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Report Highlights:

In calendar year (CY) 2019, the Government of India (GOI) extended the compliance timeline for the advertising and claims regulations, labeling of milk and milk products, standards for fortified foods and tolerance limits for contaminants. Notably, the GOI issued a (i) revised draft Food Safety and Standards Labeling and Display Regulations 2019; (ii) revised guidelines for import and export of bovine germplasm; and (iii) a 2019 edition of the food imports manual.

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Disclaimer:

This report was prepared by U.S. Embassy New Delhi's Office of Agricultural Affairs (OAA) to serve as a reference guide for stakeholders wishing to export food and agricultural products to India. Only updates from CY 2017 and 2018 are listed in this report. OAA New Delhi directs readers to the <u>USDA</u> <u>Global Agriculture Information Network (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. *Note: Readers may use Google Chrome to access the links in case they do not open in Internet Explorer.*

Executive Summary:

Laws pertaining to food and agricultural products imported into India are under the jurisdiction of multiple GOI authorities: the Food Safety and Standards Authority of India (FSSAI) of the Ministry of Health and Family Welfare; the Office of Legal Metrology of the Ministry of Consumer Affairs, Food, and Public Distribution; the Directorate General of Foreign Trade (DGFT) of the Ministry of Commerce and Industry (MOCI); Ministry of Agriculture and Farmers' Welfare (MOA), and the Ministry of Fisheries, Animal Husbandry and Dairying (MFAH&D). Exporters are advised to thoroughly research the laws and regulations applicable to their products across all relevant regulatory agencies.

In CY 2019, FSSAI continued its endeavor to issue draft and final amendments and regulations related to food safety for imported and domestic food products. A list of FSSAI amendments and regulations are as follows: (1) the revised draft Food Safety and Standards Labeling and Display Regulations 2019; (2) the extension of compliance timelines for the (i) advertising and claims regulations; (ii) labeling of milk and milk products; (iii) standards for fortified foods; and (iv) tolerance limits for contaminants, and (3) the revised guidelines for import and export of bovine were published and comments invited from World Trade Organization (WTO) members.

Section I. Food Laws:

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

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

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

Regulations: The Food Safety and Standards (FSS) Regulations 2011 are available on the <u>FSSAI website</u> and should be consulted regularly for updates, which appear periodically and are published in the Gazette of India. The regulations govern *inter alia* packaging and labeling, laboratory and sampling analysis, food additives, product standards, licensing and registration of food businesses, and maximum residue levels of contaminants. The FSS Regulations 2011 stipulate, "...all food business operators (FBOs), food processors, manufacturers, exporters, or importers shall ensure that the food he/she handles meets all the standards under the FSS Regulations 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. In 2013, FSSAI began an effort to harmonize its regulations pertaining to food safety. For information in addition to the FSSAI website, please use the <u>USDA GAIN search engine</u> to find reports on India containing the acronym *FSSAI* in "Report Highlights".

A. The Legal Metrology Act 2009 and the Legal Metrology Packaged Commodities Rules 2011

The Legal Metrology 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 Legal Metrology 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 Legal Metrology Packaged Commodities Rules 2011). The Department of Consumer Affairs under the Ministry of Consumer Affairs, Food, and Public Distribution (commonly called the Ministry of Food) is the regulatory authority for the 2009 Legal Metrology Act 2009 and the Legal Metrology Packaged Commodities Rules 2011. The full text can be accessed on the website of the Department of Consumer Affairs at <u>"Legal Metrology Act 2009"</u>, <u>"Legal Metrology (Packaged Commodities) Rules 2011"</u>, and the Legal Metrology (Packaged Commodities)(Amendment) Rules 2011<u>"</u>. The Legal Metrology Act 2009 imposes standard pack sizes for certain commodities as a consumer protection measure (see Section III. Packaging and Container Regulations).

B. Livestock Importation Act 1898

Under the Livestock Importation Act 1898, the GOI established procedures for the importation of livestock and related products to India, which are implemented by MFAH&D's DAHD. These procedures are available at:

http://www.dahd.nic.in/sites/default/filess/gazette_27June2014%20%201.pdf

Procedures for import of various livestock products are available on the website at <u>http://dahd.nic.in/trade</u>. In addition, readers may access the <u>USDA GAIN search engine</u>

to find relevant GAIN Food and Agricultural Import Regulations and Standards (FAIRS) export certification reports.

