published its new draft Regulation called the <u>"Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2016.</u>" The draft Regulation outlines new product approval procedures for all food products not already covered under any preexisting Regulations under the Food Safety Act, 2006. These products have been termed by FSSAI as "non-specified food and food ingredients." Comments are invited from the WTO member countries on the draft Regulation and the timeline to comment expires on December 16, 2016 (GAIN <u>IN6132</u>).
- On September 16, 2016, OAA New Delhi published GAIN <u>IN6119</u> regarding the modified 2016 Food Import Regulations. Point (k) in the report mentioned a clause regarding regulations applicable specifically to duty free shops. FSSAI recently deleted this clause from the document posted on its website. The OAA New Delhi staff also received verbal confirmation to this effect from an FSSAI official during a meeting on September 16, 2016 (GAIN <u>IN6124</u>, <u>IN6119</u> and <u>IN6017</u>).
- On September 20, 2016, FSSAI published a draft notification for FBOs involved in the ecommerce sector on its website and has invited comments from stakeholders. The draft notification enumerates regulatory requirements pertaining to e-commerce FBOs (GAIN <u>IN6123</u>).
- On August 22, 2016, FSSAI updated the proprietary food standards with immediate effect. The updated standards were based on the comments received from various stakeholders. FSSAI also directed its States and Union Territory enforcement officials to implement the revised standards of proprietary food. Under the new revision, nutraceuticals, health, and dietary supplements would still be not considered as proprietary foods and will be approved under a separate category (GAIN IN6114, IN6026 and IN6016).
- CBEC launched its SWIFT system. This is a GOI initiative to speed up clearances for inbound

consignments and to improve India's 'ease of doing business' (GAIN IN6101).

- On June 3, 2016, FSSAI issued an order that repeals the earlier clause on duty-free shops from the 2016 Food Import Regulations. The order states that duty-free shops would be outside the domain of the Food Safety and Standards Act, 2006 and its Regulations (GAIN <u>IN6089</u>).
- On June 16, 2016, FSSAI published a corrigendum on its website to revise clause (iii) of Item 4 in FAQs for Proprietary Food. The clause pertains to the levels of vitamins and minerals in proprietary foods. The FAQs on proprietary foods were published earlier on March 23, 2016 (GAIN <u>IN6082</u> and GAIN <u>IN6050</u>).
- On June 10, 2016, FSSAI published an updated order regarding the applicable fee to test samples for domestic and imported food products. The updated order was published in continuation to Order No. 10/QA/Lab Costing/ FSSAI/ 2016 of April 12, 2016, which listed different testing fees for various products. According to FSSAI, the new fees will help to facilitate the integration of single-window system of imports. The new testing rates for food products were implemented immediately upon publication (GAIN IN6081).
- On April 27, 2016, FSSAI issued directives under Section 16(5) of the Food Safety and Standards Act, 2006, related to the adoption and operationalization of Codex Alimentarius Standards (GAIN <u>IN6063</u>).
- On April 18, 2016, FSSAI published a document regarding specific testing parameters for various food product testing. A similar document was also published earlier on April 12 revising food product testing fees. The parameters were compiled from existing regulations and FSSAI will update them as and when new regulations are notified. FSSAI expects any errors in these parameters to be notified to them so they can be resolved (GAIN <u>IN6058</u>).
- On March 23, 2016, FSSAI published a set of FAQs pertaining to the recently amended regulations on proprietary foods. The amended regulations were recently published and immediately implemented on January 15, 2016 (GAIN <u>IN6050</u>).
- On March 30, 2016, FSSAI published an order stating that until the standards for nutraceuticals, food and health supplements are finalized, activities for FBOs handling these products will include following the status quo as per the requirements provided in the <u>FSSAI order (GAIN IN6049)</u>.
- Effective February 2, 2016, FSSAI implemented its new web portal-based Pre-Arrival Document Scrutiny (PADS) system for the clearance of food imports. Through this new system, FSSAI will review the clearing house agent's (CHAs) and the importer application documents prior to the arrival of shipments into India. The PADS application is similar to the previous requirement of a no-objection certificate (NOC) by the CHA or importer. However under PADS, certain fields and documents are not mandatory. This enables the CHA or importer to file the application and allows FSSAI to review the document prior to the arrival of the consignment at the port of entry. Also, because PADS is a web-based system, it provides 24-hour accessibility for all involved. There are no additional fees associated with using the PADS system (GAIN

<u>IN6037</u>).

 On January 14, 2016, FSSAI published its Food Import Regulations, 2016, on its website and immediately implemented the regulations. On January 29, 2016, the GOI notified these Regulations to WTO member countries and invited comments (GAIN <u>IN6034</u> and GAIN <u>IN6027</u>).

