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Report Highlights:

This report includes updates from multiple government of India authorities responsible for regulating food and agricultural product imports. The major highlights include a new Food Safety and Standards Authority of India (FSSAI) order that allows for the correction of all non-compliant labels on imported food consignments at the port-of-entry, FSSAI's implementation of its mandatory registration of foreign food manufacturing facilities, FSSAI's launch of a new portal, the Food Import Rejection Alert (FIRA), and, the Department of Consumer Affairs, Weights, and Measures Unit's proposal to amend one of their legal metrology rules.

Disclaimer: This report was prepared by the Foreign Agricultural Service's (FAS) Office of Agricultural Affairs (OAA) in New Delhi for U.S. agricultural exporters wishing to export to India. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies is not currently available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped.

FINAL IMPORT APPROVAL OF ANY PRODUCTS IS SUBJECT TO INDIA'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY."

[Note: Use Google Chrome to access the links in case they do not open using Microsoft Edge. Indian host sites geo-block site access on a rolling basis].

TABLE OF CONTENTS

EXECUTIVE SUMMARY	4
SECTION I. FOOD LAWS	5
SECTION II. LABELING REQUIREMENTS	6
SECTION III. PACKAGING AND CONTAINER REGULATIONS	13
SECTION IV. FOOD ADDITIVES REGULATIONS	14
SECTION V. PESTICIDES AND OTHER CONTAMINANTS	14
SECTION VI. OTHER REQUIREMENTS, REGULATIONS, AND REGISTRATION	
MEASURES	15
SECTION VII. OTHER SPECIFIC STANDARDS	16
SECTION VIII. GEOGRAPHICAL INDICATORS, TRADEMARKS, BRAND NAMES	5, AND
INTELLECTUAL PROPERTY RIGHTS	19
SECTION IX. IMPORT PROCEDURES	20
SECTION X. TRADE FACILITATION	22
APPENDIX I. GOVERNMENT REGULATORY KEY CONTACTS	23
APPENDIX II. OTHER IMPORT SPECIALIST TECHNICAL CONTACTS	26
ATTACHMENTS: COMMODITY-SPECIFIC FAIRS REPORTS	

EXECUTIVE SUMMARY

There are multiple authorities within the government of India with responsibilities for overseeing food and agricultural imports into the country. In 2024, India's Food Safety and Standard's Authority (FSSAI) issued various notifications pertaining to new or amended food safety requirements for both domestically produced and imported food products. In addition to highlighting these notifications, this report provides key updates relating to India's implementation of its integrated veterinary health certificate for imports of milk and milk products and the mandatory registration of foreign facilities exporting milk and milk products, meat and meat products, egg powder, infant food, and nutraceuticals to India.

It is difficult to foresee further regulatory actions from FSSAI in the near-term. However, FAS New Delhi has observed this agency over the past few years taking an increased activist role in regulatory changes, implementation, and enforcement. Over time, this could increasingly affect the exports of U.S. agricultural goods into India.

SECTION I. FOOD LAWS

India's food regulatory environment consists of various laws, rules, and regulations across multiple authorities, making enforcement an important yet opaque system. The <u>Food Safety and</u> <u>Standards Act (2006) (2006 Act)</u> is the founding law for food safety and standards. It includes a broad mandate and sets the main objective and goals. It is followed by a set of rules which apply to staff qualifications, service fees, laboratory and sampling protocols and a host of other administrative procedures that are derived from the objectives of the **2006 Act**. Whereas regulations constitute implementing guidelines of the **2006 Act** and provides details for officials at the end-user level to verify and enforce the overall goals.

As the chief food law, **2006 Act** formally repeals and replaces the prior regulatory framework and consolidates the eight prior food acts into one legal mechanism under the **Food Safety and Standards Authority of India (FSSAI)**. The **2006 Act** added provisions to strengthen the implementation of food safety rules.

Rules: The full text of the **Food Safety and Standards (FSS) Rules (2011)** is accessible from the **FSSAI website (English starts on page 36)**. The **FSS Rules** provide helpful context for U.S. food and agricultural exporters. However, they are only applicable to FSSAI, serving as guidelines for its staff.

Regulations: The **Food Safety and Standards Regulations (2011)** are also accessible on the **FSSAI website**. Updates occur periodically, followed by publication in the Official Gazette of India. The regulations govern *inter alia* packaging and labeling, laboratory and sampling analysis, food additives, product standards, licensing, and registration of food businesses, and maximum residue levels of contaminants.

The **FSS Regulations (2011)** stipulate that, "...all food business operators (FBOs), food processors, manufacturers, exporters, or importers shall ensure that the food import meets all the standards under the **FSS Regulations (2011)**." All domestic food operators, including importers, are required to have an FSSAI license to conduct business in India. The FSSAI does not require licensing of foreign companies to export food products to India.

In 2013, FSSAI began harmonizing its regulations with the *Codex Alimentarius* (CODEX), and they are continuing to issue multiple draft amendments on regulations pertaining to food safety.¹

In addition to the **2006 Act**, there is the <u>Legal Metrology Act (2009</u>), which establishes uniform standards of weights and measures for traded goods sold or distributed by weight, measure, or number. Relatedly, there is the <u>Legal Metrology Packaged Commodities Rules (2011</u>), which came into force on April 1, 2011, and prohibits the manufacturing, packing, selling or import of any pre-packaged commodity unless it is in a standardized quantity and carries all prescribed declarations (see, <u>Section 18(1)</u> of the Legal Metrology Packaged Commodities Rules [2011]).