- On January 21, 2019, DAHD revised its guidelines for export/import of bovine germplasm. Readers can access the revised guidelines from the DAHD website at: <u>Guidelines for Export/Import of</u> <u>Bovine Germplasm - January 2019</u>. The revised guidelines were not notified to the World Trade Organization (WTO).
- On June 4, 2018, FSSAI published a notification to invite comments from WTO members on its new draft standards for a wide range of meat products. The range included canned/retort pouch, comminuted/restructured, cured/pickled and/or smoked, dried/dehydrated, cooked/semi-cooked, fermented, marinated meat products, and fresh/chilled/frozen rabbit meat (<u>GAIN IN8065</u>). The comment period for trading partners expired on August 18, 2018, per WTO Notification <u>G-SPS-N-IND-217</u>.
- In March 2018, the GOI granted access to U.S. poultry and poultry products into the Indian market, following an eleven-year absence. The poultry exporting requirements for India can be accessed from the export library page of the USDA Food Safety and Inspection Service (FSIS) website at the <u>FSIS Export Library</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. On November 18, 2003, the Plant Quarantine Order (Regulation of Import into India) was published with "the purpose of prohibiting and regulating the imports into India of agricultural articles" and became effective on January 1, 2004. The implementing agency is the Directorate of Plant Protection, Quarantine, and Storage (DPPQS), under MOA. The Plant Quarantine Order 2003, as amended, is available on India's <u>DPPQS website at:</u> <u>http://plantquarantineindia.nic.in/PQISPub/pdffiles/pqorder2015.pdf</u>.

Section II. Labeling Requirements:

Three GOI authorities regulate labeling of food and agricultural products. They are FSSAI under the Ministry of Health and Family Welfare; the Office of Legal Metrology under the Ministry of Consumer Affairs, Food and Public Distribution; and the Department of Commerce under the Ministry of Commerce and Industries (MOCI).

FSSAI:

Exporters are strongly encouraged to read Chapter 2 of the <u>"FSS (Packaging and Labeling) Regulation</u> <u>2011" and the Compendium of Food Safety and Standards (Packaging and Labeling) Regulation</u> before designing labels for products to be exported to India. Exporters may also note that FSSAI revised the labeling regulation and a draft notification to that effect was published on April 11, 2018, inviting comments from WTO member countries (refer to <u>GAIN IN8043</u> for major revisions). The comments received are under FSSAI's review and the publication date for final notification remains unknown. The general requirements below are based on current requirements and not the draft FSS (Packaging and Labeling) Regulation 2018.

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 English or Hindi languages (Hindi must be in Devanagari script).
- Products only exhibiting 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.
- 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 that is placed in a package of any nature in such a manner that the contents cannot be changed without tampering with the package and 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 Details:

- 1. Name of food: The name of food shall include the 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 grams or 100 milliliters or per serving of the product shall be given on the label containing:
 - i. Energy value in kilocalorie; and
 - ii. The amount of protein, carbohydrates (specify quantity of sugar), and fat in grams or
 - iii. milliliters; and,
 - iv. 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 a 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 the name or brand name of the food. Please see the example below.
 - 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. Please see the example below.

Note: Declaration of vegetarian/non-vegetarian 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 the manufacturer: The label shall carry the name and complete address of the manufacturing, packing or bottling unit and also the name and complete address of the manufacturer or the company for and on whose behalf it is manufactured or packed or bottled.
 - i. Where an article of food is imported into India, the package of the 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 identified in the distribution shall be given on the label.

- 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.
- 10. Best before and use by dates: The month and year in capital letters up to which the product is best for consumption. Provided further that the declaration of best before date for consumption shall not be applicable to:
 - *i.* Wines and liquors; and
 - ii. Alcoholic beverages containing 10 percent or more alcohol by volume.
- 11. Country of origin for imported food:
 - i. The country of origin of the food shall be declared on the label of food imported into India.
 - ii. When a food undergoes processing in a second country, changing its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labeling.
- 12. Instructions for use: If necessary, instructions for use 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" is defined as a package containing the following:

- (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 the "Guidelines Related to Food Import Clearance Process by FSSAI's Authorized Officer" on its website. These guidelines were for labeling requirements of different types of packages for imported food consignments into India. The different categories of packages mentioned in the guidelines were: (1) pre-packaged food or pre-packed food including multipiece packages; (2) wholesale packages (including semi-finished/intermediary food products which will be further processed to make a 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 packages; and (4) primary food such as food grains, pulses, fruits, whole spices, etc. imported in loose in bulk. For more details on the guidelines, please refer to <u>GAIN IN2055</u>.

