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### India

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

### **FAIRS Country Report**

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#### **Report Highlights:**

Throughout calendar year 2015, the Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) issued multiple final and draft amendments related to food additive and standards, contaminants and toxins, and labeling and packaging regulations. The Ministry of Agriculture also issued final health certificates for pork and pork products, bovine frozen semen, in vivo bovine embryos and live bovines.

#### 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. While the OAA makes every effort to describe existing regulations accurately, exporters are strongly advised to always verify import requirements with their customers prior to shipment. THIS REPORT HAS NOT BEEN OFFICIALLY ENDORSED BY THE GOVERNMENT OF INDIA (GOI). IMPORT APPROVAL FOR ANY PRODUCT IS SUBJECT TO LOCAL RULES AND REGULATIONS AS INTERPRETED BY INDIAN BORDER OFFICIALS AT THE TIME OF ENTRY.

#### **Executive Summary:**

Laws pertaining to food and agricultural product imports into India are under the jurisdiction of multiple Government of India authorities: FSSAI of the Ministry of Health; the Office of Legal Metrology of the Ministry of Consumer Affairs, Food, and Public Distribution; the Directorate General of Foreign Trade of the Ministry of Commerce and Industry; and two departments of the Ministry of Agriculture, the Department of Animal Husbandry, Dairying and Fisheries (DAHDF) and the Department of Agriculture and Cooperation. Exporters are advised to research thoroughly the relevant laws and regulations applicable to their products across all of these regulatory agencies. The Food Safety and Standards Act, 2006, was fully implemented in 2011. In 2013, FSSAI undertook to harmonize food safety regulations with Codex Alimentarius and has since issued multiple draft amendments related to food safety, labeling and packaging regulations, as were new draft guidelines on labeling of imported products. DAHDF published the (i) veterinary health certificate for imported bovine germplasm; (iii) draft veterinary health certificate for import of pet food; and (iv) final veterinary health certificate for pork and pork products.

#### Section I. Food Laws:

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

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

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

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

Regulations: The 2011 Food Safety and Standards (FSS) Regulations are available on the FSSAI website and should be consulted regularly for updates, which appear periodically and are published in the official gazette. The regulations govern *inter alia* packaging and labeling, food additives, product standards, licensing and registration of food businesses, and maximum residue levels of contaminants. The Regulations stipulate, "...all food business operators, food processors, manufacturers, exporters, or importers shall ensure that the food s/he handles meets all the standards under the FSS Regulation 2011." All domestic food operators, including importers, are required to have an FSSAI license to conduct business in India. FSSAI does not require licensing of foreign companies to export food products to India. For further information, in addition to the FSSAI website, please use the GAIN to find reports on India containing the term *FSSAI* in "Report Highlights". In 2013, FSSAI began an effort to harmonize its regulations with Codex Alimentarius and has since issued multiple draft amendments and regulations pertaining to food safety, labeling, and packaging. The process of harmonization by FSSAI is incomplete, despite the deadline for full harmonization was July 15, 2015.

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

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

#### C. Livestock Importation Act, 1898

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

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

• On July 24, 2013, the Government of India updated the <u>Directorate General of Foreign Trade's</u> (<u>DGFT</u>) <u>Import Policy 2012</u> to reflect minor changes in Chapters 5 and 23 of the Harmonized Tariff Schedule (HTS). Policy condition 4 under Chapter 5 notes that a Sanitary Import Permit shall not be applicable to "human hair." Policy condition 1 under chapter 23 now specifies that an import permit is required for import of items of animal origin or products intended for animal feeding containing animal origin materials under IT (HS) Code 2309 "Preparations of a kind used in Animal Feeding" (IN3102).

- On January 16, 2015, FSSAI published a draft Order for domestically produced and imported meat and poultry products that note a procedure will be developed to inspect and monitor slaughtering and processing plants before granting market access to trading partners, and requires a country's competent authority to certify to Indian import requirements. Furthermore, the draft Order has introduced modified text for some requirements currently included in veterinary import certificates for imported meat and poultry products. On April 23, 2015, the draft Order was notified to the WTO for comment. However, FSSAI postponed the earlier effective date of July 1, 2015 by three months and the new date of implementation of the order was October 1, 2015 or until further orders, whichever is earlier. To date, FSSAI has not notified if the implementation date of October 1, 2015 is extended further. For further details, please refer to IN5035, IN5078 and IN5086.
- On September 28, 2015, DADF published a veterinary health certificate for the import of bovine frozen semen into India through an official gazette notification. Previously, DADF published a draft certificate in 2014 (Please see IN4041). The final certificate provides new or revised information including modified import requirements. For example, it specifically mentions that bovine frozen semen imports require a health certificate written in English that is signed by an official veterinarian of the exporting country and includes information contained in the Form section. The final certificate also added additional disease testing options for bovine brucellosis and paratuberculosis, which include the Fluroscence Polarization Assay and fecal culture test. To date, this veterinary health certificate has not been notified to the World Trade Organization (WTO). For further details, please refer to IN5132.
- On September 28, 2015, DADF published a veterinary health certificate for the import of in vivo bovine embryos through an official gazette notification. Previously, the DADF published a draft health certificate in 2014 (Please see IN4041). The final certificate provides new or revised information including modified import requirements. For example, it specifically mentions that in vivo bovine embryo imports require a health certificate written in English that is signed by an official veterinarian of the exporting country and includes information contained in the Form section. The final certificate also added additional disease testing options for paratuberculosis, which include a fecal culture test. According to paragraph (II) (10), the embryos can be stored in new or sterilized liquid nitrogen containers (the draft certificate only mentions sterilized containers). Paragraph (II) (11) requires that the straw should be labeled according to the International Embryo Transfer Society (IETS) manual. To date, this veterinary health certificate has not been notified to the WTO. For further details, please refer to IN5134.
- On September 28, 2015, DADF published a veterinary health certificate for the import of live bovines into India through an official gazette notification. The revised certificate provided new or revised information including modified import requirements. For example, it specifically mentions that live bovine imports require a health certificate written in English that is signed by an official veterinarian of the export country and includes information contained in the Form section. The revised certificate added additional disease testing options for paratuberculosis and schmallenberg serology, which include the fecal culture test and virus neutralization (VN). The

new certificate also includes a few modifications in the testing protocol for the disease enzootic bovine leucosis (EBL). To date, this veterinary health certificate has not been notified to the WTO. For further details, please refer to <u>IN5133</u>.