¹ *Codex Alimentarius* (Latin for 'Food Code') is the collection of internationally recognized standards, codes of practice, guidelines, and other recommendations published by the Food and Agriculture Organization (FAO) of the United Nations relating to food, food production, food labeling, and food safety.

The Ministry of Consumer Affairs, Food, and Public Distribution's (MoCAFPD) Department of Consumer Affairs (DoCA) is the regulatory authority for the Legal Metrology Act (2009) and the Legal Metrology Packaged Commodities Rules (2011). The Legal Metrology Act (2009) imposes standardized package size for certain products, mainly as a consumer protection measure.

The Indian government has also established procedures for the import of livestock and related products under the <u>Livestock Importation Act (1898</u>). The Ministry of Fisheries, Animal Husbandry and Dairying's Department of Animal Husbandry and Dairying (DAHD) is responsible for implementing these procedures. In July 2024, the DAHD revised its guidelines for the import of bovine germplasm which is accessible at: <u>Guidelines for Export/Import of Bovine Germplasm - July 2024</u>.

Lastly, the <u>Plant Quarantine (Regulation of Import into India) Order (2003)</u> governs plant import regulations. The **Order**'s objective is "prohibiting and regulating the imports into India of agricultural articles". It took effect January 1, 2004. The implementing agency is the Directorate of Plant Protection, Quarantine, and Storage (DPPQS), under the Ministry of Agriculture and Farmers Welfare.

SECTION II. LABELING REQUIREMENTS

Three Indian authorities regulate the labeling of food and agricultural products—the FSSAI, the Office of Legal Metrology; and the Department of Commerce.

FSSAI's Labeling Requirements: FAS New Delhi strongly encourages U.S. exporters to read the latest Food Safety and Standards (Labeling and Display) Regulations (2020), before designing labels for products for export to India. The regulations cover labeling requirements for pre-packaged foods and the conditions for displaying information such as allergens and calorie information, as well as display prerequisites on premises where food is manufactured, processed, served, and stored. Other relevant GAIN reports relating to India's labeling and display regulations are listed below.

GAIN-INDIA|IN2023-0091|India-The FSSAI Updates Rectifiable Labeling Information for Imported Food Products.

GAIN-INDIA | IN2022-0059 | India's FSSAI Announces Key Updates to Labeling and Display Regulations-Impacting US Tree Nut Products Exports

GAIN-INDIA | IN2022-0085 | India's FSSAI Publishes Draft Notification on Front-of-Pack Labeling for Packaged Food Products High in Fat and Sugar and Salt).

FSSAI's Labeling and Display Regulations (2020) stipulate the following labeling and display requirements:

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

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

B. Labeling Requirements for Pre-packaged Foods: According to the Food Safety and Standards (Packaging) Regulation (2018), "prepackaged" or "pre-packed food" means food that is placed in a package of any nature where the contents cannot be changed without tampering with the package and is ready for sale to the consumer.

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

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

Further Details:

- 1. **Name of Food**: The name of food shall include the trade name or description of food contained in the package.
- 2. List of Ingredients: Except for single ingredient foods, a list of ingredients shall be declared on the label, in descending order of their composition by weight or volume.
- 3. **Nutritional Information**: All nutritional facts per 100 grams or 100 milliliters or per serving of the product shall be given on the label containing:
 - i. Energy value in kilocalorie; and
 - ii. The amount of protein, carbohydrates (specify quantity of sugar), and fat in grams or milliliters; and,
 - iii. The amount of any other nutrient for which a nutritional or health claim is made. [Note: Nutritional information for alcoholic beverages is not required].

4. Declaration Regarding Vegetarian or Non-Vegetarian:

- i. Vegetarian food must have a symbol consisting of a green color-filled circle inside a square with a green outline prominently displayed on the package, contrasting against the background on the principal display panel, near the name or brand name of the food.
- ii. Non-vegetarian food (i.e., 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 triangle inside a square with a brown outline prominently displayed on the package, contrasting against the background on the principal display panel, near the name or brand name of the food. [Note: Declaration of vegetarian/non-vegetarian logo shall not apply for alcoholic beverages].



- 5. Declaration Regarding Food Additives: This declaration shall be made in accordance with aforementioned FSS (Labeling and Display) Regulation (2020).
- 6. Name and Complete Address of the Manufacturer: The label shall carry the name and complete address of the manufacturing, packaging, or bottling unit, as well as the name and complete address of the manufacturer or the company for whom and on whose behalf, it is manufactured, packed, or bottled.
 - i. Where an article of food is imported into India, the package of the food shall also carry the name and complete address of the importer in India.
 - ii. Any food article that is manufactured outside India and packed or bottled in India, shall also bear on the package 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. **The FSSAI Logo and License Number:** The FSSAI logo and license number shall be displayed on the label. Additionally, the license number of the manufacturer or marketer or packer or bottler shall be displayed on the label, if different from the brand owner. Where an article of food is imported into India, the importer shall display the FSSAI logo and license number along with name and address of the importer. The food business operators shall display at all premises where food is stored, processed, distributed, or

sold, the registration/license number or the food safety display board if specified, along with other information as specified by the FSSAI. Lastly, fortified food and organic food shall be marked with a logo as specified in schedule II of the labeling and display regulations.

- 8. Net Quantity, Retail Sale Price, and Consumer Care: The label should specify the net quantity of the product. Retail sale price information should be provided to guide consumers in making purchase decisions. Also, relevant consumer instructions should be incorporated.
- 9. Lot/Code/Batch Identification: A mark of identification by which the food can be traced to the manufacturer and identified in the distribution shall be provided on the label.
- 10. **Date Marking:** The "date of manufacture or packing" and "expiry/use by" shall be given on the label. The expression "Best Before" may be used as optional or additional information. The manner of declaration of date of manufacture or packaging/expiry/use by/Best Before should be in the following format:

Day, month, and year using DD/MM/YY format for products with a short shelf life of up to three months; the month and the year for products with a shelf life of more than three months, shall be declared in un-coded numerical sequence except that the month shall be indicated by capital letter and abbreviations (at least the first three letters of the month) can be used.