The new guidelines, as published on the 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 packages, 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:

- 1. Name of food
- 2. Name and complete address of the manufacturer/packer
- 3. Date of manufacture/packing
- 4. Net weight
- 5. Lot/code/batch number
- 6. Best before date, use by date, or date of expiry
- 7. Country of origin
- 8. FSSAI logo and license number (as a rectifiable label, which can also be applied upon arrival) For example, the Food Safety and Standards License will be specific to the importer:



The August 9, 2016 guidelines allowed a timeline of six months to comply with the modified labeling requirements (GAIN IN6108). However, on December 13, 2017, a new guideline, subsequent to the August 9, 2016 guideline, was published to extend the compliance date for the modified labeling requirements until the time the revised FSS (Labeling) Regulations (currently in draft format) are published and notified (GAIN IN7157).

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 (such as soluble tea, coffee, soluble coffee, coffee-chicory mixture, packaged drinking water, and packaged mineral water), alcoholic beverages, fruits and vegetables, and processed pre-packaged fruits and vegetables that are comprised of a single ingredient 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 another is 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.

Readers may note that FSSAI in its draft Food Safety and Standards Labeling and Display Regulations 2018 deleted the definition of "wholesale package."

A. Rectifiable and Non-Rectifiable Labeling:

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. On May 23, 2018, FSSAI published a notification to expand the list of labeling requirements that can be rectified at custom-bonded

warehouses before visual inspection or re-inspection by authorized officers. The labels can be rectified by affixing a single non-detachable sticker next to the principal display panel without altering or masking the original label information in any manner. Earlier, the allowable list of rectifiable labeling deficiencies included name and address of the importer; vegetarian/non-vegetarian logo; FSSAI logo and license number; and category or sub-category along with the generic name, nature and composition for proprietary food only. With this new notification, the additional labeling deficiencies for imported food products that can be rectified includes the name and complete address of the manufacturer or packer; lot/code/batch identification number; date of manufacture or packing; and food additive declarations. The FSSAI notification explains that missing information can be verified from relevant documents like invoices, ingredient list, certificate of analysis, bill of entry, etc. and by a certification from the importer on the authenticity of information (GAIN <u>IN8068</u>).

Office of Legal Metrology (OLM) under the Ministry of Consumer Affairs, Food and Public Distribution's Department of Consumer Affairs

Labeling Requirements:

Per Indian law, most OLM food labeling requirements are superseded by FSSAI's regulations. However, two regulations of the OLM apply, below:

- The retail sale price of the package: When discounting from the maximum retail price (MRP), a sticker with the revised lower MRP (inclusive of all taxes) may be affixed but the same shall not cover the MRP declaration on the label of the package. Note: As per the 2015 amendments to the Legal Metrology Rules, pre-packaged food products meant for institutional use do not require the MRP, but a 'Not for Retail Sale' declaration on the label is required.
- 2. If a product is genetically modified (GM), it must include on the label the acronym "GM" (<u>GAIN</u> <u>IN3003</u>).

For detailed information and the provision on labeling, please refer to Legal Metrology (Packaged Commodities) Rules, 2011 from the website of Department of Consumer Affairs, Ministry of Consumer Affairs, Food and Public Distribution at: <u>https://consumeraffairs.nic.in/acts-and-rules/legal-metrology/the-legal-metrology-act-2009</u>

On June 23, 2017, the GOI amended the Legal Metrology (Packaged Commodities) Rules 2011 and published the amendment in the Gazette of India: This was the first amendment to the Legal Metrology Rules 2011. On July 4, 2017, a consecutive notification related to the Legal Metrology Rules was also published to explain the impact of the Goods and Services Tax on the unsold stock of pre-packaged commodities (GAIN IN7086). Earlier on December 19, 2016, the same amendment text was published as draft, with comments invited from stakeholders. The enforcement date mentioned in the December 19, 2016 notification was extended until January 1, 2018 in the June 2017 Gazette of India notification. There are no major revisions between the draft and final June 2017 amendment, but it is recommended that interested parties who reviewed the December 19, 2016 draft document should also review the June 2017 final notification. The primary amendments of the Legal Metrology Rules are listed in <u>GAIN IN7001</u>.

