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Report Highlights:

This report discusses regulatory requirements and standards that must be fulfilled to export food and agricultural products to Ethiopia. Pertinent information on applicable laws, regulations, directives, guidelines, procedures, and key regulatory contact details included. It is recommended that this report be read with the FAIRS Export Certificate Report for a comprehensive understanding of the import regulatory requirements and standards.

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Disclaimer:

This report was prepared by the USDA/ Foreign Agricultural Service, Office of Agricultural Affairs, U.S. Embassy Addis Ababa, Ethiopia, for U.S. exporters of food and agricultural commodities. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies/regulations/directives have changed since its preparation, or because clear and consistent information was not 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, prior to shipment of goods. FINAL IMPORT APPROVAL OF ANY PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Executive Summary:

Ethiopia is one of the largest potential markets among developing countries. Data from the World Bank indicates that the country is the fifth largest economy in <u>Sub-Saharan Africa</u> and second most populous

nation in Africa with <u>estimated population</u> of 115 million people. Prior to the COVID-19 pandemic, Ethiopia exhibited steady economic growth. However, recently economic growth has slowed mainly due to COVID-19 and internal conflicts that dragged the country into a civil war. The ongoing military conflict, burgeoning consumer demand, and unabated supply-side constraints have pushed commodity prices up, especially on food and agricultural products. In recent years, the IMF slashed Ethiopia's real GDP growth rate – the economy is projected to grow at two percent by the end of 2021.

Despite being an agrarian country, Ethiopia is a net importer of food commodities. According to Trade Data Monitor (TDM), Ethiopia imported nearly \$1.8 billion worth of food and agricultural products in Calendar Year 2020 (January to December). USDA/Foreign Agricultural Service data shows that U.S. exports of agricultural and related products to Ethiopia in 2020 reached \$141 million, up by 30 percent over the previous year. This figure comprises both food assistance and commercial exports. The annual commercial export sales are approximately \$20 million. Major U.S. agricultural exports to Ethiopia include wheat, pulses, vegetable oils, dairy products, and coarse grains. Future imports of agro-food products could increase if Ethiopia's economy rebounds from the effects of COVID-19 and civil war. Meanwhile, total U.S. imports of agricultural products from Ethiopia totaled \$153 million in 2020. Leading exports are coffee (unroasted), oilseeds, fresh cut flowers and flower buds, spices, planting seeds, wine, and beer.

The Ethiopian Government (GOE) has recently shown increased emphasis on enhancing Ethiopia's food safety, animal and plant health regulatory system. This effort is being led by the Ethiopian Food and Drug Authority (EFDA) that has a statutory authority to enforce and implement food safety and quality regulations. In addition to food products, EFDA has a mandate to regulate medicine, tobacco, cosmetics, and medical devices. The Ministry of Agriculture (MoA) regulates import-export of plant and plant materials as well as livestock and livestock products. The Ethiopian Standards Agency (ESA) establishes national standards and hosts the Ethiopian Codex Contact Point and WTO Inquiry Point. The Ministry of Trade and Industry (MoTI) regulates mandatory Ethiopian standards for import and export of agricultural goods.

Under the current administration, the Ethiopian government is taking various economic reforms and initiatives that could positively influence the future of Ethiopia's food and agricultural trade system. In this regard, Ethiopia has signed the African Continental Free Trade Area (AfCFTA) agreement and has reinstated negotiations to WTO accession. In January 2021, Ethiopia launched a ten-year economic development plan (2021-2030) to spur economic growth, enhance productivity, and competitiveness. In the agriculture sector, the Ethiopia Government plans to improve the role and participation of the private sector, expand small-to-large-scale irrigation development, improve supply of inputs and finance, enhance the productivity of livestock, and protect the environment and natural resources. It also plans to improve agricultural production methods, reduce post-harvest loss, promote research-based food security systems, and import substitution of major agricultural products. In general, these ongoing reforms and initiatives are expected to pave the way for transparent and predictable trade policies and regulatory systems that would boost international trade.

Section I: General Food Laws

The GOE is undergoing various reforms and economic liberalizations. Over the past few years, the GOE has been in the process of updating and modernizing the country's food safety, animal and plant health regulatory systems. This ongoing and evolving modernization process is in part attributed to the nation's fast-paced, export-oriented economic growth, which has spurred a rising number of retail and wholesale food outlets, restaurants, and food manufacturers, especially in and around the capital city, Addis Ababa. The GOE has subsequently taken steps to regulate these establishments to ensure the food they produce, distribute, or sell comply with food safety and quality requirements.