Amendments to the Food Safety and Standards (Food Product Additives and Food Standards) Regulation, 2011

- On November 24, 2016, FSSAI issued new standards for table olives. The November standards are in addition to a March 2016 draft, which India notified to the WTO. FSSAI will provide a grace period of 180 days after the publication of the final notification in the Official Gazette, as to provide industry with time to comply. FSSAI expects that full enforcement will occur on July 1, 2017(GAIN IN6149).
- On October 4, 2016, FSSAI issued the draft Food Safety and Standards (Fortification of Foods) Regulation, 2016. The new draft Regulation pertains to standards for fortified food products under the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011. The fortified food products include salt, vanaspati, wheat flour (*atta*), vegetable oil, milk, refined wheat flour (*maida*), and rice with essential micronutrients. FSSAI has invited comments from the WTO member countries on the draft Regulation and the timeline for comments will be for 60 days following the date it is notified on the WTO's website (GAIN IN6130).
- On August 23, 2016, FSSAI notified Food Safety and Standards (Food Product Standards and Food Additives) Sixth Amendment, 2016 and the Food Safety and Standards (Packaging and Labeling) Fourth Amendment, 2016, related to standards and labeling requirements for irradiated foods. The implementation of the amendment starts from the date of its final publication in the Official Gazette, *i.e.*, August 23, 2016. The full text of the final amendment is available on the website of FSSAI at: http://www.fssai.gov.in/ (GAIN IN6118).
- On August 10, 2016, FSSAI issued a notice to postpone the enforcement date for maximum limits of trans fatty acid levels. The new deadline for compliance is February 27, 2017 (GAIN <u>IN6110</u>).
- On July 20, 2016, FSSAI published a notification for new draft cereal and cereal product standards in the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011. The notification invites comments from the WTO member countries, which would expire 60 days from the date it is notified on WTO website (GAIN <u>IN6107</u>).
- FSSAI notified its (i) Food Safety and Standards (Food Product Standards and Food Additives) Fourth Amendment Regulations, 2016, regarding the use of arachidonic acid (ARA), cocosahexaenoic acid (DHA), isomaltulose, and high fiber dextrin in various food products; and (ii) Food Safety and Standards (Packaging and Labeling) Third Amendment Regulations, 2016, regarding the use of plant sterosls (phytosterols), isomaltulose, and high fibre dextrin. Both

amendments are finalized and effective as of the date of publication in the official Gazette, i.e., July 13, 2016 (GAIN <u>IN6106</u>).

- On July 12, 2016, FSSAI has published a revised table 4 in Appendix B of Food Safety and Standards (Food Additives and Food Standards) Regulations, 2011. The draft notification defines the microbiological standards for fruit and vegetables and their products. The comment period for the trading partners expires 30 days from the date of publication of the draft notification (GAIN IN6097).
- On July 12, 2016, FSSAI published a Gazette notification to include new draft standards for fats, oils, oats and pasta products. The notification invites comments from the WTO member countries and the comment period for trading partners expired on August 12, 2016 (GAIN <u>IN6093</u>).
- On June 29, 2016, FSSAI published a draft amendment relating to adoption of 46 BIS for various food additives, on its website. The draft amendment was notified to the WTO member countries and comments invited. The comment period for trading partners expires 60 days from the date it is notified on WTO website (GAIN <u>IN6094 and IN6120</u>).
- On June 29, 2016, FSSAI invited comments on a draft notification related to additional additives/enzymes/processing aids for use in alcoholic beverages including alcohol free and low alcoholic counterparts and for non-carbonated water based beverages (non-alcoholic) (GAIN IN6092).
- FSSAI published a draft amendment related to norms for carbonated fruit beverages or fruit drinks. The GOI will accept comments from the WTO trading partners for 60 days beyond the notification date as listed on the WTO's website (GAIN <u>IN6086</u>).
- On June 20, 2016, FSSAI published its final list of food additives used in various food products. The food additives list that was made operational in December 2015 contained only those additives for which no comments were received. The comprehensive list of food additives published now includes the comments received from various stakeholders. Along with this document, FSSAI has also released a press note on its website that talks about the harmonization process which started in February 2013. Operationalization of 11,000 food additives provision has begun through this process of harmonization and the food businesses can refer to this list of additives for various food categories. It is also mentioned in the press note that FSSAI has convened a meeting of its Scientific Committee on June 28, 2016, to discuss issues with respect of additives which were received after the finalization of the document. This also includes the issue on the use of potassium iodate (GAIN IN6083).
- India notified its revised draft standards for chocolates to the WTO and invited comments. The comment period for trading partners expires 60 days beyond the notification date as listed on the WTO's website (GAIN <u>IN6066</u>).
- The GOI notified Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016 to the WTO for comments. The draft

regulation defines the standards for fortified milk and edible lactose (GAIN IN6055).