Special conditions that impact the validity of the date range for the storage of food should be declared. If required, storage conditions after opening the pack may also be specified.

Declaration of expiry date for consumption shall not be applicable to:

- a. Fresh fruits and vegetables, including potatoes, which have not been peeled, cut, or similarly treated.
- b. All types of wine.
- c. Alcoholic beverages containing 10 percent or more by volume of alcohol.
- d. Vinegar
- e. Sugar boiled confectionery.
- f. Food grade salt for industrial use.
- g. Solid sugars.
- h. Chewing gum and bubble gum.
- 11. **Country of Origin for Imported Food:** The country of origin of imported foods shall be declared on the label. When a food undergoes processing in a second country, changing its nature, the country in which the processing is performed shall be considered the country of origin for the purposes of labeling.

- 12. **Instructions for Use**: If necessary, instructions for use shall be included on the label to ensure correct utilization of the food.
- 13. **Food Allergens:** Food products should have allergen information on their labels to warn people who have food allergies that the food might be contaminated with an allergen.
- 14. **Packaging Material:** All packaged materials sold in retail and not intended for human consumption shall bear a declaration to this effect by a symbol of a black color cross inside a square with black outline having the sides of square not less than the minimum size specified in Table 1 of the regulation.

The symbol is included below for reference. Examples include *Pooja* water (water from a sacred source), oils, clarified butter, and other items used for religious purposes.



15. Other Packaging and Labeling Requirements: India specifies that imported prepackaged 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 (e.g., almonds, apples, grapes, peas, and lentils, etc.) must have an accompanying certificate that specifies the country of origin. However, there is currently no requirement to label imported loose or unbranded products at the retail point of sale.

Raw agricultural commodities, spice mixes, condiments, non-nutritive products (such as soluble tea, coffee, soluble coffee, coffee-chicory mixture, packaged drinking water, and packaged mineral water), alcoholic beverages, fruits, and vegetables, and processed pre-packaged fruits, and vegetables that are comprised of a single ingredient are exempted from nutritional labeling requirements. Original manufacturer's labels on wholesale packages, applied in the country of origin, that fulfill the labeling requirements of the FSSAI's regulations is permissible. However, tampering with labels and pasting/affixing of one label over another is not permissible. 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.

16. Rectifiable and Non-Rectifiable Labeling: All exporters and importers are responsible for ensuring that the food products entering India from the United States are in full compliance with Indian food laws. In the previous Food Safety and Standards (Labeling and Display) Regulations (2020), there were no provisions for labels to be rectified. However, on November 28, 2023, the FSSAI published an order that now allows for the rectification of all non-compliant labels on imported food consignments at the port of entry. This can be accomplished by affixing a single non-detachable sticker or by any other non-detachable methods next to the principal display panel. This process would occur within the confines of an India Central Board of Excise and Customs (Customs) bonded warehouse before the visual inspection, or re-inspection by the FSSAI

authorities. The list of permissible rectification label components, however, excludes: (i) Lot number/Code number/Batch identification, (ii) Date marking ("Date of manufacturing or packaging" and "Expiry /Use by/Best before") and (iii) Country of origin for imported foods. These labeling components cannot be changed, altered, modified, or rectified and should be on the label of the imported food product when it arrives at the Indian port (see, <u>GAIN-INDIA|IN2023-0091|India-The FSSAI Updates</u> Rectifiable Labeling Information for Imported Food Products).

<u>The Office of Legal Metrology (OLM)'s Labeling Requirements</u>: Per Indian law, FSSAI regulations supersede most OLM food labeling requirements. However, two regulations of the OLM continue to apply:

- 1. **The Retail Sale Price of the Package:** When discounting from the maximum retail price (MRP), a sticker with the revised lower MRP (inclusive of all taxes) may be affixed but the same shall not cover the MRP declaration on the label of the package. [Note: As per the Amendments to the Legal Metrology Rules (2015), pre-packaged food products meant for institutional use do not require the MRP, but a 'Not for Retail Sale' declaration on the label is required].
- 2. If a product contains ingredients from crops that are genetically engineered or genetically modified (GM), the label must include the acronym, "GM" (see, <u>GAIN-INDIA | IN3003 |</u> India-Mandatory GM Labeling on Packaged Food [January 15, 2013]).

[Note: FSSAI stipulates in its recently published <u>draft regulations</u> that "All food products having individual GM ingredients of 1% or more should be labeled as "Contains Genetically Modified Organisms /Ingredients derived from GMO" (see, <u>GAIN-INDIA</u> | <u>IN2021-0138</u> | <u>India's FSSAI Proposes New Regulations for Genetically Modified or Engineered Foods</u>).

The Ministry of Commerce and Industry (MOCI)'s Labeling Requirements: As per Notification Number 44 (RE-2000)/1997-2002 issued by the Ministry of Commerce and Industry/Department of Commerce/Directorate General of Foreign Trade on November 24, 2000, all packaged commodities, including pre-packaged food, imported into India must bear the following declarations:

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

products meant for institutional use do not require the MRP, but a 'Not for Retail Sale' declaration on the label is required].

The full notification is available on the website of Directorate General of Foreign Trade (DGFT).