Another key driver underpinning this modernization effort is the GOE's interest in boosting agricultural exports, like coffee, sesame, and livestock products, to grow the economy and generate much needed foreign exchange. In particular, the GOE recognizes that to export these products abroad the country needs a reliable food safety system in place to meet the demands of foreign buyers mainly in Europe, Asia, and North America. At the same time, the country's economic growth has resulted in increased demand for imported food and agricultural products. The GOE is regulating these imported products to ensure their safety and quality.

Despite this modernization, there are still major capacity-related gaps, including a shortage of qualified technical staff and insufficient laboratory capacity, which in turn limits the country's ability to enforce food safety regulations. The GOE is trying to tackle these issues through awareness creation programs, both inside and outside the government, on the importance of food safety.

Broadly speaking, the country's food safety regulatory system is authorized and mandated in 2019 in the Parliamentary Proclamation of the Ethiopian Food, Medicine and Healthcare Administration and Control Authority – Proclamation No. 661/2009. This legislation provides the legal authorities for the government to consolidate the pre-existing food regulatory system with the aim of better "protecting the public from health risks emerging from unsafe and poor-quality food." In particular, the proclamation authorizes the setting of standards and regulations for locally produced and imported foods, in areas such as production, promotion, storage, packaging and labeling, distribution, and laboratory testing.

In 2010, in a subsequent Parliamentary Proclamation – the Ethiopian Food, Medicine and Healthcare Administration and Control Authority Regulation No. 189/2010 – the Food, Medicine, Healthcare and Control Authority (FMHACA) was established, under the purview of the Ministry of Health, as the competent authority responsible for setting and enforcing food safety standards and regulations. Under this proclamation, food is defined as "any raw, semi-processed or processed substance for commercial purpose or to be served for the public in any way intended for human consumption that includes water and other drinks, chewing gum, supplementary food and any substance, which has been used in the manufacture, preparation or treatment of food."

FMHACA was given further statutory authority to enforce and implement food safety and quality regulations as defined in the Food, Medicine and Healthcare Administration and Control Councils of Ministers Regulation No. 299/2013. This legislation states that food must be wholesome and produced in accordance with the relevant safety and quality requirements. Imported products failing to meet these standards will be returned to the country of origin or destroyed at the point of entry. For example, products that are expired or have deteriorated in quality may be seized and returned or destroyed. In a case where the offending product was detected in post-market surveillance, FMHACA has the authority to pull it from stores' shelves and destroy it. This regulation also provides broadly defined requirements dealing with food storage, handling, and transportation, and prohibits counterfeiting and adulteration.

In 2019, the Ethiopian Food Medicine and Healthcare Administration and Control Authority (FMHACA) carried out organizational restructuring with a new institutional name and a revised mandate. In February 2019, the GOE Council of Ministries issued a new Proclamation (No.1112/2019) authorizing a revised mandate of FMHACA. With the revised structure, FMHACA is renamed as the Ethiopian Food and Drug Authority (EFDA). The EFDA is mandated to regulate only products related to food, medicine, tobacco, cosmetics, and medical devices. The new mandate of EFDA has similarities to the U.S. Food and Drug Administration.

The Plant Health Directorate at the Ministry of Agriculture (MoA) regulates the safety of imported plant and plant products, as authorized in the Plant Quarantine Regulation, Council of Ministers Regulation

No. 4/1992. The definition of 'plants' includes living plants, plant products and seeds. Plants and other related articles must be accompanied by an import permit, a phytosanitary certificate from the competent authority from the country of origin and are subject to quarantine inspection. Shipping containers carrying plants or plant articles must be marked with the following information: contents, origin, address of shipper, supplier, or freight forwarder; name of consignee; and entry point in Ethiopia. In cases where pests are detected in an incoming shipment, MoA may allow the cargo to undergo treatment to destroy or inactivate the pest.

The Livestock Resources branch of the Ministry of Agriculture is responsible for quarantine and livestock disease issues. Imports of livestock, meat and by-products, and genetics require an import permit along with a health certificate from the country of origin. When applying for an import permit, the importer must identify the type of product, country of origin, means of transport, date of arrival, countries transited, and port of entry. Upon arrival, livestock, meat and by-products, as well as genetic materials will be subject to inspection. The Guidelines for Import and Export of Animal Genetic Materials spell out the recommended procedures and requirements in great detail.

The Ethiopian Food and Drug Authority (EFDA) has a <u>Directive</u> to Food Exporters, Importers, and Wholesalers to remind traders of the requirements that must be met to sell and distribute food and beverage products in the local marketplace.

In coordination with EFDA and MoA, the <u>Ethiopian Standards Agency (ESA)</u> develops the national food safety standards, some of which are mandatory while others are voluntary. EFDA and these Ministries enforce the national standards that correspond to their respective jurisdictions.