Ministry of Commerce and Industry (MOCI)

As per <u>Notification Number 44 (RE-2000)/1997-2002</u> issued by MOCI's Department of Commerce on November 24, 2000, all packaged commodities, including pre-packaged 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.

Note: Pre-packaged food products meant for institutional use do not require the MRP, but a 'Not for Retail Sale' declaration on the label is required.

The full notification is available on the **DGFT** website.

Please see following packaged food label samples:



(12)

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
- 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:

On March 19, 2018, the FSS (Packaging) Regulation was published in the Gazette of India. The FSS Packaging Regulation 2018, formerly combined with the FSS Labeling Regulation, is now a separate regulation and broadly covers the following topics:

- General and Specific Requirements of Packaging and Packaging Materials
- Schedule I: List of Standards for Paper and Board Materials
- Schedule II: List of Standards for Metal and Metal Alloys
- Schedule III: List of Standards for Plastic Materials
- Schedule IV: List of Suggestive Packaging Materials

Please refer to <u>GAIN IN7128</u>. The compliance date for the regulation started from July 1, 2019.

Section IV. Food Additives Regulations:

Information regarding permitted food colorings and preservatives is published in various sections of the Food Safety and Standards Regulation 2011. For detailed information, please refer to Food Safety and Standards (Food Product Standards and Food Additives) Regulation 2011 and the Compendium of Food Safety and Standards (Food Product Standards and Food Additives) Regulation. Amendments related to food product standards and additives published by FSSAI in CY 2019 are detailed in the "Chronology of FSSAI Regulations and Notifications" at the end of this report.

Section V. Pesticides and Other Contaminants:

FSSAI sets maximum residue levels (MRLs) for pesticides, toxins, and other contaminants. Please refer to the <u>Food Safety and Standards (Contaminants, Toxins and Residues) Regulation 2011</u>, See Chapter 2, Regulation 2.3 for the complete list.

A list of banned or restricted pesticides and pesticide formulations that have been refused registration or face restricted use in India is available at the following link: http://ppgs.gov.in/sites/default/files/restricted and http://ppgs.gov. MOA 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 at http://ppgs.gov.in/divisions/cib-rc/about-cibrc.

Section VI. Other Regulations and Requirements:

Product Approval:

On September 11, 2017, India implemented its <u>Food Safety and Standards (Approval for Non-Specified</u> <u>Food and Food Ingredients) Regulations 2017</u>. This regulation has been finalized after incorporating comments from stakeholders on the draft regulation. Previously on January 31, 2017, FSSAI published a draft regulation on new product approval procedures in the Gazette of India and invited a 30-day comment period from domestic stakeholders only. FSSAI termed these categories of food or food ingredients as "non-specified food and food ingredients." The draft regulation outlined new product approval procedures for the following foods and food ingredients:

- Novel foods or food containing novel ingredients with no history of human consumption in India
- Food ingredients with a history of human consumption in India, but not specified under any other regulations made under the Food Safety and Standards Act 2006
- New additives and processing aids
- Foods manufactured or processed through novel technologies

Please refer to GAIN IN7026 for more information.

Product Sampling:

On November 14, 2017, FSSAI published an order revising the inspection and sampling fees for imported food products. The revised rates were implemented immediately upon publication (<u>GAIN</u><u>IN7133</u>).

In June 2019, FSSAI published a comprehensive "Food Import Clearance Manual" and provided a state by state list of FSSAI notified referral laboratories along with their scope as Annexure 4. In the same manual, a list of 18 FSSAI-notified referral laboratories was listed as Annexure 5.

For details on the procedure of sampling, please refer to the latest "Manual for Food Imports." FSSAI has published these manuals detailing its requirements on test methods and analysis by laboratories for the following: 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, meat and fish; antibiotics and hormones residues, pesticide residues and water analysis. Apart from these manuals, FSSAI also published a manual to provide general guidelines on sampling methodologies. Readers can access the manuals on FSSAI's website at http://www.fssai.gov.in/home/food-testing/food-testing-manual.html.

Shelf Life:

Notification Number 22 (RE-2001)/1997-2002, dated July 30, 2001, issued by MOCI's Department of Commerce, states the following:

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 have 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.