Shelf Life Requirements: <u>Notification Number 22(RE-2001)/1997-2002 (July 30, 2001)</u>, issued by the MoCI/Department of Commerce, states the following:

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

Other Specific Labeling Requirements

A. **Organic Food Labeling:** The labeling for organic food products should convey full and accurate information about the organic status of the product and comply with the Labeling and Display Regulations (2020), in addition to FSSAI's logo (see, <u>GAIN-INDIA|IN7139|FSSAI</u> <u>Organic Standards Operationalized</u>)

B. **Bioengineered Labeling**: FSSAI stipulates in its proposed draft regulations for genetically engineered foods and food ingredients that "All food products having individual GM ingredients of 1% or more should be labeled as "Contains Genetically Modified Organisms /Ingredients derived from GMO" (see, <u>GAIN-INDIA | IN2021-0138 | India's FSSAI Proposes New</u> Regulations for Genetically Modified or Engineered Foods).

C. **Halal Food Labeling**: In India, there are no specific labeling requirements for imports of halal food products. For all U.S.-origin meat and non-plant-based food products shipped to India, halal certification is strictly voluntary.

D. **Infant Nutrition Food Labeling**: The labeling of food for infant nutrition should comply with the Food Safety and Standards (Labeling and Display) Regulations, 2020 and the specific labeling requirements provided in the <u>Food Safety and Standards (Foods for Infant Nutrition)</u> <u>Regulations, 2020</u>. Interested stakeholders may read through this regulation to get complete details on the labeling requirements for such foods.

E. **Fortified Food Labeling**: Every package of fortified food shall carry the words "fortified with (name of the fortificant)" and the logo specified in Schedule-II of the Food Safety and Standards (Fortification of Foods) Regulation (2018). Beneath the logo, a tag line "Sampoorna Poshan Swasth Jeevan" also needs to be put. For additional details, refer to Food Safety and Standards (Fortification of Foods) Regulation (2018).

F. **Functional Food Labeling:** The label on such foods should specify the purpose, the target consumer group and the physiological or disease conditions which is addressed, recommended

duration of use, and the specific labeling requirements against each type of food item. The label, accompanying leaflet or other labeling and advertisement of each type of food item, referred in the regulations should provide sufficient information on the nature and purpose of the food item along with detailed instructions and precautions for its use, and the format of information provided should be appropriate to the intended consumer. For additional details, refer to Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations (2016).

SECTION III. PACKAGING AND CONTAINER REGULATIONS

On March 19, 2018, the FSS (Packaging) Regulation (2018) was published in the official gazette. The Food Safety and Standards Packaging Regulation (2018), formerly combined with the FSS Labeling Regulation, is now a separate regulation and went into effect on July 1, 2019. The regulation covers the general requirements of packaging material that can be used by the FBOs including the specific requirements for primary food packaging. Plastic materials used in the manufacture of containers for packing or storing of food products must conform to the Indian Standards specifications provided in <u>Schedule III of the regulation (page 7</u>). Products made of recycled plastics, including carry bags, are not authorized for use in the packaging, storing, carrying, or dispensing of food items. A list of suggested packing materials for different product categories is provided in <u>Schedule IV (page 8)</u> of the regulations.

On July 15, 2024, the Department of Consumer Affairs, Weights and Measures Unit published its proposal to amend Rule 3 of the Legal Metrology (Packaged Commodities) Rules, 2011. The amendment, if implemented, would require mandatory declaration of information as specified in the Legal Metrology (Packaged Commodities) Rules 2011, for pre-packaged products over 25 kilograms and sold in retail outlets. Comments from interested parties were considered by the August 30, 2024 deadline. See, <u>GAIN-INDIA|IN2024-0035|Indian Government Amends Rule 3 of Legal Metrology Packaged Commodities Rules.</u>

Packaging Sustainability Measures:

India is actively developing and implementing packaging sustainability measures, with a growing market for sustainable packaging options such as biodegradable plastics, recycled paper, and plant-based materials, driven by increasing consumer demand as well as government initiatives to reduce plastic waste. Guidelines for recycling of plastics are specified in <u>Indian</u> <u>Standard IS 14534:1998 by the Bureau of Indian Standards</u>. Challenges, however, remain regarding waste collection and recycling infrastructure. Some examples of sustainable packaging practices in India include biodegradable packaging, paper-based packaging, plant-based materials such as bamboo and banana leaves for disposable food packaging and reusable packaging.

Additionally, the Legal Metrology Act (2009) imposes standardized package size for certain products, mainly as a consumer protection measure (see, <u>Section III, Packaging and Container</u> <u>Regulations</u>).

SECTION IV. FOOD ADDITIVES REGULATIONS

Information regarding permitted food colorings and preservatives is published in <u>Chapter 3-</u> <u>Substances Added to Food (pages 5-14)</u> of the Compendium of Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011

Any proprietary food or food ingredients, including additives (known as non-specified food as per the FSSAI definition) for which standards have not been specified in any regulation under the Food Safety Act will require prior approval of the food authority before it is imported. The domestic manufacturer or the importer of non-specified food products shall submit the required application, Form-I (pages 5-15), along with listed documents (pages 4-7) and a fee of INR 50,000 (\$587) per application to the Food Safety and Standards Authority.

In case new additives are to be added to the regulation, FSSAI requires the following information:

- (a) Chemical Name and International Numbering System Number
- (b) Purity (Food grade or equivalent)

(c) Acceptable Daily Intake specified by Joint Food and Agriculture Organization/World Health

Organization Expert Committee on Food Additives or any other risk assessment body

- (d) Proposed level of use in food category
- (e) In case of coloring agent provide (color index) color number, where applicable.