- DADF revised the Guidelines for Export/import of Bovine Germplasm, which mainly adds a few additional requirements for importing young bulls. Previous draft guidelines were published in February 2011, March 2013, and October 2013. Although the Government of India supports the National Dairy Plan, which focuses on increasing animal productivity (Please see GAIN report IN5009 India's National Dairy Board Looks to Grow), it is unclear if the Guidelines for Export/import of Bovine Germplasm will provide a boost to the Indian dairy industry on a national scale. In addition to the Guidelines, exporters should research whether there are additional requirements for exporting germplasm to a specific Indian state. Although not notified to the WTO, the new Guidelines were published on the DADF website (unspecified date). For further details, please refer to IN5019.
- On October 26, 2015, DADF published a draft veterinary health certificate for dog and cat food (containing animal origin material) imports. This revised draft certificate introduces some new language and requirements in comparison to the earlier protocol. For example, the draft certificate specifically requires imported pet food to be manufactured from certain animal meat / products and specifies that ingredients cannot include animal meat that is prohibited under any Indian law. Other modifications or additions include new heat treatment processing guidelines, specifying the ports that can accept imported pet food, new testing requirements for sulphite reduced clostridium for canned and moist pet food, and manufacturer/exporter declarations. The new draft certificate removed the earlier requirement that a processing facility needed to be located 25 km radius from an avian influenza infected area. To date, this draft veterinary health certificate has not been notified to the WTO for comment. For further details, please refer to IN5157.
- On November 6, 2015, the Department of Animal Husbandry, Dairying, and Fisheries (DAHDF) published a final veterinary health certificate for pork and pork product imports on its website. The revised certificate introduces additional requirements as compared to the draft protocol notified to the WTO on March 16, 2015 (Please see GAIN report IN5036). For example, the final certificate introduces new import requirements under para 6 (f) of section IV, which notes that the consignment of pork and pork products should be produced according to the Codex Code of Hygienic Practice for Meat and sourced from pigs that are slaughtered in an approved slaughter house/abattoir. The final certificate also notes requirements for the *taenia solium* and provides procedures for the inactivation of the *taenia solium cysticerci*. To date, this veterinary health certificate has not been notified to the WTO. For further details, please refer to IN5144.

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

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

amended, is available on India's Plant Quarantine website.

#### Section II. Labeling Requirements:

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

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

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

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

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

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

#### **Pre-packaged Foods:**

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

#### Overview:

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

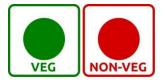
- 1. The name of the food,
- 2. List of ingredients, except for single ingredient foods,
- 3. Nutritional information,
- 4. Declaration regarding vegetarian and non-vegetarian,
- 5. Declaration of food additives,
- 6. Name and address of the manufacturer,
- 7. Net quantity,
- 8. Lot/code/batch identification,

- 9. Date of manufacture or packing,
- 10. Best before date or use by date or date of expiry,
- 11. Country of origin,
- 12. Instructions for use, if applicable.

#### Further detail:

- 1. Name of food: The name of food shall include trade name or description of food contained in the package.
- 2. List of ingredients: Except for single ingredient foods, a list of ingredients shall be declared on the label, in descending order of their composition by weight or volume.
- 3. Nutritional information: All nutritional facts per 100 gram or 100 ml or per serving of the product shall be given on the label containing
  - i. Energy value in Kcal;
  - ii. The amount of protein, carbohydrates (specify quantity of sugar) and fat in grams or milliliters;
  - iii. The amount of any other nutrient for which a nutritional or health claim is made.
    - Note: Nutritional information for alcoholic beverages is not required.
- 4. Declaration regarding vegetarian or non-vegetarian:
  - i. Vegetarian food must have a symbol consisting of green color-filled circle inside a square with a green outline prominently displayed on the package, contrasting against the background on the principal display panel, in close proximity to name or brand name of the food.
  - ii. Non-vegetarian food (any food which contains whole or part of any animal including birds, marine animals, eggs, or products of any animal origin as an ingredient, excluding milk or milk products), must have a symbol of a brown color-filled circle inside a square with a brown outline prominently displayed on the package, contrasting against the background on the principal display panel, in close proximity to the name or brand name of the food.

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



- 5. Declaration regarding food additives: This declaration shall be made in accordance with FSS (Packaging and Labeling) Regulation, 2011.
- 6. Name and complete address of manufacturer: The label shall carry the name and complete address of the manufacturing or packing or bottling unit and also the name and complete address of the manufacturer or the company for and whose behalf it is manufactured or packed or bottled.
  - i. Where an article of food is imported into India, the package of food shall also carry the name and complete address of the importer in India.
  - ii. Provided further that where any food article manufactured outside India is packed or bottled in India, the package containing such food article shall also bear on the label, the name of the country of origin of the food article and the name and complete address of the importer and the premises of packing or bottling in India.
- 7. Net quantity: By weight or volume or number, shall be declared on every package of food.
- 8. Lot/code/batch identification: A mark of identification by which the food can be traced in the

manufacture and identify in the distribution shall be given on the label. FSSAI has advised verbally that this information may be ink jetted or stamped on the product label or carton.

- 9. Date of manufacture or packing: The date, month and year in which the commodity is manufactured, packed or pre-packed, shall be given on the label. FSSAI has advised verbally that this information may be ink jetted or stamped on the product label or carton.
- 10. Best before and use by date: The month and year in capital letters up to which the product is best for consumption. FSSAI has advised verbally that this information may be ink jetted or stamped on the product label or carton.
- 11. Provided further that the declaration of best before date for consumption shall not be applicable to:
  - i. Wines and liquors,
  - ii. Alcoholic beverages containing 10 percent or more by volume of alcohol.
- 12. Country of origin for imported food:
  - i. The country of origin of the food shall be declared on the label of the food imported into India.
  - ii. When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed, shall be considered to be the country of origin for the purposes of labeling.
- 13. Instructions for use: If necessary, shall be included on the label to ensure correct utilization of the food.

#### Wholesale food packages:

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

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

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

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

\*This is a rectifiable labeling requirement and the latest FSSAI notification for logo and license requirements mentions the compliance date as December 31, 2015, unless otherwise extended further.

India specifies that imported pre-packaged food products must meet India's country of origin food labeling requirements at the port of entry. Imported bulk food items sold in loose or unpackaged form

(almonds, apples, grapes, peas and lentils, etc.) must have an accompanying certificate that specifies country of origin. However, there is currently no requirement to label imported loose or unbranded products at the retail point of sale.

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

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

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

#### A. Rectifiable and Non-Rectifiable Labeling:

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

FSSAI issued an order dated August 11, 2015 (posted on FSSAI website August 13) to extend the deadline for printing FSSAI logo and license numbers on food labels to December 31, 2015. FSSAI previously announced that as of July 1, 2015, labels on all packages of food products should bear the FSSAI logo, as well as the food business operator's (importer in the case of imported products) FSSAI registration number (GAIN report IN5104).

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

#### Labeling requirements:

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

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

information, please refer to GAIN report IN3003).

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

On May 14, 2015, the GOI, Department of Consumer Affairs published a notification in the Indian official gazette, amending the Legal Metrology (packaged commodities) Rules, 2011. Important highlights of the amendment include: (a) Adopting the definition of retail packages as defined by the FSSAI; and (b) Allow the use of stickers to include all labeling requirement data on imported food packages. The publication is not yet WTO notified, nor is there any reference to a specific comment period for domestic stakeholders. With the first amendment of 2015, these rules are called as Legal Metrology (Packaged Commodities) (First Amendment) Rules, 2015 (<u>IN5076</u>).

