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India

Food and Agricultural Import Regulations and Standards Report

FAIRS Annual Country Report - 2018

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Report Highlights:

In calendar year (CY) 2018, the Government of India (GOI) granted access to U.S. poultry in the Indian market and issued multiple food safety draft and final amendments and regulations for imported and domestic food products. Notably, the GOI issued the draft Food Safety and Standards Labeling and Display Regulations 2018, expanded the rectifiable labeling list, revised guidelines for import and export of bovine germplasm, and issued new draft standards for a wide range of meat products.

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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 CYs 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. *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; 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); and two Ministry of Agriculture and Farmers' Welfare (MAFW) 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 2018, the GOI granted access to U.S. poultry in the Indian market and FSSAI continued its endeavor to issue multiple draft and final amendments and regulations related to food safety for imported and domestic food products. An overview of those FSSAI amendments and regulations follows: the draft Food Safety and Standards Labeling and Display Regulations 2018, published and comments invited from World Trade Organization (WTO) members; an expanded rectifiable labeling list for food imports; final standards for alcoholic beverages published in the Gazette of India; the final Regulation on Fortification implemented; and a published List of Health Claims for Fortified Foods. Lastly, the MAFW revised its guidelines for export/import of bovine germplasm and published new draft standards for a wide range of meat products.

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 are derived from the core objective of the Food Safety and Standards Act for governing certain actions and decisions of concerned administrative authorities (e.g., staff qualifications, fees, and laboratory and sampling protocols). Regulations constitute implementing guidelines of the parent Food Safety and Standards Act for use by officials at the end-user level (e.g., labeling requirements and food additive limitations).

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 the 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 website</u>. While useful to know, the FSS Rules are not generally instructive to U.S. food and agricultural product exporters.

Regulations: The Food Safety and Standards (FSS) Regulations 2011 are available on the <u>FSSAI</u> website 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 s/he 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 with Codex Alimentarius and continues to issue multiple draft amendments on 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". 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 MAFW's DAHDF. These procedures are available at: <u>http://www.dahd.nic.in/sites/default/filess/gazette_27June2014%20%201.pdf</u>

Procedures for import of various livestock products are available on the website at http://dahd.nic.in/trade. In addition, readers may access the USDA GAIN search engine to find relevant GAIN Food and Agricultural Import Regulations and Standards (FAIRS) export certification reports.

- On September 17, 2018, DAHDF revised its guidelines for export/import of bovine germplasm. Readers can access the guidelines from the DAHDF website at <u>Guidelines for Export/Import of</u> <u>Bovine Germplasm</u>. The revised guidelines were not notified to the 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>.
- In January 2017, DAHDF notified the standard operating procedure (SOP) for traceability of imported bovine germplasm. The SOP notification provides a detailed procedure for traceability of imported bull semen doses produced from imported bulls and imported embryos. The SOP can be accessed at <u>Standard Operating Procedure (SOP) for Traceability of Imported Bovine Germplasm</u>. The publication date of the notification on DAHDF's website is missing (<u>GAIN IN7005</u>).
- On February 17, 2017, the GOI published a Gazette of India notification to amend the requirements for poultry and poultry product imports from countries reporting avian influenza. The amendment was issued to rectify the inadvertent omission of the term "the areas of low pest or disease prevalence" in paragraph 1(d) of the earlier notification (see GAIN reports <u>IN6095</u> and <u>IN6105</u>). The amended text should now be read as "Pest-or disease-free areas and areas of low pest or disease prevalence means the pest- or disease-free areas and areas of low pest or disease prevalence as defined in the World Trade Organization Agreement on Sanitary and Phytosanitary Measures." The regulation was not notified to the WTO (<u>GAIN IN7038</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 MAFW's DAC. The Plant Quarantine Order 2003, as amended, is available on India's DPPQS website at: http://plantquarantineindia.nic.in/PQISPub/pdffiles/pqorder2015.pdf.