FSSAI's permissible list of additives are available at:

<u>https://fssai.gov.in/upload/uploadfiles/files/appendix_a_and_b_revised(30-12-2011).pdf</u>. There is no negative list of food additives on FSSAI's website.

SECTION V. PESTICIDES AND OTHER CONTAMINANTS

The FSSAI establishes the maximum residue limits (MRLs) for pesticides, toxins, and other contaminants (see, Food Safety and Standards (Contaminants, Toxins and Residues) Regulation [2011] Chapter 2, for the complete list of contaminants, toxins, and permissible residue levels). For additional guidance on the new standard operating procedures setting MRLs for pesticides in agricultural commodities and products (mainly milk and milk products, and meat and meat products), see <u>GAIN-INDIA | IN2022-0030 | India's FSSAI Publishes Guidance Document and New Standard Operating Procedures Setting Maximum Residue Limits for Pesticides in Agricultural Commodities and Products.</u>

Banned or restricted pesticides and pesticide formulations that are refused registration or face restricted use in India are listed at: http://ppqs.gov.in/sites/default/files/restricted_and_banned_product_list.docx.

For additional information on approved pesticides and the procedures for registration of new pesticides, see the Central Insecticide Board and Registration Committee website located at: http://ppgs.gov.in/divisions/central-insecticides-board-registration-committee.

SECTION VI. OTHER REQUIREMENTS, REGULATIONS, AND REGISTRATION MEASURES

Novel Foods Product Approval: On September 11, 2017, India implemented its Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations (2017).

The FSSAI identified the following categories of food or food ingredients as "non-specified food and food ingredients" and outlined a new product approval procedure for these categories:

- Novel foods or food containing novel ingredients with the use of novel technology.
- New additives.
- New processing aids including enzymes.
- Articles of food and food ingredients consisting of or isolated from microorganisms.

Non-specified food is defined as "any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the Act." For additional specifics on this regulation, see FSSAI's Frequently Asked Questions published May 6, 2020.

Product Sampling: On February 8, 2023, FSSAI notified on its website the Corrigendum 12014/01/2020-QA (January 19, 2022). This corrigendum modifies the earlier FSSAI Order No. 12014/01/2020-QA (November 3, 2021) referred in <u>GAIN-INDIA | IN2021-0134 | FSSAI</u> <u>Publishes Sample Testing Fees for Domestic and Imported Food Products</u>. FAS New Delhi observes that the revised FSSAI order primarily impacts the testing fees for fruits and vegetable products and cereal and cereal products (see, <u>GAIN-INDIA | IN2023-0017 | India's FSSAI</u> <u>Revises the 2021 Sample Testing Fees for Domestic and Imported Food Products</u>).

For details on the sampling procedures, please refer to the latest <u>Manual for Food Imports</u>. The FSSAI has also <u>published manuals detailing its requirements for testing and lab analysis for the following</u>: 1) oils and fats, 2) fruit and vegetable products, 3) cereal and cereal products, 4) food additives, 5) mycotoxins, 6) spices, herbs and condiments, 7) metals, 8) meat and fish, 9) antibiotic and hormone residues, 10) pesticide residues, 11) water analysis, and 12) alcoholic beverages.

On October 7, 2022, FSSAI published a <u>revised manual for methods of analysis for dairy and</u> <u>dairy food products</u>.

Facility Registration: On October 10, 2022, FSSAI published an order requiring the mandatory registration of all foreign food manufacturing facilities (FFMF) exporting milk and milk products; meat and meat products; egg powder; infant food; and nutraceuticals to India. The order requires the competent authorities of all exporting countries to email FSSAI a list of existing manufacturers exporting the aforementioned food categories to India in FSSAI's mandated format.

The implementation date for this requirement was extended to September 1, 2024, and is currently effective. The order encourages all concerned stakeholders to provide the information required in the FSSAI format to the designated competent authority who will submit the information to the FSSAI. The FSSAI has designated FAS New Delhi as the competent authority

to submit details for U.S. manufacturing food facilities for poultry and poultry products, and egg powder. For other categories of foods products mentioned above, the U.S. Food and Drug Administration (FDA) office is the competent authority to submit details. Any U.S. food establishment interested to export any of these categories of food products may apply to be on a list of establishments eligible for export via the Export Listing Module (ELM). Interested stakeholders may visit the <u>online applications for Export Lists site</u> to access the electronic application system and step-by-step instructions. For any questions about the process, the Export Certification Staff at USFDA may be contacted at: <u>CFSANExportCertification@fda.hhs.gov</u>.

Once FSSAI reviews the submitted information by the designated competent authority, FSSAI registers the facility and generates a unique registration number. Interested stakeholders can check their registration status via the online portal <u>ReFoM</u>.

Miscellaneous Requirements: There is no requirement for U.S. exporters to register products for import into India. Export certification requirements for imports of food products in India are summarized in <u>GAIN-INDIA IN2023-0082 FAIRS Export Certificate Report-Annual 2023</u>

India permits the import of product samples via commercial express mail couriers or parcel post (e.g., FedEx, UPS, and DHL), subject to the DGFT's prior permission (see, <u>Customs Import</u> <u>Export Procedures(pages 9 and 11)</u>. Mail order imports are not permissible. Contact information to arrange sample shipments is found in this report's Appendix I. Once the products enter the Indian domestic market, they are subject to random monitoring at the retail and wholesale levels by the relevant regulatory authorities.

FSSAI's amendments to the <u>Food Safety and Standards (Import) Regulation (2017)</u> mandate that Indian customs officials only clear imported food product if it has a valid shelf life of not less than 60 percent, or three months before expiry, whichever is less, at the time of import. The amendments also include the requirement of the food importers to register with the Directorate General of Foreign Trade. Importers must possess a valid import-export code and create a profile that includes their custom house agents, imported products, list of manufacturers of the imported products, country of origin, source country of the consignment, port of entry, compliance history, and any other parameters required to determine the risk associated with the food product.