On December 29, 2015, the GOI's Department of Consumer Affairs published an advisory to extend the timeline for the implementation of Legal Metrology (Packaged Commodities) (Amendment) Rules, 2015. The amendment is now due to come into force as of June 30, 2016. The extension of enforcement date applies to Rules 6,7 (Sub-rule 5) and 9 of the Legal Metrology (Packaged Commodities ) Rules, 2011.

#### Ministry of Commerce and Industry

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

- 1. Name and complete address of the importer in India.
- 2. Generic or common name of the commodity packed.
- 3. Net quantity using standard units of weights and measures. If the net quantity of the imported package is given in any other unit, its equivalent terms of standard units shall be declared by the importer.
- 4. Month and year in which the commodity was manufactured/packed, or imported.
- 5. The maximum retail price (MRP) at which the commodity, in packaged form, may be sold to the ultimate consumer. This price shall include all taxes, local or otherwise, freight, transport charges, commission payable to dealers, and all charges towards advertising, delivery, packing, forwarding, and any other relevant charges.

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



#### **FSSAI requirements:**

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

#### **Commerce requirements:**

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

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:

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

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

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

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

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

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

Please see GAIN report IN3067 for more details.

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

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

#### Section IV. Food Additives Regulations:

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

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

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

A list of banned/restricted pesticides/pesticide formulations that have been refused registration or face restricted use in India is available at <u>http://cibrc.nic.in/list\_pest\_bann.htm</u>. The Ministry of Agriculture has discontinued pesticide registration through the Pesticide Registration Committee when no MRLs are established.

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

#### Section VI. Other Regulations and Requirements:

**Product Approval:** 

As per the Food Safety and Standards Act, 2006, any proprietary food requires product approval under Section 22 of the FSS Act, 2006. However, this existing process of product approval for such food products has been discontinued by FSSAI as of August 26, 2015. This is in response to the recent ruling by India's Supreme Court in August 2015, wherein an appeal by FSSAI was dismissed and upheld a June 30, 2013, decision by the Bombay High Court which determined that FSSAI did not have the legal authority to issue advisories under the Food Safety Act, 2006. The earlier Bombay court determined, FSSAI cannot legally continue to issue advisories, and makes all earlier advisories null and void, including its May 11, 2013, advisory on product approval for processed food products. FSSAI published an official notice on its website on August 26, 2015, that it would no longer "continue with the process of Product Approvals". Products designated under Section 22 include foods derived from genetically engineered sources, nutritional supplements, special foods for medical or dietary requirements, traditional Indian *ayurvedic, sidha* and *unani* foods, organic and "novel foods".

FSSAI is in the process of reframing the right kind of regulations through the engagement of legal assistance. It is hoped that the new regulations will substantially ease the difficulties faced in getting approvals for the launch of new products into the market.

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

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

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

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

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

1(d) along with the supporting documents.

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

#### **Product Sampling:**

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

FSSAI published draft manuals in May 2015 for its requirements on sampling methods and analysis by laboratories which pertain to a variety of food and beverage products, including alcoholic beverages, meat and meat products, fish and seafood products, milk and milk products, cereal and cereal products, sugar and sugar products, and confectionary products, horticultural products, spices and condiments, and oils and fats. Apart from these manuals, FSSAI has also published a draft manual to provide general guidelines on sampling methodologies. FSSAI accepted public comments on these draft manual through May 25, 2015. For more details on the list of manuals, please see GAIN Report <u>IN5056</u>.

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

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

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

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

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

ascertain the quality and health safety standards of the consignment.

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

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

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

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

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

Other important circulars/notifications:

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

#### Shelf Life:

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

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

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

#### **Miscellaneous Requirements:**

There is no requirement to register products formally. Export certification requirements for imports of food products in India are summarized in FAIRS Export Certification Report 2015.

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

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

Since July 8, 2006, the GOI Foreign Trade Policy (2004-2009) specified that all imports containing products of modern biotechnology must have prior approval from GEAC, Ministry of Environment and Forests. The policy also stipulates a mandatory biotech declaration. The only biotech food product officially permitted for commercial importation is soybean oil derived from Roundup Ready Soybeans. For more information on India's biotech import policy, please refer to GAIN report "IN5088, "Agricultural Biotechnology Annual 2015".

#### Section VII. Other Specific Standards:

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

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

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

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

for the trademark to be officially accepted and notified.

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

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

#### Section IX. Import Procedures:

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

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

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

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

The procedures for product sampling and laboratory analysis are described in <u>FSS (Laboratory and Sample Analysis) Regulation, 2011</u>. Prior to sampling a product, the FSSAI port officer will ascertain whether the imported food item is in compliance with the labeling provisions under FSSAI rules so as to ensure that adequate and accessible information is available to the handler, processor or consumer to enable them to handle, store, process, prepare, and display the food products safely, and that the lot or batch can be easily traced and recalled if necessary. If labeling is found deficient, the product will be

rejected without further inspection or sampling. For additional information please contact:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### I. Genetic Engineering Approval Committee (GEAC) Ministry of Environment and Forests

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

#### Website: http://envfor.nic.in/

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

A. Director

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

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

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

| IN5166        | FAIRS Certification  |
|---------------|--|
| <u>IN5165</u> | Food Processing Ingredients  |
| <u>IN5164</u> | Retail Foods 2015  |
| <u>IN5163</u> | Food Service – Hotel Restaurant Institutional                        |
| IN5162        | Exporter Guide   |
| <u>IN5157</u> | GOI Release Draft Health Certificate for Dog and Cat Food Imports    |
| <u>IN5156</u> | Final Amendment on Food Additives Used in Breads and Biscuits        |
| <u>IN5153</u> | Final Amendment on Pullulan as a Food Additive                       |
| <u>IN5152</u> | Final Amendment on Standards for Various Food Contaminants           |
| <u>IN5151</u> | Final Amendment on Glazing Agents and Lubricants as Food Additives   |
| <u>IN5150</u> | Final Amendment on Naturally Occurring Toxic Substances              |
| <u>IN5149</u> | Final Amendment on Standards for Artificial Sweeteners               |
| <u>IN5148</u> | Final Amendment on Standards for Chromium Present in Gelatine        |
| <u>IN5147</u> | Final Amendment on Use of Lecithin as Food Additive                  |
| <u>IN5144</u> | GOI Release Health Certificate for Pork and Pork Product Imports     |
| <u>IN5140</u> | Draft Alcoholic Beverages Standards Notified for Comments            |
| <u>IN5138</u> | FSSAI Draft Food Standards Open for Domestic Comments                |
| <u>IN5136</u> | FSSAI Publishes Draft Guidelines for Safe Food to School Children    |
| <u>IN5134</u> | GOI Releases Veterinary Health Certificate for Bovine Embryo Imports |
| <u>IN5133</u> | GOI Releases Veterinary Health Certificate for Live Bovines Import   |