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

FSSAI's <u>amendments in the Food Import Regulations 2017</u> mandates that Indian Customs officials shall clear any imported food product only if it has valid shelf life of not less than sixty percent, or three months before expiry, whichever is less, at the time of import. The amendments also include the requirement of the food importers to register with DGFT, possess a valid import-export code; create a profile of the importer, custom house agents, imported product, manufacturer of the imported products, country of origin, source country of the consignment, port of entry, compliance history and any other parameters required to determine the risk associated with the food product. In addition, food importers should submit the certificate of sanitary export from authorized agencies in the exporting country for the categories of food as may be specified by FSSAI from time to time. These amendments became effective on December 6, 2017 (see GAINs IN7076, IN7097, and IN7158).

Miscellaneous Requirements:

There is no requirement for U.S. exporters to register products formally for import. Export certification requirements for imports of food products in India are summarized in FAIRS Export Certification Report 2019 (<u>GAIN IN2019-0106</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 http://www.cbec.gov.in/). Mail order imports are not allowed. Contact information to arrange sample shipments is provided in Appendix I below. Once the products enter the Indian domestic market, they are subject to random monitoring at the retail and wholesale levels by the relevant regulatory authorities.

Since July 8, 2006, the GOI's Foreign Trade Policy (2004-2009) specified that all imports containing products of modern biotechnology must have prior approval from Genetic Engineering Appraisal Committee (GEAC). The Foreign Trade Policy also stipulates a mandatory biotech declaration. "The only GE food products currently authorized for import into India are soybean oil derived from GE soybeans (glyphosate tolerant and five other events) and canola oil derived from GE canola (a select herbicide tolerant event)."

Indian regulations stipulate that the GEAC, India's apex regulatory body, must conduct an appraisal of all biotech food and agricultural products, and of products derived from biotech plants and animals or other biotech organisms. The Food Safety and Standards Act of 2006 includes specific provisions for regulating GE food products, including processed foods. However, the Food Safety and Standard

Authority of India (FSSAI) had deferred the approval of GE food products to GEAC in the absence of regulations and operational infrastructure. In August 2017, the Supreme Court of India issued directives to FSSAI for framing regulations for approval of GE food products. Subsequently, GEAC has forwarded the applications for approval of processed GE food products to FSSAI. However, FSSAI is still in the process of making these regulations. Until the FSSAI regulations are formulated, approved and implemented, the approval of GE food products are currently on hold in India. For more information on India's biotechnology import policy, please see the latest annual GAIN report on "Agricultural Biotechnology 2018." For additional information, please refer to GAIN "Agricultural Biotechnology".

Section VII. Other Specific Standards:

Department of Commerce Notification Number 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 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 new 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 (<u>www.ipindia.nic.in</u>). Please note that the registration process can take between 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) under the 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-2007/circ41-2k7-cus</u>

For additional information, please contact:

Office of Agricultural Affairs Embassy of the United States of America Shantipath, Chanakyapuri New Delhi, 110021, India Phone: (+91-11) 2419-8000, Fax: (+91-11) 2419-8530 E-Mail: agnewdelhi@fas.usda.gov

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 local Indian languages, 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 the Inland Container Depots in the Tuglaqabad and Patparganj areas of New Delhi.

Procedure for Clearance:

In June 2019, FSSAI published its 2019 edition of the 'Manual for Food Imports' that explains in detail the overall food import clearance process. It is important that exporters maintain close contacts with their agents on import procedures (<u>GAIN IN9074</u>).

The procedures for product sampling and laboratory analysis are thoroughly defined in the <u>Food</u> <u>Import Regulations 2017</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.

Review Process:

Any food importer may file a review application to the review officer if he/she is distressed by the rejection of his/her consignment of imported food products. The review application should be sent within fifteen working days from the date of receipt of the report of rejection along with the fee which

may be changed by FSSAI from time to time. For additional details on the review process, readers may refer to the Food Safety and Standards (Import) Regulation, 2017.

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: <u>dirwm-ca@nic.in</u> Website: http://fcamin.nic.in/index.asp

C. Phytosanitary Issues Department of Agriculture Cooperation and Farmers' Welfare Ministry of Agriculture and Farmers' Welfare

Joint Secretary - Plant Protection and Quarantine Department of Agriculture Cooperation and Farmers' Welfare Ministry of Agriculture and Farmers' Welfare Krishi Bhawan, New Delhi – 110 001 Phone: (91-11) 23070306 Fax: (91-11) 23070306 Email: jspp-dac@gov.in Website: www.plantquarantineindia.org

D. Livestock and Products Imports Department of Animal Husbandry, Dairying and Fisheries Ministry of Agriculture and Farmers' Welfare Joint Secretary Department of Animal Husbandry, Dairying and Fisheries Ministry of Agriculture and Farmers' Welfare Krishi Bhawan, 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 Industry