In addition, food importers should submit a sanitary certificate from authorized agencies in the exporting country for categories of food specified by FSSAI. These amendments became effective on December 6, 2017 (see, GAIN-INDIA reports: <u>IN7076 | India - Amendments in Food Import Regulations [June 27, 2017]</u>, <u>IN7097 | India - WTO Notified-Amendments in Food Import Regulations [August 4, 2017]</u>, and <u>IN7158 | India-First Amendment of 2017 Food Import Regulations is Operational [December 15, 2017]</u>.

SECTION VII. OTHER SPECIFIC STANDARDS

Biotechnology: Since July 8, 2006, the Indian government's foreign trade policy has specified that all imports containing products of modern biotechnology (biotech) must have prior approval from the Genetic Engineering Appraisal Committee (GEAC). There is also a stipulation

requiring a biotech declaration by the importer at the port of entry. The only genetically engineered (GE) food products authorized for import into India are soybean oil derived from GE soybeans and canola oil derived from GE canola.

Indian regulations stipulate that the GEAC must conduct the biosafety appraisal of all biotech plants, animals, and other biotech organisms, and of products derived from biotech plants and animals or other biotech organisms including food and agricultural products. The **Food Safety and Standards Act (2006)** <u>on page 2</u> also includes specific provisions in its definition of food, as noted below, which empowers FSSAI to regulate GE food products, including processed foods:

According to the Food Safety Act, 2006, "food" means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk)², genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotics or psychotropic substances

Due to the lack of regulations and adequate operational infrastructure to regulate GE products, the FSSAI deferred the approval of GE food products to the GEAC. In August 2017, the Supreme Court of India issued directives to the FSSAI for framing regulations for approval of GE food products. Subsequently, the GEAC has forwarded the applications for approval of processed GE food products to the FSSAI. However, the FSSAI is still reviewing the process of formulating regulations. GE food product approval remains on hold until regulations are framed, approved, and implemented (see, <u>GAIN-INDIA | IN2024-0048 | India - Agricultural Biotechnology Annual – 2024</u>).

Effective March 1, 2021, FSSAI requires a "non-GM" or "GM-Free" certificate for 24 selected crops listed in the **FSSAI Order of August 21, 2020**. Since implementation, FSSAI has issued a series of clarifications that, among other things, confirm the measure is not applicable to processed foods and allow certification from sub-national authorities (see, <u>GAIN-INDIA</u> | IN2021-0042 | India - Requirement of a Certificate of Non-Genetically Modified and GM-Free Status for Apple Consignments - A Workaround Solution and <u>GAIN-INDIA</u> | IN2021-0034 | India - The FSSAI Issues Compliance Clarifications for its Genetically Modified-Free Certificate Order for Imported Food Products).

On November 21, 2022, FSSAI published draft regulations on "Genetically Modified Foods." A similar draft regulation, published in November 2021, was withdrawn (see, <u>GAIN-INDIA</u> | <u>IN2022-0113</u> | <u>India Proposes Draft Regulation for Genetically Modified Food for Second</u>

 $^{^{2}}$ ZK- "primary food" means an article of food, being a produce of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form, resulting from the growing, raising, cultivation, picking, harvesting, collection or catching in the hands of a person other than a farmer or fisherman.

<u>Time</u>). The November 2022 draft addresses: Genetically Modified Organisms (GMO) intended for food use; food ingredients produced from GMOs that contain modified DNA; and food ingredients produced from GMOs that do not contain modified DNA, including ingredients/additives/processing aids derived from GMOs. FSSAI, however, to date has not taken any further steps toward implementation.

India's <u>Department of Commerce Notification No. 44 (RE-2000)/1997-2002 (November 24, 2000)</u>, 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.

Vegan Foods and Plant-Based Meat Substitutes: On June 10, 2022, the FSSAI issued a notification which requires that food imports labeled as "vegan" comply with a clause which specifies that "no vegan food products shall be imported except with a certificate issued by the recognized authorities of the exporting countries in the format as specified by the recognized authority (see, <u>GAIN-INDIA | IN2022-0057 | More Vegan than a Vegan - India's FSSAI Issues</u> Regulation Requiring Vegan Certification for Food Products Imports Labeled as Vegan).

On September 8, 2021, FSSAI proposed its draft **Food Safety and Standards (Vegan Foods) Regulations (2021)**. The draft regulation defines vegan foods as being foods or food ingredients that have not made use of any ingredients, additives, and processing aids of animal origin. These include milk and milk products, fish, poultry, and meat, egg or egg products, honey or honeybee products, materials of insect origin (such as silk, dyes, chitin/chitosan, etc.) or ingredients that are clarified using animal sourced products (e.g., bone char used in sugar bleaching, isinglass (obtained from the dried swim bladders of fish and used for clarifying beer). The proposed FSSAI vegan foods logo is shown below:



In the logo, the green color and the leaf depict that the ingredient/product is of plant origin. The letter 'V' and or text 'VEGAN' identifies the product as being vegan.

The concept of plant-based meats is still nascent in India. However, the growing demand for healthy foods is fueling expansion of these products in India. Opportunities for U.S. exporters exist in both consumer-oriented products, and raw materials to support Indian manufacturers of plant-based meat products (see, <u>GAIN-INDIA | IN2021-0064 | India Emerges as a Burgeoning Market for Plant-based Meat Substitutes</u>).