Section II. Labeling Requirements:

Three GOI authorities regulate labeling of food and agricultural products. They are the 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"</u> and the <u>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 (<u>GAIN IN8043</u> to note 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 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.
- 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 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 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 milliliters; and,
 - 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 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 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 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 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 "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 multipiece 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 bulk. For more details on the guidelines, please refer to GAIN IN2055.

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 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:

- 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) Example (FSSL 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 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 comprise of 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 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.

Note: 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 IN8068).

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 this office 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 <u>Legal Metrology (Packaged</u> <u>Commodities) Rules 2011</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 amendments text was published as draft, with comments invited from stakeholders. The enforcement date mentioned in the December 19, 2016 notification has been 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 GAIN IN7001.

MOCI

As per Notification Number 44 (RE-2000)/1997-2002 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 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:



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.

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) 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 GAIN IN7128. The compliance date for the Packaging Regulation is 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 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 2018 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 Food Safety and Standards (Contaminants, Toxins and Residues) Regulation 2011, 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 <u>http://ppqs.gov.in/sites/default/files/restricted_and_banned_product_list.docx</u>. MAFW 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://ppqs.gov.in/divisions/cib-rc/about-cibrc.

Section VI. Other Regulations and Requirements:

Product Approval:

On September 11, 2017, India implemented its Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations 2017. The Regulation has been finalized after incorporating comments received from the stakeholders on the draft Regulation. Earlier 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 outlines 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>).

On November 8, 2017, FSSAI published the "<u>Food Import Clearance Manual</u>" and provided a regionwise list of 142 FSSAI notified laboratories. In the same manual, a list of 16 FSSAI-notified referral laboratories is also covered under Annex VIII.

For details on the procedure of sampling, please refer to the latest "Manual for Food Imports". FSSAI has published 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 line up the risk associated with the food product; and lastly 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 to register products formally. Export certification requirements for imports of food products in India are summarized in FAIRS Export Certification Report 2018 (GAIN <u>IN8134</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 Indian 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, Forest and Climate Change 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's Foreign Trade Policy (2004-2009) specified that all imports containing products of modern biotechnology must have prior approval from GEAC. The Foreign Trade 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 <u>GAIN IN8129</u> "Agricultural Biotechnology Annual 2018".

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 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 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: <u>agnewdelhi@fas.usda.gov</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 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 Tuglaqabad and Patparganj areas of New Delhi.

Procedure for Clearance:

On November 8, 2017, FSSAI published <u>Food Import Clearance Manual</u> in order to explain the step-bystep procedure for food imports and their clearance process. It is important that exporters maintain close contacts with their agents on import procedures (<u>GAIN IN7144</u>).

The procedures for product sampling and laboratory analysis are well defined in the Food Import Regulations 2017. 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.

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 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 Ministry of Environment, Forest and Climate Change

Chairman, 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: parsheera-mef@nic.in Website: http://envfor.nic.in/

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: <u>www.ficci.com</u>

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: <u>www.cii.in</u>

Author Defined:

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

IN8136	Revision in Standards for Varied Food Products
IN8134	FAIRS Export Certificate Report 2018
IN8127	Timeline Extended on Medical and Therapeutic Specialty Food Imports
IN8126	India Publishes Clarification on Food Fortification Regulations
IN8125	India Issues Guidance on the Use of Stickers on Fruits and Vegetables
IN8107	FSSAI Notifies Tolerance Limits for Additional Antibiotics
IN8105	FSSAI Grants Extension in Use of Organic Sticker
IN8104	FSSAI Publishes Revised Standards for Varied Food Products
IN8103	New FSSAI Directives for Certain Ingredients Under Functional Foods
<u>IN8101</u>	FSSAI Bans Import of Four Specialty Foods
<u>IN8096</u>	Organic Sticker Temporarily Allowed on Imported Organic Products
<u>IN8095</u>	FSSAI Recognizes Technological Need of Lecithin in Infant Formula
<u>IN8094</u>	WTO Member Comments Invited on Draft Standards for Synthetic Syrups
<u>IN8092</u>	Draft Amendments in Contaminants, Toxins and Residues Regulation
<u>IN8091</u>	India Invites WTO Member Comments on Inclusion of Processing Aids
<u>IN8090</u>	Food Service Outlets Required to Display Calorie Information
<u>IN8075</u>	India Extends Ban on Milk and Dairy Product Imports from China
<u>IN8074</u>	Final Regulation on Fortification Implemented Prior to Publication
<u>IN8071</u>	Revised Standards for Coconut Milk and Select Herbs
<u>IN8070</u>	Amendments in the Food Product Standards and Additives Regulation
<u>IN8068</u>	Rectifiable Labeling List for Food Imports Gets Expanded
<u>IN8065</u>	WTO Comments Invited on New Standards for Meat Products
<u>IN8055</u>	GOI Invites Comments on Standards for Coffee and Packaged Water
<u>IN8053</u>	FSSAI Notifies Microbiological Standards for Fruits and Vegetables
<u>IN8052</u>	Amendments in Food Import Regulation Published and Operationalized
<u>IN8045</u>	Functional Food Regulation Amendments Open for WTO Member Comments
<u>IN8043</u>	Draft Labeling and Display Regulations Invite WTO Member Comments
<u>IN8041</u>	Final Standards for Alcoholic Beverages Published in Indian Gazette
<u>IN8031</u>	FSSAI Allows Pre-existing Labels for Seasoning of Instant Noodles
<u>IN8030</u>	FSSAI Allows Pre-Printed Package Materials for Functional Foods
<u>IN8029</u>	Amendments in Licensing Regulation Invite WTO Comments
<u>IN8021</u>	Amendments in Food Licensing and Registration Made Operational
<u>IN8019</u>	FSSAI-Draft Notice on Standards for Fruits and Vegetable Products
<u>IN8017</u>	FSSAI Notifies Sixteenth Amendment of Food Additives Regulations
<u>IN8016</u>	Extension Given in Compliance Directions for Caffeinated Beverages
<u>IN8009</u>	Use of Stickers as Fortification Logo for Edible Oils
<u>IN8008</u>	Standards for Spices and Additional Additives List Invite Comments
<u>IN8007</u>	Amendments in Functional Foods Regulation Invite WTO Member Comments
<u>IN8006</u>	FSSAI Publishes List of Health Claims for Fortified Foods
<u>IN8005</u> IN8004	Compliance Timeline Extended on Labeling for Instant Noodles Draft Standards for Infant Nutrition Foods Invite WTO Member Comments
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<u>IN8003</u>	FSSAI Operationalizes Certain Provisions of Food Additives
<u>IN8002</u>	Additional List of Permissible Import of Specialty Foods with Labels
<u>IN8001</u>	FSSAI Publishes Product Approval Revalidation Procedures

Appendix IV. Chronology of FSSAI Regulations and Notifications in 2018

- On January 1, 2018, FSSAI published a notification explaining revalidation procedures by FBOs in case their products are not covered under any of the food product and standards regulations published since 2016. In such cases, FBOs are required to submit necessary documentation quoting their previous application number as per the requirements specified under the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations 2017. There will be no additional fees for re-validation. However, FSSAI requires that FBOs submit their documentation for revalidation within a timeline of 30 days from January 1, 2018; that is, from the date of issuance of the current notification (GAIN IN8001).
- FSSAI amended Regulation 9 of the Food Safety and Standards (Import) Regulations 2017, which deal with sampling of imported foods having a shelf life of less than seven days. The amendments relate to (a) insertion of additional clauses to sub-regulation 3; and (b) requirement of an additional undertaking by the importer in Form 13A that no part of the food consignment shall be released in the market for sale until the no-objection certificate is issued by the Authorized Officer. FSSAI, in order to facilitate the ease of doing business and speed up the clearance process for imported food products, has operationalized the above-mentioned amendments effective immediately (GAIN IN8052).
- 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 Food Safety and Standards (Food Product Additives and Food Standards) Regulation 2011

- On December 29, 2017, FSSAI operationalized certain provisions of food additives notified through amendments dated September 5, 2016. FSSAI operationalized these revised provisions because their finalization would take more (GAIN IN8003).
- On December 27, 2017, FSSAI published the draft Food Safety and Standards (Foods for Infant Nutrition) Regulations 2017 and invited WTO member countries to offer comments. The

comment period expired 60 days from the date it was published on the WTO website <u>www.wto.org</u> (<u>GAIN IN8004</u>).