| IN5123   WTO Notified Draft Standards for Phytosterols     IN5122   WTO Notified Draft Standards for Metal Contaminants     IN5121   WTO Notified – Microbiological Standards for Milk and Milk Products     IN5119   WTO Notified – Microbiological Standards for Milk and Milk Products     IN5111   WTO Notified – Microbiological Standards for Milk and Milk Products     IN5112   Amendments in Regulations Relating to Phytosterols     Amendments on Trans Fatty Acid Levels   India Notified – Draft Amendment in Packaging and Labeling Regulations     IN5109   WTO Notified – Draft Amendment in Packaging and Labeling Regulations     IN5108   WTO Notified – Draft Amendment in Packaging and Labeling Regulations     IN5109   WTO Notified Draft Regulations Relating to Food Additives     IN5101   FSSAI Sets Standards for Chromium Present in Gelatin     IN5102   Printing of FSSAI Logo and License Gets Further Extension     IN5101   FSSAI Food Business License Deadline Extended by Six Months     IN5020   Draft Regulations Relating to Food Additives     IN5092   Draft Regulations Relating to Food Additives     IN5093   FSSAI Updates Standards of Melamine in Infant and Other Foods     IN5094   Draft Amendments on the Biotoxins Limit in Fish and Fish Products     IN5095   F  | <u>IN5132</u> | GOI Releases Health Certificate for Bovine Frozen Semen Imports |
|--|---------------|---|
| IN5122   WTO Notified Draft Standards for Metal Contaminants     IN5121   WTO Notified Draft Standards for Metal Contaminants     IN5120   WTO Notified – Microbiological Standards for Meta and Meat Products     IN5119   WTO Notified – Microbiological Standards for Milk and Milk Products     IN5111   Amendments in Regulations Relating to Phytosterols     IN5111   FSSAI Scraps Food Product Approval Following Supreme Court Ruling     IN5110   India Notifies WTO - Regs on Supplements – Functional-Novel Foods     IN5109   WTO Notified Draft Amendment in Packaging and Labeling Regulations     IN5109   WTO Notified Draft Regulations Relating to Food Additives     IN5101   FSSAI Sets Standards for Chromium Present in Gelatin     IN5102   Printing of FSSAI Logo and License Gets Further Extension     IN5103   WTO Notified Draft Standards for Melamine in Infant and Other Foods     IN5090   New Regulation for Nutraceutical-Functional-Novel Foods etc.     IN5092   FSSAI Updates Standards of Dried Salted and Fishery Products     IN5093   FSSAI Sets Draft Standards for Melamine in Infant and other Foods     IN5094   Draft Amendments on the Declaration of Trans-fat Content Levels     IN5095   FSSAI Sets Draft Standards for Melamine in Infant and other Foods     IN5092   |               | -   |
| INS121     WTO Notified Draft Standards for Biotoxins       INS120     WTO Notified – Microbiological Standards for Meat and Meat Products       INS111     WTO Notified – Microbiological Standards for Milk and Milk Products       INS111     Amendments in Regulations Relating to Phytosterols       INS111     FSSAI Scraps Food Product Approval Following Supreme Court Ruling       INS110     India Notifies WTO - Regs on Supplements – Functional-Novel Foods       INS109     WTO Notified Draft Amendment in Packaging and Labeling Regulations       INS109     WTO Notified Draft Regulations Relating to Food Additives       INS101     FSSAI Sets Standards for Chronium Present in Gelatin       INS101     FSSAI Food Business License Deadline Extended by Six Months       INS100     WTO Notified Draft Standards of Melamine in Infant and Other Foods       INS097     New Regulation for Nutraceutical-Functional-Novel Foods etc.       INS095     FSSAI Updates Standards of Dried Salted and Fishery Products       INS095     FSSAI Sets Draft Standards for Melamine in Infant and other Foods       INS097     Draft Amendments on the Biotoxins Limit in Fish and Fish Products       INS098     Draft Amendments on Product Aprovals       INS092     Draft Amendments in Contaminants Toxins and Residues Regulations  |               | -   |
| INS120     WTO Notified – Microbiological Standards for Meat and Meat Products       INS111     WTO Notified – Microbiological Standards for Milk and Milk Products       INS111     Amendments in Regulations Relating to Phytosterols       Amendments on Trans Fatty Acid Levels       INS111     FSSAI Scraps Food Product Approval Following Supreme Court Ruling       INS100     India Notifies WTO - Regs on Supplements – Functional-Novel Foods       INS101     India Notified Draft Amendment in Packaging and Labeling Regulations       INS102     WTO Notified Draft Amendment in Packaging and Labeling Regulations       INS103     WTO Notified Draft Acgunations Relating to Food Additives       INS104     Printing of FSSAI Logo and License Gets Further Extension       INS105     FSSAI Food Business License Decalline Extended by Six Months       INS100     WTO Notified Draft Standards for Melamine in Infant and Other Foods       INS097     New Regulation for Nutraceutical-Functional-Novel Foods etc.       INS094     Draft Amendments on the Biotoxins Limit in Fish and Fish Products       INS093     FSSAI Sets Draft Standards for Melamine in Infant and other Foods       INS094     Draft Amendments on the Declaration of Trans-fat Content Levels       INS085     More Amendmentin Pood Recal Procedure   |               |   |
| IN5119     WTO Notified – Microbiological Standards for Milk and Milk Products       IN5118     Amendments in Regulations Relating to Phytosterols       IN5111     F8SA1 Scraps Food Product Approval Following Supreme Court Ruling       IN5111     F8SA1 Scraps Food Product Approval Following Supreme Court Ruling       IN5100     India Notifies WTO - Regs on Supplements – Functional-Novel Foods       IN5101     India Notified Draft Regulations Relating to Food Additives       IN5102     WTO Notified Draft Regulations Relating to Food Additives       IN5103     WTO Notified Draft Standards for Melamine in Infant and Other Foods       IN5104     Printing of FSSA1 Logo and License Geats Further Extension       IN5105     FSSA1 Food Business License Deadline Extended by Six Months       IN5006     Draft Regulations Relating to Food Additives       IN5007     New Regulation for Nutraceutical-Functional-Novel Foods etc.       IN5096     Draft Regulations Relating to Food Additives       IN5097     New Regulation and the Biotoxins Limit in Fish and Fish Products       IN5098     Draft Amendments on the Biotoxins Limit in Fish and Fish Products       IN5093     FSSA1 Updates Standards for Melamine in Infant and other Foods       IN5094     Draft Amendments on Contaminants Toxins and Residues Regulations   |               |   |