Halal in India: India interprets halal as a religious claim; the Indian government consequently neither mandates halal certification nor provides a unifying regulatory law. Currently, FSSAI's standard certification is the requirement for consumer edible products. Halal certification, in the form of an internationally recognized certificate, is not necessary to obtain trade permission

either for exports or imports. There are no specific labeling requirements for halal food products imported into India.

On October 1, 2024, the Ministry of Commerce and Industry (MOCI)/Directorate General of Foreign Trade (DGFT) issued **Notification No. 34/2024/25** to amend its export policy for certain meat and meat products. The notification specifies that Indian meat and meat products will be allowed to be exported as halal certified to 15 countries included in the DGFT notification. The 15 countries include Bahrain, Bangladesh, Indonesia, Iran, Iraq, Jordan, Kuwait, Malaysia, Oman, Philippines, Qatar, Saudi-Arabia, Singapore, Turkey, and United Arab Emirates. The implementation date for the amendment started on October 16, 2024. See, <u>GAIN-INDIA | IN2023-0054 | India Halal Market – Update July 2023, GAIN-INDIA | IN2023-0010 | India Halal Market Update - 2023 and GAIN-INDIA | IN2022-0005 | India Halal Overview-2022 to get additional information on the Indian Halal market.</u>

Note: On January 5, 2020, India's Agricultural and Processed Food Products Export Development Authority (APEDA), removed the word 'halal' from its <u>'Red Meat Manual'</u> stating that "the animals are slaughtered according to the requirement of the importing country." Until that point, halal had been an important pre-condition, which an Indian exporter had to meet to export to Muslim countries.

SECTION VIII. GEOGRAPHICAL INDICATORS, TRADEMARKS, BRAND NAMES, AND INTELLECTUAL PROPERTY RIGHTS

The **Indian Copyright Act (1957)** is based on the Bern Convention on Copyrights, to which India is a party. The May 1995 and December 1999 amendments increased protections and introduced stiff mandatory penalties for copyright infringement.

Trademarks: Trademarks are protected under the <u>Trademarks Act (1999)</u> and the <u>Trademarks</u> <u>Rules (2002)</u> (in force since September 2003), which repealed the **Trademark and Merchandise Marks Act (1958)**. The changes introduced by the new act include protection of well-known trademarks, as well as service and collective marks. It also provided an extension of the period of protection from seven to ten years, established an appellate board, and increased penalties for infringement of trademarks. Currently the Indian government's enforcement of intellectual property rights is weak. However, the situation is slowly improving, as the courts and police are becoming more responsive to domestic stakeholders concerns with the effects of piracy.

Foreign firms can register trademarks through a local agent by applying at the <u>Office of the</u> <u>Registrar of Trademarks</u>. The registration process can take between three-to-five years for the trademark to be officially accepted and notified.

Intellectual Property Rights: The Ministry of Finance's Central Board of Excise and Customs (CBEC) issued the **Intellectual Property Rights (Imported Goods) Enforcement Rules** (2007) (see https://cbic.gov.in/entities/cbic-content-mst/NjIwNw%3D%3D) to protect the intellectual property of imported products. Instructions regarding the implementation of the rules

are available on the CBEC website located at: <u>https://cbic.gov.in/entities/cbic-content-mst/NjIwMg%3D%3D</u>.³

Geographical Indicators: The Indian government has put forth multiple initiatives to further develop the economy through the use of promoting geographical indicators. The <u>Geographical</u> <u>Indications of Goods (Registration and Protection) Act, 1999 (GI Act)</u> is the chief law in India that protects geographical indicators (GIs). The GI Act protects the reputation, standing, and distinctive characteristics of products from specific regions in India. It also ensures that consumers can trust the quality and authenticity of products linked to a particular region. A GI registration is valid for 10 years and can be renewed for additional 10-year periods. As of Indian Financial Year 2024, (April-March), India has 643 registered geographical indicators. Basmati rice and Darjeeling tea are the most notable examples.

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 (that is in the case of agricultural commodities), along with supporting documentation such as commercial sales invoices and freight and insurance certificates. The bill of entry is filed with India's Customs via their <u>ICE</u> <u>GATE</u> system, a single window customs interface for facilitating trade.

There is no need to translate the import documents into local Indian languages, as English is an official national language. Consignment inspection occurs prior to clearance. FSSAI stations its <u>authorized officers</u> at six locations: Chennai, Kolkata, Mumbai, Delhi, Cochin, Tuticorin, covering 21 ports-of-entries for ensuring compliance to the provisions of the **Food Safety and Standards Act (2006)** and regulations made thereafter. An importer can clarify technical queries with any of the authorized officers before importing a food consignment.

Procedure for Clearance: In June 2019, FSSAI published its <u>2019 Edition of the Manual for</u> <u>Food Imports</u>, explaining in detail the food import clearance process. Below is a flow chart of the step-by-step import procedures:

³ Indian host sites geo-block access on a rolling basis. This link is often unstable.



Source: FSSAI

U.S. exporters are advised to maintain contact with their agents on import procedures (see, https://gain.fas.usda.gov/Recent GAIN Publications/FSSAI Publishes Manual for Food Imports_New Delhi_India_12-6-2017.pdfGAIN-INDIA | IN9074 | India, 2019 Edition of Food Imports Manual Released [August 8, 2019]).

The <u>Food Import Regulations (2017)</u> define the procedures for product sampling and laboratory analysis. Prior to sampling, the FSSAI port officer ascertains whether the imported food complies with the FSSAI's labeling rules. This is intended to ensure that adequate and accessible information is available to the handler, processor, and the consumer to enable them to handle, store, process and prepare, and display the food products safely. It also facilitates lot or batch traceability and recall, if necessary. If labeling is deficient, the product faces rejection without further inspection or sampling.