- On January 2, 2018, FSSAI published a draft notification related to the inclusion of provision for additional additives in various food categories and microbiological standards for spices. The notification invited comment from WTO member countries, which expired 60 days from the date it was published on the WTO website (GAIN IN8008).
- On December 21, 2017, FSSAI notified standards for caffeinated beverages and use of blue tint in plastic container via notification number P. 15025/93/2011-PFA/FSSAI. FSSAI stated that FBOs must comply with provisions of the said regulations by July 1, 2017. Earlier on June 15, 2017 FSSAI announced on its website that it has extended the time period allowed for compliance by the FBOs until December 31, 2017, which it has now further extended to June 30, 2018 (GAIN IN8016).
- India's FSSAI notified the amended Food Safety and Standards (food Products Standards and Food Additives) Regulations 2011. These regulations will be known as Food Safety and Standards (Food Products Standards and Food Additives) Sixteenth Amendment Regulations 2017. FBOs have been advised to comply with all the provisions of these regulations by July 1, 2018 (GAIN IN8017).
- On January 5, 2018, GOI's FSSAI published notice on the draft amendment notification of Food Safety and Standards (Food Product Standards and Food additives) Regulation 2011 regarding standards of fruit and vegetable products such as quick frozen french fried potatoes; canned chestnuts; canned chestnut puree; edible fungus products, ginger; and tomato ketchup and tomato sauce. The regulation has not been notified to the WTO. The deadline for suggestions and comments is sixty days form the date of publication of the notification (GAIN IN8019).
- On March 5, 2018, FSSAI published directions to allow FBOs to use their existing labels for seasoning of instant noodles until June 30, 2018. FSSAI has facilitated this arrangement to FBOs due to various representations received from stakeholders (<u>GAIN IN8031</u>).
- FSSAI notified the Food Safety and Standards (Food Products Standards and Food Additives) Fourth Amendment Regulations 2018, with revised microbiological standards for fruits and vegetables and their products. The said notification will come in force on immediate basis and FBOs will need to comply with all the provisions of the regulations by January 1, 2019 (<u>GAIN</u> <u>IN8053</u>).
- On April 26, 2018, FSSAI published a Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations 2018 containing proposed changes to its existing standards for coffee and packaged drinking water. The amendments, as printed in the draft notification, relate to the following beverage categories under the food product standards: coffee (sub-regulation 2.10.2); coffee-chicory mixture (sub-regulation 2.10.4); and packaged drinking water (other than mineral water) (sub-regulation 2.10.8) (GAIN IN8055).

- On June 4, 2018, FSSAI published a notification to include new draft standards for the following meat products: canned/retort pouch meat products; comminuted/restructured meat products; cured/pickled meat and/or smoked meat products; dried/dehydrated meat products; cooked/semi-cooked meat products; fermented meat products; marinated meat products; and fresh/chilled/frozen rabbit meat. FSSAI invited WTO member countries to comment on this notification. The comment period for trading partners expired 60 days from the date it was notified on WTO website (GAIN IN8065).
- FSSAI published a draft notification to invite comments from WTO member countries on revisions relating to flavors and additives used in food products. The comment period for trading partners expires 60 days beyond the notification date as listed on the WTO's website (<u>GAIN IN8070</u>).
- On June 4, 2018, FSSAI published a draft notification on the revised standards for coconut milk and coconut cream; dried oregano (whole and powder); pimento (allspice, whole and powder); formulation of laurel (bay leaf, whole and powder); dried mint; and dried rosemary. The draft notification invites comments from the WTO member countries, which expired 60 days from the date it was published on the WTO website (GAIN IN8071).
- On July 17, 2018, FSSAI published a <u>draft notification</u> to amend Chapter 3, "Substances Added to Food" of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations 2011. FSSAI has defined a processing aid as "any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional, but unavoidable, presence of residues or derivatives in the final product." On July 27, 2018, India notified this draft amendment to the WTO for comments (WTO Notification Number G/SPS/N/IND/222). The deadline to provide comments was September 24, 2018 (<u>GAIN IN8091</u>).
- On July 17, 2018, FSSAI published a draft notification to amend Regulation 2.3, "Fruit and Vegetable Products" of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations 2011. In the draft regulation, FSSAI removed fruit syrup and fruit *sharbat* from sub-regulation 2.3.21 and added certain requirements, including permissible limits of citric acid, specific gravity, total soluble solids, and pH levels, for *sharbat* and synthetic syrup in sub-regulation 2.3.24. On July 26, 2018, India notified this draft amendment to the WTO for comments (WTO Notification Number G/SPS/N/IND/221). The deadline to provide comments was September 23, 2018. The full text of the draft notification is available online at FSSAI's website (GAIN IN8094).