| IN5118     Amendments in Regulations Relating to Phytosterols       IN5117     Amendments on Trans Fatty Acid Levels       IN5111     FSSAI Scraps Food Product Approval Following Supreme Court Ruling       IN5110     India Notifies WTO - Regs on Supplements – Functional-Novel Foods       IN5109     WTO Notified Draft Amendment in Packaging and Labeling Regulations       IN5107     FSSAI Sets Standards for Chromium Present in Gelatin       IN5101     FSSAI Sets Standards for Chromium Present in Gelatin       IN5101     FSSAI Food Business License Deadline Extended by Six Months       IN5100     WTO Notified Draft Standards for Melamine in Infant and Other Foods       IN5097     New Regulation for Nutraceutical-Functional-Novel Foods etc.       IN5096     Draft Regulations Relating to Food Additives       IN5097     New Regulation for Nutraceutical-Functional-Novel Foods       IN5095     FSSAI Updates Standards of Dried Salted and Fishery Products       IN5095     FSSAI Updates Standards for Melamine in Infant and other Foods       IN5098     Poraft Amendments on the Declaration of Trans-fat Content Levels       IN5080     Effective date extended for Draft Order on Meat-Poultry Products       IN5082     More Amendments in Contaminants Toxins and Residues Regulations       I   |               | 6   |
| IN5117   Amendments on Trans Fatty Acid Levels     IN5111   FSSAI Scraps Food Product Approval Following Supreme Court Ruling     IN5110   India Notifies WTO - Regs on Supplements – Functional-Novel Foods     IN5109   WTO Notified Draft Amendment in Packaging and Labeling Regulations     IN5108   WTO Notified Draft Regulations Relating to Food Additives     IN5107   FSSAI Sets Standards for Chromium Present in Gelatin     IN5101   FSSAI Food Business License Deadline Extended by Six Months     IN5100   WTO Notified Draft Standards for Melamine in Infant and Other Foods     IN5097   New Regulations Relating to Food Additives     IN5096   Draft Regulations Relating to Food Additives     IN5097   New Regulations Relating to Food Additives     IN5096   Draft Amendments on the Biotoxins Limit in Fish and Fishery Products     IN5092   Draft Amendments on the Declaration of Trans-fat Content Levels     IN5093   FSSAI Sets Draft Standards for Melamine in Infant and other Foods     IN5082   More Amendments in Contaminants Toxins and Residues Regulations     IN5083   WTO Notified Draft Order on Meat-Poultry Products     IN5084   WTO Notified Draft Standards for Food Contaminants     IN5085   WTO Notified Draft Standards for Carboxymethyl Cellulose <td></td> <td>—</td>   |               | —   |
| IN5111     FSSAI Scraps Food Product Approval Following Supreme Court Ruling       IN5110     India Notifies WTO - Regs on Supplements – Functional-Novel Foods       IN5109     WTO Notified – Draft Amendment in Packaging and Labeling Regulations       IN5108     WTO Notified Draft Regulations Relating to Food Additives       IN5107     FSSAI Sets Standards for Chromium Present in Gelatin       IN5101     FSSAI Food Business License Deadline Extended by Six Months       IN5102     WTO Notified Draft Standards for Melamine in Infant and Other Foods       IN5097     New Regulation for Nutraceutical-Functional-Novel Foods etc.       IN5096     Draft Regulations Relating to Food Additives       IN5097     New Regulation for Nutraceutical-Functional-Novel Foods etc.       IN5096     Draft Amendments on the Biotoxins Limit in Fish and Fish Products       IN5093     FSSAI Sets Draft Standards for Melamine in Infant and other Foods       IN5094     Draft Amendments on the Declaration of Trans-fat Content Levels       IN5095     FSSAI Sets Draft Standards for Food Recall Procedure       IN5086     Effective date extended for Draft Order on Meat-Poultry Products       IN5085     More Amendments in Contaminants Toxins and Residues Regulations       IN5074     FSSAI Publishes Guidelines on Product Approvals  |               |   |
| IN5110India Notifies WTO - Regs on Supplements – Functional-Novel FoodsIN5109WTO Notified – Draft Amendment in Packaging and Labeling RegulationsIN5108WTO Notified Draft Regulations Relating to Food AdditivesIN5101FSSAI Sets Standards for Chromium Present in GelatinIN5102Printing of FSSAI Logo and License Gets Further ExtensionIN5103FSSAI Food Business License Deadline Extended by Six MonthsIN5104Printing of FSSAI Logo and License Gets Further ExtensionIN5105FSSAI Food Business License Deadline Extended by Six MonthsIN5006Draft Regulations Relating to Food AdditivesIN5095FSSAI Updates Standards of Dried Salted and Fishery ProductsIN5095FSSAI Standards for Melamine in Infant and Other FoodsIN5095FSSAI Standards for Melamine in Infant and other FoodsIN5096Draft Amendments on the Biotoxins Limit in Fish and Fish ProductsIN5092Draft Amendments on the Declaration of Trans-fat Content LevelsIN5082More Amendments in Contaminants Toxins and Residues RegulationsIN5082WTO Notified Draft Order on Meat-Poultry ProductsIN5075WTO Notified Draft Standards for Food ContaminantsIN5074FSSAI Publishes Oright Standards for Carboxymethyl CelluloseIN5065FSSAI Publishes SOP for Online Food Import Clearance at Indian PortsIN5062Draft Amendments in Contaminants Toxins and Residues RegulationsIN5075WTO Notified Draft Manuals on Sampling Methods and AnalysisIN5065FSSAI Publishes Draft FSS (Food Recall Procedure) Regulations 2015IN5065  |               | •   |
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| IN5034 Draft Amendment on Gluten and Gluten Free Foods   |               |   |
|  | <u>IN5034</u> |   |
| <b>IN5033</b> Draft Amendments on Standards and Labeling Regulations   | <u>1N5033</u> | Draft Amendments on Standards and Labeling Regulations          |