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

F. Registry of Trademarks Department of Commerce Ministry of Commerce and Industry

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 Cooperation and Farmers' Welfare Ministry of Agriculture and Farmers' Welfare

Secretary

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

I. Genetic Engineering Appraisal Committee Ministry of Environment, Forest and Climate Change

Chairperson, GEAC Ministry of Environment, Forest and Climate Change Paryavaran Bhawan CGO Complex, Lodi Road New Delhi – 110 003 Phone/Fax: (91-11) 24363967, 24361308 Email: <u>anilk.jain@gov.in</u> Website: <u>http://geacindia.gov.in/</u>

Appendix II. Other Import Specialist Contacts:

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: www.ficci.com

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 Email: <u>info@cii.in</u> Website: www.cii.in

Author Defined:

Appendix III. Important Commodity-Specific Reports Submitted Since Last FAIRS Country Report

IN2019-2438	FSSAI Directives for Nutraceutical Foods Regulation
	-
<u>IN2019-2810</u>	Rectifiable Labeling for Alcoholic Beverages
<u>IN2019-2151</u>	Compliance Timeline Extended for Labeling of Milk and Milk Products
<u>IN2019-2152</u>	Compliance Timeline Extended on Standards for Fortified Foods
<u>IN2019-2153</u>	Compliance Timeline Extended on Tolerance Limits for Contaminants
<u>IN2019-2450</u>	GOI Invites Comments on Fortified Foods Regulation
<u>IN2019-2148</u>	Comments Invited – Revised Standards for Fruits and Vegetable Products
<u>IN2019-2877</u>	Revised List of Antibiotics and Veterinary Drugs
<u>IN2019-2691</u>	New Directives on Organic Foods Regulations Benefit Small Producers
<u>IN2019-2502</u>	Implementation of Alcoholic Beverages Regulations 2018
<u>IN2019-2440</u>	FSSAI Publishes FAQs on Alcoholic Beverages Regulation
<u>IN2019-3013</u>	Timeline to Import Specialty Foods Gets Extended Further
<u>IN2019-2019</u>	Additional Directives on Nutraceutical Foods Regulation
<u>IN2019-2453</u>	GOI Publishes New Draft Labeling and Display Regulations
<u>IN2019-2150</u>	Compliance Timeline Extended for Advertising and Claims Regulations
<u>IN2019-2439</u>	FSSAI Lists Allowable Imports of Edible Truffle Species
<u>IN2019-2449</u>	GOI Invites Comments on Draft Alcoholic Beverages Regulations
<u>IN2019-2010</u>	2019 Edition of Food Imports Manual Released
<u>IN2019-3103</u>	WTO Member Comments Invited for Draft Standards for Food Products
<u>IN2019-2517</u>	India Invites Comments on Draft Trans Fat Limits for Processed Foods
<u>IN2019-2519</u>	India Revises Food Business Licensing and Registration Regulations
<u>IN2019-0106</u>	FAIRS Export Certificate Report

Appendix IV. Chronology of FSSAI Regulations and Notifications in 2019

Amendments to the Food Safety and Standards (Import) Regulation, 2017

FSSAI published its 2019 edition of the 'Manual for Food Imports' that explains in detail the
overall food import clearance process. In comparison with the earlier food imports manual
published in 2016, the new manual has a broad table of contents ranging from an introduction to
FSSAI and imports, to guidelines relating to labeling of imported food products and food import
clearance processes. Readers may note that the new manual has an additional annex with a list
of Indian Trade Clarification-Harmonized System (ITC-HS) codes of food products (Annexure-1).
The manual also includes all relevant forms (Form-1 to Form-13A) available in the import
regulation (GAIN IN9074).

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

- On December 27, 2018, FSSAI extended the timeline to comply with the labeling provisions for 'Frozen Dessert or Confection' products with added vegetable oil/fat, or vegetable protein, or both. With the new compliance date mentioned as July 1, 2019, this was the third consecutive time FSSAI extended the timeline in order to resolve the issue of nomenclature of these products as defined in clause 6 (c) of sub-regulation 2.1.15 of the Food Safety and Standards (Food Products Standards and Food Additives) (GAIN IN9009).
- On March 19, 2019, FSSAI published a Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2019 containing proposed changes to its existing standards for fruit and vegetable products (GAIN <u>IN9024</u>).
- On July 17, 2019, FSSAI published its permissible list of edible truffle species that can be imported into India. The Food Product Standards and Food Additives Regulation implemented in 2011 did not include the edible truffle specifies and therefore this list was added (GAIN IN9066).