Food Safety and Standards (Organic Foods) Regulation 2017

Effective July 1, 2018, Food Business Operators in India are required to follow the <u>Food Safety and</u> <u>Standards (Organic Foods) Regulations 2017</u>, which mandates the use of a FSSAI organic logo on the primary label of all certified organic products entering India. Temporarily, until September 30, 2018, FSSAI will allow the use of a non-detachable sticker to display the FSSAI organic logo. The FSSAI organic logo will be required, in addition to the FSSAI logo. However, on August 21, 2018, FSSAI issued an additional order announcing that use of a non-detachable sticker to display FSSAI's organic logo would be permissible until December 31, 2018 (see GAINs <u>IN8096</u> and <u>IN8105</u>).

Amendments to the Packaging and Labeling Regulation 2011

- FSSAI, in its notification published on December 13, 2017, allowed food business operators to use their existing packaging material with respect to the labeling of instant noodles until June 30, 2018. The extension was granted on the basis of several representations received from stakeholders (GAIN IN8005).
- On April 11, 2018, FSSAI published a draft notification on the Food Safety and Standards Labeling and Display Regulations 2018. The draft notification invited comments from WTO member countries, which expired 60 days from the date it was published on the WTO website <u>www.wto.org (GAIN IN8043</u>). The draft regulation, when finalized, will cover only labeling and display features, as packaging is now a separate regulation.
- On July 17, 2018, FSSAI published a draft notification to add a new clause in the packaging and labeling regulation relating to display of information in food service establishments and invited WTO member countries to comment. WTO notification Number G/TBT/N/IND/81 dated July 24, 2018, specifies the comment period for trading partners expires 60 days from the date notified on WTO website, meaning the final date of comment period ended on September 21, 2018 (GAIN IN8090).

Amendments to the Licensing and Registration of Food Businesses Regulation 2011

- On February 16, 2018, FSSAI operationalized the draft Food Safety and Standards (Licensing and Registration of Food Businesses) Amendment Regulations 2018 because the final Regulation was not notified and implemented (GAIN IN8021).
- On March 6, 2018, FSSAI published the draft Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations 2018 and invited WTO member countries to offer their comments. The comment period expired 60 days from the date it was published on the WTO website (GAIN IN8029).

Amendments to the Contaminants, Toxins and Residues Regulations 2011

• On July 24, 2018, FSSAI issued draft amendments to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations 2011. The draft amendments pertain to Chapter 2 titled "Contaminants, Toxins and Residues" and include updates relating to limits for metal contaminants, aflatoxin and mycotoxin (<u>GAIN IN8092</u>).

Fortification of Foods Regulation 2018

• In order to maintain uniformity in claims for fortified foods, FSSAI published a scientifically validated list of health claims for fortified foods and their micronutrients (<u>GAIN IN8006</u>).