| <u>IN5030</u> | Livestocks and Products Semi-Annual                             |
|---------------|---|
| <u>IN5029</u> | Draft Amendment on Naturally Occurring Toxic Substances         |
| <u>IN5028</u> | Timeline on License and Registration by FBOs gets an Extension  |
| <u>IN5024</u> | Draft Veterinary Certificate for Pork and Pork Products         |
| <u>IN5019</u> | Bovine Germplasm Guidelines for Trade – Revised December 2013   |
| <u>IN5018</u> | FSSAI Guidelines for Export or Re-export of Imported Food Items |
| <u>IN5013</u> | Compliance Date Extended on Packaging and Labeling Regulations  |
| <u>IN5010</u> | Codex India Publishes a Strategic Plan for 2015-19              |

#### APPENDIX IV: CHRONOLOGY OF FSSAI REGULATIONS/NOTIFICATIONS (2015)

- On October 23, 2015, FSSAI published draft Alcoholic Beverages Standards. Domestic stakeholders have been invited to comment on these draft standards. The same draft standards were re-published on October 29, 2015, with comments invited by WTO members (IN5140).
- On October 14, 2015, in order to comply with the July 31, 2015 order from the High Court of India, FSSAI published <u>Draft Guidelines for Making Available Wholesome</u>, <u>Nutritious</u>, <u>Safe and Hygienic Food to School Children in India</u>. To date, FSSAI has provided no comments deadline for the draft guidelines or notified the document to the World Trade Organization (IN5136).
- On August 26, 2015, FSSAI officially announced on its website that it would no longer continue with its product approval process, as per the August 19, 2015 ruling by India's Supreme Court. The Supreme Court's ruling upheld a June 30, 2014, decision by the Bombay High Court which ruled that FSSAI is not legally authorized to unilaterally issue 'advisories'(<u>IN5111</u>).
- FSSAI published <u>new draft regulations</u> for nutritional supplements, nutraceuticals, foods for special diets, foods for special medical purpose, specialty foods that include ingredients based on *Ayurveda, Siddha, Unani* and other traditional Indian health systems, functional foods, and novel foods (See GAIN Report <u>IN5097</u>). Previously there were no specific regulations for nutraceuticals and dietary supplements (<u>IN5110</u>).
- On July 23, 2015, FSSAI published <u>new draft regulations pertaining to health supplements</u>, nutraceuticals, special dietary and medical purpose foods, functional and novel foods. The GOI is seeking comments from the WTO-SPS member countries and the deadline for comments is September 23, 2015(<u>IN5097</u>).
- FSSAI published draft regulations on food recall procedures for all food products (see GAIN Report IN5073). On June 22, 2015, these draft regulations were published on the WTO's website for comment (WTO Notification Number: G/SPS/N/IND/106). The deadline provided for comments is August 21, 2015 (IN5080).
- On May 11, 2015, FSSAI published guidelines on the food product approval system to explain the entire process of product approval. These guidelines have been published with a cover note addressed by the CEO, FSSAI, wherein he emphasizes the stakeholders to fill in the product approval application with due diligence and avoid any unnecessary delays in the approval process. Important highlights include information on (a) vertical and horizontal food standards;

(b) product approvals in respect of proprietary food; (c) the working of product approval system; (d) statistics on product approval; (e) future roadmap and action plan; (f) online food product approval system (FPAS); and (h) new standards and regulations (IN5074).

- On May 29, 2015, FSSAI published Draft Food Safety and Standards (Food Recall Procedure) Regulations, 2015. Although the GOI has still not notified the draft regulation with the WTO, FSSAI will accept suggestions and comments on these draft regulations through August 1, 2015 (<u>IN5073</u>).
- On May 26, 2015, FSSAI published SOPs for online food clearance at Indian ports or entry. Important highlights include information on: (a) prerequisites for imports; (b) information on arrivals of consignment and review of documents; (c) inspection and sampling procedures; (d) laboratory analysis; (e) import clearance for specific purposes, such as diplomatic missions, quality, research, exhibition, and sporting events; and (f) provisional 'no objections certificates' for perishable food items (<u>IN5065</u>).
- On April 9, 2015, FSSAI introduced new procedures for its Food Import Clearance System (FICS). Under the new process, exporters can "self-declare" the category for their respective exports from a prescribed list of "annexures" as a condition for obtaining a provisional 'No-Objection-Certificate' (NOC) from FSSAI. Previously exporters were required to provide a notarized affidavit to obtain an NOC under the FICS (<u>IN5048</u>).
- On January 22, 2015, FSSAI issued guidelines to clarify that imported food items meant for export or re-export shall not be subject to the same Indian regulatory requirements as applicable to food items imported for consumption within the domestic Indian market. Although FSSAI had also issued earlier notification along the same parameters, Indian customs officials did not distinguish between food products, ingredients, and/or food additives destined for re-export versus imported food for domestic consumption. FSSAI has further clarified that these food products for export or re-export will only be required to meet the standards and/or regulatory requirements of the importing countries (IN5018).
- FSSAI published its Strategic Plan of the National Codex Committee (NCC), per the Codex Alimentarius Commission's mandate (CAC) for the period 2015-19 (<u>IN5010</u>).

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

- On November 12, 2015, FSSAI published <u>Food Safety and Standards (Food Products Standards</u> <u>and Food Additives) Amendment Regulations, 2015</u>. The final amendment relates to Table 1 of Appendix A and adds serial number "P" to include the list of food additives used as processing aid in bread and biscuits (cookies) (<u>IN5156</u>).
- On November 12, 2015, FSSAI published <u>Food Safety and Standards (Food Product Standards</u> <u>and Food Additives) Amendment Regulations, 2015</u>, to include pullulan as a food additive. The final amendment is based on public comments received from various stakeholders on the draft regulations published on December 8, 2014 (<u>IN5153</u>).

- On November 20, 2015, FSSAI published Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2015. The final amendment relates to Appendix A and covers the list of food additives used in (i) glazing agents (Table 2), and (ii) cocoa powder, chocolate, sugar boiled confectionary, and chewing gum/bubble gum as lubricants (Table 13) (IN5151).
- On November 20, 2015, FSSAI published <u>Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2015</u>, which establishes standards for artificial sweeteners. The amendment is in final form and is based on public comments received during the public comment period from various stakeholders on the draft regulations published on March 23, 2015 (<u>IN5149</u>).
- On November 20, 2015, FSSAI published <u>Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2015</u>, on the use of lecithin as a food additive in biscuits (cookies). The amendment is in final form and is based on public comments received during the public comment period from various stakeholders on the draft regulations published on February 5, 2015 (<u>IN5147</u>).
- On October 13, 2015, FSSAI re-published <u>Draft Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2015 (FSSR, 2015)</u> relating to the harmonization of standards for food additives for use in certain food categories or individual food items. According to official contacts, domestic stakeholders, including international stakeholders that have offices in India, are only invited to comment on these draft standards. The deadline for comments is December 13, 2015 (IN5138).
- On August 27, 2015, FSSAI published Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2015, and amended the maximum allowable limits of trans fatty acids in fats, oils, and fat emulsions. The amendments are based on feedback received following the public comment period from draft regulations published on November 11, 2014 (IN4114). (NOTE: although the most recent 2015 amendments are listed as officially published on August 4, 2015, there were not actually posted on FSSAI's website until August 27, 2015.) To date, the amended regulations have not been notified to the World Trade Organization (WTO) (IN5117).
- On August 5, 2015, India notified the draft regulations pertaining to standards for food additives as mentioned in GAIN Report IN5096, to WTO for comments (WTO Notification Number: G/SPS/N/IND/108). The deadline to provide comments is October 4, 2015. The implementation date starts with effect from the ensuing January 1 or July 1 of the year, as the case may be, subject to a minimum of 180 days from the date of final notification of the regulations in the Official Gazette (IN5108).
- On July 23, 2015, FSSAI published Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2015 pertaining to standards for food additives. The draft regulations defines the conditions under which food additives may be used in all foods, whether or not they have previously been permitted by the Food Standards and Food Additives Regulations, 2011. The standards have been drafted to harmonize with the global food standards of Codex. The GOI is seeking comments from the WTO-Sanitary Phytosanitary (SPS) member

countries and the deadline for comments is September 23, 2015 (IN5096).