Food Safety and Standards (Organic Foods) Regulation 2017

FSSAI published a directive related to the Food Safety and Standards (Organic Foods) Regulations, 2017, which were implemented on July 1, 2018. Based on representations received from stakeholders, FSSAI re-examined the provisions of the regulations and revised them to be 'Enabling Regulations' rather than for prosecution. This approach by FSSAI is expected to encourage a more business-friendly environment for small organic producers (GAIN IN9031).

Amendments to the Packaging and Labeling Regulation 2011

- On July 2, 2019, FSSAI published new <u>Draft Labeling and Display Regulations, 2019</u> covering the labeling requirements for pre-packaged foods and the display of essential information, such as allergens, calorie information, etc., on any premises where food is manufactured, processed, served and stored. The new draft regulation invited comments from interested stakeholders for a period of thirty days, though it does not specify if only domestic stakeholders can comment. Most modifications are in serial number (5) (Principal Display Panel) of Chapter 2 of the regulation. In particular, it includes the color coding information on the front of pack for products high in fat, sodium and sugar (GAIN IN9060). The draft regulation, when finalized, will cover only labeling and display features, as packaging is now a separate regulation.
- On May 23, 2018, FSSAI, in order to facilitate trade as well as ensure food safety, published a
 notification on the additional labeling requirements that can be rectified at custom-bonded
 warehouses before visual inspection or re-inspection by authorized officers. The labels can be
 rectified by affixing a single non-detachable sticker next to the principal display panel without
 altering or masking the original label information in any manner. Currently, the allowable list of
 rectifiable labeling deficiencies includes the following: name and address of the importer;
 vegetarian/non-vegetarian logo; FSSAI logo and license number; and category or sub-category

along with the generic name, nature and composition for proprietary food. With this new notification, the additional labeling deficiencies for imported food products that can be rectified includes the name and complete address of the manufacturer and or packer; lot/code/batch identification number; date of manufacture or packing; and declarations regarding food additives (GAIN IN8068).

Amendments to the Licensing and Registration of Food Businesses Regulation 2011

 On August 29, 2019, FSSAI issued directions related to revisions of the Draft Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations. Per FSSAI, the final regulation on Licensing and Registration of Food Businesses will be published within the next six months. In the meantime, FSSAI has extended and re-operationalized the draft regulations with revisions, including major revisions for e-commerce licensing and registration (GAIN IN9081).

Amendments to the Contaminants, Toxins and Residues Regulations 2011

- On December 31, 2018, FSSAI extended the timeline to comply with residue level limits for various food contaminants as prescribed in an earlier notification dated July 20, 2018. The new compliance due date was April 1, 2019. The timeline had been extended to accommodate requests from industry stakeholders facing technical issues with the new levels prescribed (GAIN IN9011).
- On March 29, 2019, FSSAI notified a revised list of tolerance limits for antibiotics/veterinary drugs. The revisions listed in Annexure-I of the notification is a sub-set of the list earlier provided in the Food Safety and Standards (Contaminants, Toxins and Residues) Second Amendment Regulations, 2018 (GAIN <u>IN9030</u>).

Fortification of Foods Regulation 2018

- On December 27, 2018, FSSAI extended the timeline to comply with their fortified food product standards prescribed in an earlier notification dated August 2, 2018. The new compliance due date was July 1, 2019 and the timeline had been extended in order to accommodate requests from industry stakeholders. No further notification has been published indicating this compliance deadline has been extended beyond July 1, 2019. Industry required more time to reformulate their premixes in-line with the new standards, as well as, to adhere to the labeling requirements (GAIN IN9010).
- On February 19, 2019, FSSAI published the Food Safety and Standards (Fortification of Foods) Amendment Regulations, 2019 relating to proposed changes mainly in the standards for fortified processed foods, multi-grain *atta* (flour) and fortified milk. These amendments will come into force on the date of their final publication in the Official Gazette of India (GAIN <u>IN9023</u>).