- On January 19, 2018, FSSAI issued direction to allow the use of stickers for stamping fortification logos on the existing labels for edible vegetable oil fortified with vitamins A or D until June 30, 2018 (GAIN IN8009).
- On May 10, 2018, FSSAI issued a directive to implement the Food Fortification Regulation effective April 19, 2018. As the publication of the final regulation could take a long time, FSSAI decided to implement the regulation prior to its publication. From the time the draft regulation was published, FSSAI has moved back the implementation date for the third consecutive time. A chronology of the food fortification regulation is provided in <u>GAIN IN8074</u>.

Food Safety and Standards (Alcoholic Beverages) Regulations 2018

On April 5, 2018, FSSAI published the final version of the Food Safety and Standards (Alcoholic Beverages) Regulations 2018, related to standards for alcoholic beverages. According to FSSAI, the implementation of the notification will commence on April 1, 2019. Please refer to GAIN IN5140 for details on the draft regulation first published for Indian industry stakeholders in October 2015. After first notifying the draft to Indian domestic stakeholders for comment, FSSAI and the GOI submitted the draft Alcoholic Beverage Standards to the WTO Committee on Technical Barriers to Trade and to the Committee on Sanitary and Phytosanitary Measures. Subsequent to the WTO notification, India again notified revisions to the draft to the domestic industry in the Gazette of India on September 9, 2016 (GAIN IN8041).

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

- FSSAI published an order to revise its permissible list of specialty foods and their labels. Through this order, FSSAI has also instructed its Authorized Officers to issue a no-objectioncertificate for such products as per the present procedure of food import clearance and frequently asked questions issued recently (<u>GAIN IN8002</u>).
- On January 9, 2018, FSSAI published amendments related to health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food, and novel food. The notification invites comments from WTO member countries, which expired 60 days from the date it was published on the WTO website (<u>GAIN IN8007</u>).
- On March 12, 2018, FSSAI published directions to extend the timeline for FBOs to comply with the labeling requirements specified in the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional food and Novel Food) Regulations 2016. The new compliance date is June 30, 2018. FSSAI extended the timeline due to various representations received from stakeholders (GAIN IN8030).
- On April 11, 2018, FSSAI published draft amendments to the Food Safety and Standards (Health

Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations 2016 and invited comments from WTO member countries. The comment period expired 60 days from the date it was published on the WTO website (<u>www.wto.org</u>). The amendments, as printed in the notification, are copied below and relate to the following food categories: health supplements (Regulation 6); nutraceuticals (Regulation 7); food for special dietary use, other than infants, and those products intended to be taken under medical advice (Regulation 8); food for special medical use (Regulation 9); novel foods (Regulation 13); standards for ingredients (Regulation 14 is a new addition); values for vitamins and minerals and trace elements allowed to be used in food for special dietary use and food for special medical purpose, other than those intended for use in infant formula (Schedule III); and list of food additives for health supplements, nutraceuticals and food with added probiotics and prebiotics (Schedule VA) (<u>GAIN IN8045</u>).

- On August 31, 2018, FSSAI issued a notification to withdraw four products from its permissible list of imported specialty foods meant to treat infants and children suffering from special medical conditions. The four products are as follows: Similac Total Comfort OptiGRO (for infants from birth to 12 months); Similac Total Comfort Intellipro2 (for infants after 6 months); NAN Optipro HA 1; and NAN Optipro HA 2 (GAIN IN8101).
- The latest FSSAI notification of August 24, 2018 allows the sale of food products containing ingredients listed in Appendix-1 of the FSSAI notice issued on June 29, 2018. However, the notification clarifies that these food products should not have a manufacturing date after June 29, 2018 and that the restriction imposed on the new production of such products after this date remains in place, per the previous notice. FSSAI granted relaxation for these ingredients only until FSSAI's scientific panel finishes its review (GAIN IN8103).

Food Safety and Standards (Foods for Infant Nutrition) Regulations 2017

On July 7, 2018, FSSAI issued a directive that includes lecithin as an approved emulsifier in infant formula, up to a level of 0.5 grams for every 100 grams of formula, until the final regulation on infant nutrition comes into effect. FSSAI's directive recognizes the technological need to include lecithin in infant formulas, as represented by various stakeholders (GAIN IN8095).

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

On June 29, 2015, the MAFW 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