- FSSAI published a draft of the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2015, which updates standards for dried/salted and dried fishery products. To date, these draft regulations have not been notified to the WTO. FSSAI is accepting public comments from interested public stakeholders through September 4, 2015 (IN5095).
- FSSAI published Food Safety and Standards (Food Product Standards and Food Additives) and Amendment Regulations, 2014, and updated its standards for carboxymethyl cellulose, and natural food coloring products. FSSAI also updated its (Packaging and Labeling) Amendment Regulations, 2014, for carboxymethyl cellulose. The GOI notified these changes to WTO, and on April 23, 2015, and the draft regulations were published on WTO website. FSSAI is currently accepting public comments for both the amendments and will continue to accept comments through June 22, 2015 (IN5063).
- FSSAI published Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations to allow the use of lecithin as a food additive in biscuits (cookies). The GOI has notified these changes to WTO, and on April 16, 2015, the draft regulations were published on WTO's website (Notification Number: G/SPS/N/IND/100). FSSAI is currently accepting public comments regarding this amendment through June 15, 2015 (<u>IN5054</u>).
- FSSAI published Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2015, and amended its standards pertaining to steviol glycoside in various food items. The Government of India has notified these changes to WTO, and on April 16, 2015, the draft regulations were published on WTO website. FSSAI is currently accepting public comments regarding this amendment and will continue to accept comments through June 15, 2015 (IN5051).
- FSSAI published the Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2015, and amended standards for (i) infant foods; (ii) cereal and cereal products; and (iii) processed foods. The amendments are based on feedback received following the public comment period from draft regulations published on May 16, 2013 (<u>IN3092</u>). (NOTE: although the amendments are listed as officially published on May 16, 2013, there were not actually posted on FSSAI's website until August 1, 2013.) To date, the most recent 2015 amended regulations have not been notified to WTO (<u>IN5046</u>).
- FSSAI recently published draft regulations to establish maximum limits and labeling requirements for gluten and non-gluten foods. These draft regulations were published on the WTO website for comment (WTO Notification Number: G/SPS/N/IND/97). The deadline for comments is May 12, 2015 (IN5038).
- FSSAI published updated draft regulations regarding limits of isomaltulose, high-fiber dextrin, arachidonic acid (ARA), and docosahexaenoic acid (DHA) in various infant food products. The updated draft also mandatory infant food labeling requirements, as well as mandates that infant food products cannot be sourced from genetically engineered materials. On February 20, 2015,

these draft regulations were published on the WTO website for comment (WTO Notification Number: G/SPS/N/IND/96). The deadline for final comments is April 17, 2015 (<u>IN5037</u>).

- FSSAI published <u>Draft Food Products Standards cum Packaging and Labeling (Amendment)</u> <u>Regulations, 2015</u> to set maximum limits and labeling requirements for gluten and non-gluten foods. To date, these draft regulations have not been notified to the WTO. FSSAI is seeking public comments from interested stakeholders through April 17, 2015 (<u>IN5034</u>).
- FSSAI published <u>Draft Food Product Standards cum Packaging and Labeling (Amendment)</u> <u>Regulations, 2015</u>, relating to limits of isomaltulose, high fiber dextrin, arachidonic acid (ARA) and docosahexaenoic acid (DHA) in various infant food products. The amendment also includes requirements and restrictions relating to the manner of labeling of these food products and a requirement for the source of ingredients to be non-genetically modified. To date, these draft regulations have not been notified to WTO. However, FSSAI is seeking public comments from interested stakeholders through April 6, 2015 (<u>IN5033</u>).

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

- FSSAI published <u>Draft Food Product Standards cum Packaging and Labeling (Amendment)</u> <u>Regulations, 2015</u>, regarding the use of plant sterol (phytosterols) as a food ingredient in yellow fat spreads, milk products, milk based fruit drinks, fermented milk products, cheeses, salad dressings, juices and nectars, edible oils, and baked products such as breads. The amendment further updates requirements and restrictions regarding the labeling of these food products containing plant sterols. To date, these draft regulations have not been notified to the WTO. However, FSSAI will accept public comments from interested stakeholders through October 28, 2015 (IN5118).
- On June 5, 2015, FSSAI amended the Food Safety and Standards (Packaging and Labeling) <u>Regulations, 2011</u>, to update labeling requirements pertaining to declarations of trans-fat contents in packaged food products. On August 10, 2015, India notified this draft regulation (2.2 and 2.4) to the WTO for comments (WTO Notification Number: TBT/N/IND/49). The deadline to provide comments is October 9, 2015 (IN5109).
- On August 11, 2015, FSSAI issued an order to extend the deadline for printing FSSAI logo and license number on food labels to December 31, 2015. The previous deadline was July 1, 2015. The order also reports that FSSAI received representations from various stakeholders, including associations, and businesses seeking such an extension. This most recent extension marks the fourth extension granted by FSSAI (IN5104).
- FSSAI published the draft <u>Food Safety and Standards (Packaging and Labeling) Amendment</u> <u>Regulations, 2015</u>, to update labeling requirements pertaining to declarations of trans-fat content in packaged food products. Although the draft amendment has not been notified to the WTO, FSSAI will accept comments from interested public stakeholders through August 5, 2015 (IN5092).
- On May 14, 2015, the GOI, Department of Consumer Affairs published a notification in the

Indian official gazette, amending the Legal Metrology (packaged commodities) Rules, 2011. Important highlights of the amendment include: (a) Adopting the definition of retail packages as defined by FSSAI; and (b) Allow the use of stickers to include all labeling requirement data on imported food packages. The publication is not yet WTO notified, nor is there any reference to a specific comment period for domestic stakeholders. With the first amendment of 2015, these rules may now be called as Legal Metrology (packaged commodities)(First Amendment) Rules, 2015(IN5076).

- FSSAI published the Food Safety and Standards (Packaging and Labeling) Amendment Regulations, 2015, to include updated requirements and restrictions for nutritional ingredient labels for trehalose, plant stanol ester, and oligofructose in specified food products. The amendments are based on public comments received from various stakeholders on the draft regulations published on May 16, 2013 (<u>IN3104</u>). (NOTE: although the amendments are listed as officially published on May 16, 2013, there were not actually posted on FSSAI's website until September 10, 2013.) To date, the most recent 2015 amended regulations have not been notified to WTO (<u>IN5047</u>).
- On December 17, 2014, FSSAI issued a notification to postpone the enforcement date for additional labeling requirements for pre-packaged food, edible oils, and fats until December 31, 2015. Previously, FSSAI had announced the enforcement date as December 6, 2013. However, this enforcement date was never actually enforced. After a year of no movement or additional clarity, FSSAI announced it would further postpone the date of implementation until December 31, 2015 (IN5013).