Review Process: Any food importer may file an application to review an officer's rejection of a consignment of food products. The review application is sent within 15 working days from the date of receipt of the report of rejection along with the fee (subject to revision). For additional details, see the <u>Food Safety and Standards (Import) Regulation (2017)</u>.

SECTION X. TRADE FACILITATION

India is introducing innovative and efficient use of technology to reduce clearance time for food import consignments, as well as ensure transparency through paperless transactions. However, India does not use the global e-Phyto hub for its exports. It does, however, accept an e-Phyto issued by the exporting country subject to the submission of an original phytosanitary certificate. Food importers need to comply with certain prerequisites to import food products into India from different countries. These include:

- a) A valid FSSAI import license.
- b) A valid importer exporter code (IE code) issued by the Directorate General of Foreign Trade. Importers are required to check the latest Indian Trade Clarification based on Harmonized System of Coding (HS) import policy of the DGFT to see whether their products fall under the free, prohibited, or restricted category and follow the import provisions accordingly. In case food products fall under the restricted category, the importer must obtain a DGFT license, in addition to other product-specific import requirements.
- c) The importing food business operator must submit an approval letter identifying a customs-handling agent (CHA) to the FSSAI authorized officer, if they choose to work through a customs-handling agent.

The FSSAI has developed its online <u>Food Import Clearance System (FICS)</u> for food imports, seamlessly integrated with the Customs <u>ICE-GATE (Indian Customs Electronic</u> <u>Commerce/Electronic Data Interchange (EC/EDI) Gateway</u> under SWIFT (Single Window

Interface for Facilitating Trade).⁴ Selective sampling and testing of food articles based on risk profiling done by the FSSAI occurs at the Customs ICE-GATE.

FSSAI has reinstated its web portal-based pre-arrival document review. This feature allows the importer/CHA to file documentation prior to the arrival of the consignment at the port-of-entry, ensuring that all the specified regulations/standards for various food and food ingredients including food additives comply with the import provisions. While reviewing the documents, the FSSAI officer can seek clarifications from the importer and request additional information.

On September 20, 2024, FSSAI launched a new portal, Food Import Rejection Alerts (FIRA), during the inauguration of its Global Food Regulators Summit. FIRA is a digital system that provides information on food import rejections. It also serves as a database for tracking rejected food products and strengthens FSSAI's risk management system. The portal can be found on the FSSAI website (https://fira.fssai.gov.in/).

Lastly, the <u>Frequently Asked Questions on FICS for Importers</u> covers detailed procedures on FSSAI's food import clearance procedures, including inspection and sampling procedures, fee structure, payment modes and risk management system (RMS). Additional reference information is available on the <u>Manual for Food Import Clearance System</u> and the <u>Food Safety and Standards</u> (Import) Amendment Regulation (2020).

APPENDIX I. GOVERNMENT REGULATORY KEY 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 Help desk toll free number: 1800-112-100 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

⁴ Indian host sites geo-block site access on a rolling basis. Access to sites often require registration.

Website: <u>https://consumeraffairs.nic.in/organisation-and-units/division/legal-metrology/overview</u>

C. Phytosanitary Issues

Department of Agriculture Cooperation and Farmers Welfare Ministry of Agriculture and Farmers Welfare

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

D. Livestock and Products Imports

Department of Animal Husbandry, Dairying and Fisheries Ministry of Agriculture and Farmers Welfare

Joint Secretary Department of Animal Husbandry, Dairying and Fisheries Ministry of Agriculture and Farmers Welfare Krishi Bhawan, New Delhi - 110 001 Phone: (91-11) 23387804 Fax: (91-11) 23386115 E-mail: jsadd@nic.in Website: https://dahd.gov.in/

E. Foreign Trade Notifications

Department of Commerce Ministry of Commerce and Industry

Director General of Foreign Trade Ministry of Commerce and Industry Udyog Bhawan, New Delhi - 110 011 Phone: (91-11)23062777 Fax: (91-11)23061613 E-mail: dgft@nic.in Website: https://www.dgft.gov.in/

F. Registry of Trademarks Department of Commerce

Ministry of Commerce and Industry

Controller General of Patents, Designs and Trademarks 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: Mumbai-patent@nic.in Website: https://ipindia.gov.in/about-us.htm

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: https://www.cbic.gov.in/

H. Pesticide Registration Department of Agriculture Cooperation and Farmers Welfare Ministry of Agriculture and Farmers Welfare

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

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

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

APPENDIX II. OTHER IMPORT SPECIALIST TECHNICAL CONTACTS

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

Senior Technical Advisor Confederation of Indian Industry The Mantosh Sondhi Center 23, Institutional Area, Lodhi Road New Delhi – 110 003 Phone: (91-11) 4577 1000 Fax: (91-11) 2462 6149 Email: info@cii.in Website: www.cii.in

ATTACHMENTS: COMMODITY-SPECIFIC FAIRS REPORTS

 IN2024-0036 More Time for Implementation of Integrated Veterinary Health Certificate for Importing Milk and Milk Products
IN2024-0035 Indian Government Amends Rule 3 of Legal Metrology Packaged Commodities Rules
IN2024-0030 India Extends Timeline for Implementation of Integrated Veterinary Health Certificate for Milk and Milk Products
IN2024-0019 India's FSSAI Extends Effective Implementation Date for Mandatory Registration of Foreign Food Manufacturing Facilities
IN2024-0001 Timeline for Implementation of Integrated Veterinary Health Certificate Gets Another Extension

Attachments:

No Attachments