- On January 19, 2016, the GOI published the Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2016, relating to 'fruit and vegetable products.' On March 30, 2016, the GOI notified the amended draft standards to the WTO and accepted comments from member countries. The comment period for trading partners expired on May 29, 2016. The amendments mainly relate to "Thermally Processed Vegetables" after clause 2 in Regulation 2.3.3 of the Food Safety and Standards (Food Product Additives and Food Standards) Regulation, 2011. Readers may refer to the <u>FSSAI Notice</u> for more details on the amendment. The full text of the FSSAI notice can also be accessed on FSSAI's website: http://www.fssai.gov.in/ (GAIN <u>IN6052</u>).
- On March 2, 2016, FSSAI published a notification to include new draft standards for oats and revised description for pasta products. The notification invites comments from the WTO member countries and the comment period for trading partners expires 60 days from the date it is notified on WTO website (GAIN <u>IN6042</u>).
- On January 25, 2016, FSSAI notified Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2016, related to standards for salted fish and dried salted fish. The implementation of the amendment starts from the date of its final publication in the Official Gazette, *i.e.*, January 15, 2016. The full text of the final amendment published by FSSAI on January 25, 2016, is available on their website http://www.fssai.gov.in/ (GAIN IN6018).
- On August 1, 2011, FSSAI published the Food Safety and Standards (Food Product Additives and Food Standards) Regulation, 2011. On January 19, 2016, an amended draft regulation was notified to the WTO pertaining to Regulation 2.3 for fruits and vegetables, and Regulation 2.3.3 pertaining to thermally processed vegetables. The comment period for trading partners expires on March 19, 2016 (GAIN <u>IN6015)</u>.
- On December 23, 2015, FSSAI published an interim order to immediately implement updated draft standards of food additives. These standards are in addition to the provisions under Regulation 3.1 of the Food Safety and Standards (Food Product Additives and Food Standards) Regulation, 2011(GAIN <u>IN6013</u>).
- On November 23, 2015, FSSAI amended the Food Safety and Standards (Food Product Additives and Food Standards) Regulation, 2011, to update microbiological standards for fish and fish products. On January 4, 2016, the amended draft regulation was notified to the WTO. The comment period for trading partners expires on March 4, 2016 (GAIN <u>IN6012</u>).
- On November 26, 2015, FSSAI amended the Food Safety and Standards (Food Product Additives and Food Standards) Regulation, 2011, to update standards for malt and malt based foods in Chapter 2 of the Regulations. These standards are proposed by BIS. On January 4, 2016, the draft regulation was notified to the WTO for comments. The trading partner comment period deadline is March 4, 2016 (GAIN <u>IN6010</u>).

• On November 23, 2015, FSSAI amended the Food Safety and Standards (Food Product Additives and Food Standards) Regulation, 2011, to update standards and labeling requirements for irradiated foods. On January 4, 2016, the amended draft regulation was notified to WTO for comments. The comment period for trading partners expires on March 4, 2016 (GAIN <u>IN6006</u>).

Amendments to the Packaging and Labeling Regulation, 2011

- On December 19, 2016, Ministry of Consumer Affairs, Food and Public Distribution's Department of Legal Metrology invited comments on its Legal Metrology (Packaged Commodity) (Second Amendment) Rules, 2016, which are scheduled to come into force as of July 1, 2017. A separate GAIN report will be published shortly to this effect.
- On December 5, 2016, the Ministry of Consumer Affairs, Food and Public Distribution's Department of Legal Metrology, issued an advisory to postpone its timeline for the implementation of Legal Metrology (Packaged Commodities) (Amendment) Rules, 2015. The objective of this extension is primarily for Rule 7 (Sub-rule 5 Principal Display Panel for labeling) of the Legal Metrology (Packaged Commodities) Rules, 2011, as a means to provide commercial stakeholders an adequate adjustment period. For background details on the subject, readers may access GAIN <u>IN5076</u> and the Legal Metrology (Packaged Commodities)
 (Amendment) Rules, 2015. The amendment is now scheduled to be fully enforced as of March 31, 2017 (GAIN <u>IN6156</u>).
- On September 7, 2016, the Indian Ministry of Consumer Affairs, Food, and Public Distribution's Department of Legal Metrology amended the Legal Metrology (Packaged Commodities) Rules, 2011. The amendment empowers GOI and state-level competent authorities to establish prices and quantity limits for retail-sale price of anything deemed an "essential commodity" under the Essential Commodities Act, 1955. This is 2016's first amendment to the Legal Metrology Rules (GAIN IN6129).
- On August 9, 2016, FSSAI issued new guidelines to modify its earlier guidelines dated March 23, 2012, on the labeling requirements for imported primary food packages. Specifically, the new guidelines state that for all primary food products, such as food grains, pulses, fruits, dry fruits, whole spices, etc. imported in package, the name and address of the importer can be verified from the documents that accompany the consignment (GAIN <u>IN6108</u>).
- FSSAI issued instructions to its food safety commissioners regarding MSG which notes that the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 allows the use of MSG in specific foods, as per the provisions of Appendix A. MSG use is subject to good manufacturing practices and proper labeling declarations as required under the Food Safety and Standards (Packaging and Labeling) Regulations, 2011. The most recent order clarifies that there are no specific post-production testing methodology to determine whether MSG was added during the production process or if it naturally occurs in the product (barring inspection at the manufacturing site). Hence, the food safety commissioners cannot take action against manufacturers of noodles/pasta based on the presence of MSG/glutamic acid, unless there is confirmation that MSG flavor enhancer (INS E-621) was deliberately added during the manufacturing process and not declared on the label (GAIN <u>IN6048</u>).