Food Safety and Standards (Alcoholic Beverages) Regulations 2018

- On January 14, 2019, FSSAI, in order to facilitate trade as well as ensure food safety, published a notification on the additional labeling requirements for alcoholic beverages that can be rectified at custom-bonded warehouses before visual inspection or re-inspection by authorized officers. FSSAI amended point 5.12 under Part 5 Specific Labeling Requirements for Alcoholic Beverages of the Food Safety and Standards (Alcoholic Beverages) Regulations, 2018. The statutory warning— *"consumption of alcohol is injurious to health"* and *"be safe-don't drink and drive"* can be rectified by affixing a single non-detachable sticker next to the principal display panel without altering or masking the original label information in any manner. Prior to this amendment, the allowable list of rectifiable labeling requirements for imported alcoholic beverages include name and address of the importer, FSSAI logo and license number. The regulation was implemented on April 1, 2019. (GAIN IN9002).
- On March 29, 2019, FSSAI published a notification to announce the alcoholic beverages standards implementation date as April 1, 2019. However, implementation of certain provisions was deferred related to yeast in beer, tolerance limits for low alcoholic beverages and wines, new category definitions and labeling requirements. These provisions when modified will be officially notified and incorporated into the final regulation (GAIN <u>IN9032</u>).
- On April 9, 2019, a list of FAQs with FSSAI clarifications on the recently implemented Food Safety and Standards (Alcoholic Beverages) Regulations, 2018, was published (GAIN <u>IN9035</u>).
- On July 5, 2019, FSSAI published its draft 2019 Food Safety and Standards (Alcoholic Beverages) Amendment Regulations. The draft regulations detail the requirements for low alcoholic beverages other than wine and beer, geographical indications, and select labeling requirements. The draft amendment was notified to the WTO Technical Barriers to Trade (TBT) Committee on July 22, 2019 and WTO Sanitary and Phytosanitary Measures (SPS) Committee on July 26, 2019. Comments, on the draft regulations were invited from WTO members for a period of sixty days from the date of the notification on the WTO website after which the notification will go into effect for final approval and implementation. The deadline for comments on the TBT notification was September 23, 2019, and the deadline for comments on the SPS notification was September 20, 2019 (GAIN IN9068).

Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations 2016

- On December 31, 2018, FSSAI issued a notice that disallowed the use of several ingredients in nutraceutical foods. This was an addition to Appendix 1 of the previous FSSAI nutraceutical foods notification issued on June 29, 2018 (GAIN <u>IN9001</u>).
- On May 2, 2019, the GOI's Food Safety and Standards Authority of India (FSSAI) published a notice to extend its timeline for imports of specialty foods for special medical and therapeutic

purposes. In its earlier notification published on November 1, 2018 (uploaded on FSSAI's website on November 2), import of such foods were allowed until May 2, 2019. The current notification extends the timeline for another year starting from May 2, 2019, or until FSSAI establishes their corresponding standards (GAIN IN9038).

Since the inception of the Nutraceutical Regulations in January 2018, FSSAI has published notifications on the use of specific ingredients in the manufacture of food products contained in the regulations. On May 10, 2019, FSSAI issued a directive to extend the timeline on the use of formulations containing vitamin and mineral combinations by three months, until June 30, 2019 or till further FSSAI orders, whichever is earlier. This is the fifth directive in the series that extends this timeline on formulations containing vitamins and mineral combinations, and the previous four directives were published on December 12, 2017, June 29, 2018, August 24, 2018, and December 31, 2018 respectively. The current notification also has a conditional clause stating that an ingredient, if not included in the list under Nutraceutical Regulations, will not be allowed to be used in any food product, unless if use of this ingredient is specifically allowed by other regulations under the Food Safety and Standards Regulations (GAIN IN9052).

Food Safety and Standards (Advertising and Claims) Regulations, 2018

 On November 19, 2018, FSSAI published the final Food Safety and Standards (Advertising and Claims) Regulations, 2018. The previous compliance date, as per the final regulations, was July 1, 2019. On June 28, 2019, FSSAI extended the timeline to comply with the advertising and claims regulations for six months until December 28, 2019 or until such time the final regulation, inclusive of the amendments, are published in the Official Gazette of India, whichever is later (GAIN IN9063).

Compendium of Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011

 On August 30, 2019, FSSAI published a draft amendment to its Food Safety and Standards (Prohibition and Restriction on Sales) Regulations related to trans-fat limits in processed food products. The notification invited comments from WTO member countries, with the comment period expiring 60 days from the date the notification is published on the WTO website (GAIN IN9080).

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

On June 29, 2015, the MOA 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 the U.S.</u> for details). This will be implemented when officially published in the Gazette of India

Attachments:

No Attachments