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

- On August 6, 2015, FSSAI issued an order extending the deadline to obtain an FBO license to February 4, 2016. The previous deadline was August 4, 2015. The order also reports that the GOI's Ministry of Health and Family Welfare (MOHFW) received broad feedback from various stakeholders, including individuals, associations, and businesses seeking such an extension. This most recent extension marks the sixth consecutive extension granted by FSSAI (IN5101).
- FSSAI extended its deadline requiring all local food service, food processors, food importers, and related establishments covered under Schedule 1 of the Food Safety and Standards (Licensing and Registration) Regulations, 2011 to obtain food business operators' (FBO) licenses. The previous deadline was February 4, 2015, and the recent extension postpones the deadline by an additional six months to August 4, 2015 (IN5028).

#### Amendments to Contaminants, Toxins and Residues Regulations, 2011

• On November 20, 2015, FSSAI published <u>Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2015</u>, to update FSSAI's standards for various food contaminants. The amendment is in final form and is based on public comments received during the public comment period from various stakeholders on the draft regulations published on May 12, 2015 (IN5152).

- On November 12, 2015, FSSAI published Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2015, which primarily cites updated maximum limits for NOTS present in (i) foods containing mushrooms, (ii) alcoholic beverages, (iii) nougat, marzipan or related substitutes, (iv) canned stoned fruits and juices, (v) confectionery foods, (vi) meat and meat products, including poultry and game; (vii) fish and fish products, (viii) soups and sauces, (ix) non-alcoholic beverages, and (x) food containing mace and nutmeg. The amendment is in final form and is based on public comments received during the public comment period from various stakeholders on the draft regulations published on May 12, 2015 (IN5150).
- On November 17, 2015, FSSAI published Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2015, which establishes standards for levels of chromium present in gelatin. The amendment is in final form and is based on public comments received from various stakeholders on the draft regulations published on August 7, 2015 (IN5148).
- On August 27, 2015, FSSAI amended the Food Safety and Standards (Food Products Standards and Additives) Regulations, 2011, and the Food Safety and Standards (Packaging and Labeling) Regulations, 2011, to establish permissible limits and labeling requirements for phytosterol as a food ingredient in certain foods. On September 15, 2015, India notified these draft regulations to the WTO for comment (WTO Notification Number: G/SPS/N/IND/117). The deadline to provide comments is November 14, 2015(IN5123).
- On June 24, 2015, FSSAI amended the <u>Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011</u>, which included the addition of a new draft regulation (Regulation 2.1) which establishes permissible limits for metal contaminants, including lead, arsenic, tin, cadmium, chromium, and mercury in various food product categories. On September 8, 2015, India notified this draft regulation to the WTO for comment (WTO Notification Number: G/SPS/N/IND/112). The deadline to provide comments is November 7, 2015 (IN5122).
- On July 7, 2015, FSSAI amended the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011, which included the addition of new draft regulations (Regulations 2.2 and 2.3) to establish permissible limits for biotoxins in fish and fish products. On September 9, 2015, India notified these draft regulations to the WTO for comment (WTO Notification Number: G/SPS/N/IND/113). The deadline to provide comments is November 8, 2015 (IN5121).
- On August 7, 2015, FSSAI issued a draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2015. The amendment pertains to Chapter 2 of the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011, and includes the addition of chromium standards present in gelatin (IN5107).
- FSSAI amended the <u>Food Safety and Standards (Contaminants, Toxins and Residues)</u> <u>Regulations, 2011</u>, which included the addition of a new draft regulation (regulation 2.4) that sets maximum levels for melamine in infant and other foods (see GAIN Report IN5093). On August 4, 2015, India notified this draft regulation (regulation 2.4) to WTO (WTO Notification Number: G/SPS/N/IND/107). The deadline to provide comments is October 3, 2015 (<u>IN5100</u>).

- FSSAI published draft <u>Food Safety and Standards (Contaminants, Toxins and Residues)</u> <u>Amendment Regulations, 2015</u>, which primarily focuses on biotoxins limits in fish and fish products. To date, these draft regulations have not been notified WTO. However, FSSAI is accepting public comments from interested public stakeholders through September 4, 2015 (<u>IN5094</u>).
- On July 7, 2015, FSSAI issued a draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2015. The amendment pertains to Chapter 2 of the Food <u>Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011</u> and includes the insertion of regulation 2.4 to set maximum levels for melamine in infant and other foods (IN5093).
- On June 24, 2015, FSSAI published draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2015, to set permissible limits for metal contaminants such as lead, arsenic, tin, cadmium, chromium and mercury in various food product categories. The categories include fruits, vegetables, assorted and canned eatables, cereals, edible oils, packaged drinking water, milk, wine, juices, fish, meat and meat products among others. To date, these draft regulations have not been notified to WTO. However, FSSAI is accepting public comments from interested stakeholders through August 22, 2015 (<u>IN5082</u>).
- On May 12, 2015, FSSAI amended the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011, to update standards for various food contaminants (see GAIN Report IN5062). On June 8, 2015, these draft regulations were published on the WTO's website for comment (WTO Notification Number: G/SPS/N/IND/105). The deadline provided for comments is August 7, 2015 (IN5075).
- On May 12, 2015, FSSAI issued a draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2015, which primarily updates maximum limits for contaminants present in (i) cereals and cereal products; (ii) pulses; (iii) nuts; (iv) oil and oilseeds products; (v) spices; (vi) milk and milk products; and (vii) wheat. To date, these draft regulations have not been notified to WTO. However, FSSAI is accepting public comments from interested stakeholders through June 15, 2015 (<u>IN5062</u>).
- FSSAI published updated draft regulations regarding maximum limits for NOTS in some foods and beverages. On April 16, 2015, these draft regulations were published on the WTO's website for comment (WTO Notification Number: G/SPS/N/IND/101). The deadline provided for comments is June 15, 2015 (IN5053).
- FSSAI recently published <u>Draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2014</u>, which primarily cites updated maximum limits for NOTS. To date, these draft regulations have not been notified to WTO. However, FSSAI is seeking public comments from interested stakeholders through March 18, 2015 (<u>IN5029</u>).

#### Amendments to Laboratory and Sample Analysis Regulations, 2011

FSSAI published draft manuals for its requirements on sampling methods and analysis by laboratories

which pertain to a variety of food and beverage products, including alcoholic beverages, meat and meat products, fish and seafood products, milk and dairy products, cereal and cereal products, sugar and sugar products, and confectionary products, horticultural products, spices and condiments, and oils and fats. Apart from these manuals, FSSAI has also published a draft manual to provide general guidelines on sampling methodologies. Although the GOI has still not notified changes to WTO, FSSAI will accept public comments on these draft manuals through May 25, 2015 (<u>IN5056</u>).

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

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