• On December 31, 2015, FSSAI issued a notification to postpone the enforcement date for additional labeling requirements for pre-packaged food, edible oils, and fats. The new deadline for compliance is July 1, 2016. Previously, FSSAI had announced the enforcement date as December 31, 2015 (GAIN <u>IN6008</u>).

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

- FSSAI published a document containing a set of 27 FAQs and a flow chart to explain the stepby-step process to the FBOs while they apply for license/registration on the Food Licensing Registration System. The document is also accessible on the FSSAI website at: <u>http://www.fssai.gov.in/</u> (GAIN <u>IN6121</u>).
- FSSAI issued an order on May 30, 2016, to postpone the timeline for converting or renewing existing Food Business Operator (FBOs) licenses and registrations. The order postponed the previous deadline of May 4, 2016, to August 4, 2016 and clearly stated that no further extensions will be granted to stakeholders. This most recent extension was the eighth consecutive extension granted by FSSAI (GAIN IN6075).
- On February 9, 2015, FSSAI issued an order extending the deadline to obtain an FBO license to May 4, 2016. The previous deadline was February 4, 2016 (GAIN <u>IN6025)</u>.

Amendments to the Contaminants, Toxins and Residues Regulations, 2011

- The GOI notified Draft Food Safety and Standard (Contaminants, Toxins and Residues) Amendment Regulations, 2016 to the WTO for comments. The draft regulation defines the list of histamine forming fishes and standards for histamine level in fish and fishery products (GAIN <u>IN6054</u>).
- FSSAI published the final Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2016. This amendment established India's biotoxin limits in fish and fish products. The implementation commenced from the date of the final publication in the Official Gazette, which is January 6, 2016. FSSAI also noted that the final amendment was based on public comments received from various stakeholders during the comment period (GAIN <u>IN6019)</u>.
- On November 23, 2015, FSSAI amended the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011. The amendment relates to the residue levels for pharmacologically active substances. On January 4, 2016, the amended draft regulation was notified to the WTO. The comment period for trading partners expires on March 4, 2016 (GAIN <u>IN6011</u>).
- On November 23, 2015, FSSAI amended the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011, to remove zinc from its list of metal contaminants. On January 4, 2016, the amended draft regulation was notified to the WTO. The comment period for trading partners expires on March 4, 2016 (GAIN <u>IN6009</u>).

• FSSAI notified Food Safety and Standards (Contaminants, toxins and residues) Amendment Regulations, 2016, relating to standards for levels of melamine present in infant formula and other foods. The final amendment reflects changes based on feedback from the public (GAIN <u>IN6007</u> and GAIN <u>IN5093</u>).

Amendments to the Laboratory and Sample Analysis Regulations, 2011

• In June, 2016, FSSAI published manuals for its requirements on test methods and analysis by laboratories which pertain to a variety of milk and milk products, oils and fats, fruit and vegetable products, cereal and cereal products, food additives, mycotoxins, spices and condiments, metals. Apart from these manuals, FSSAI has also published a manual to provide general guidelines on sampling methodologies. For details, please refer to GAIN <u>IN6074</u>.

Appendix V: Chronology of Ministry of Agriculture, Directorate of Plant Protection, Quarantine and Storage Actions

• On June 29, 2015, the MinAg issued a draft notification proposing phytosanitary requirements for the import of hay from the United States (see <u>Draft Notification on the Import of Hay from</u> the U.S. for details). This will be implemented when officially published in the Gazette of India.