As part of its standards development process, ESA consults with industry and public stakeholders to take their comments and concerns into account. In fact, ESA publishes the draft national standards online along with an open solicitation for <u>public comments</u>. Given this high degree of transparency, the ESA, from Post's perspective, is a model for the broader GOE in open and inclusive rulemaking.

The Ministry of Trade and Industry (MoTI) is responsible for the establishment and enforcement of the legal metrological system. In coordination with EFDA and MoA, the ministry has the authority to control the quality of imports and to restrict entry of products that do not comply with compulsory Ethiopian standards. MoTI regulates import and export of goods, including certain food items that must comply, where applicable, with ESA Mandatory Standards.

Third-party inspection bodies, which have been approved by MoTI, can certify the subjected products meet the national standard. Pre-certified products will clear arrival inspection without delay, though MoTI reserves the right to conduct random sampling and testing. Uncertified products will be subject to normal inspection procedures at the point of entry.

Summary of Food Regulatory Agencies, Quality Infrastructure Institutes and Responsibilities					
Government	Regulatory				
Ministry	Authority/Agency/Directorate	Key Responsibilities			

Ministry of		EFDA is responsible to ensure:
Health (MoH)	Ethiopian Food and Drug Authority (EFDA)	• Food safety and quality; regulates processed and semi-processed food products.
		• Safety, efficacy, quality, and proper use of
		medicines; and
		• Safety, quality, and performance of medical
		devices.
Ministry of		• Control quality of export and import goods
Trade and	Import and Export Goods Quality Control Directorate	• Regulatory oversight on the importation and
Industry (MoTI)		exportation of goods that do not comply with the
		Ethiopian mandatory standards.
		• Inspection of consignments of plants/other
		regulated articles including import and export of
		plants and plant products and provide import and
	Plant Health Regulatory Directorate	export permits
		• Inspection of required phytosanitary documents
		and issuance of phytosanitary certificates.
		• Fumigation of consignments to meet phytosanitary
		requirements
		• Supervise quarantine treatments including
		fumigation and weed cleaning processes.
Ministry of Agriculture		 Advise and supervise disposal of plant and plant products
(MoA)		• Crop surveillance for pests mainly cereals, fruits, and vegetables
		• Protection of endangered areas – maintenance and
		surveillance of pest-free area(s) with low pest
		prevalence
		• Inspection, approval, and registration of pesticides
		• Food safety risk assessment in different crops
		including pests and pesticide application.
	Animal Health Regulatory Directorate	• Establish a system that ensures access to quality
		veterinary services to improve the prevention and
		timely control of animal diseases.
		• Quarantine on import and export of livestock, fish,
		and their byproducts; prevent communicable
		livestock diseases and the outbreak of migratory
		parasites.
		• Ensure the proper administration and quality

		control of veterinary drugs and feeds as well as veterinary services.
	Veterinary Drug and Feed Administration and Control Authority (VDFACA)	 Responsible for registration and certification of feeds and veterinary drugs that are produced, imported and in use in the country. Setting standards for quality control activities, Marketing surveillance, banning, revoking and suspension of registrations, packaging and labeling, trade, and licensing of veterinary drugs and animal feed.
Ministry of Innovation and Technology	Ethiopian Standards Agency (ESA)	Establishment of national standards.
	Ethiopian Conformity Assessment Enterprise (ECAE)	Provides certification, inspection, and laboratory testing services.
	Ethiopian National Accreditation Office (ENAO)	Provide accreditation services, by formal third- party recognition, the competence of Conformity Assessment Bodies (CABs) to perform specific activities, such as tests, calibrations, certifications, or inspections.
	National Metrology Institute (NMI)	 Responsible for the maintenance of Ethiopian National Measurement Standards and Certified Reference Materials (CRM). Provides calibration, training, and consultancy services in the areas of metrology and scientific equipment.
	National Radiation Prevention Authority (NRPA)	Monitor and control of radiation levels in food, water, etc.
Environment, Forest, and Climate Change Commission	Biosafety Regulatory Directorate	 Prevention and control of environmental contamination. Approval and permit for importation of GM seeds and unprocessed GM crops.

Section II: Labeling Requirements

The Ethiopian Standards Agency (ESA) has Compulsory Ethiopian Standards (CES 73 and CES 197) applicable to labeling of prepackaged food products. These are general standards for all prepackaged

foods intended for human consumption. CES 73 is the most actively used and referenced general standard for labeling of prepackaged food products. While CES 197 is applicable to labeling of foods for special dietary uses. The following sub-section describes these general standards for labeling of prepackaged foods.

CES 73:2013 - General Standard for Pre-Packaged Foods Labeling

This compulsory Ethiopian standard stipulates general principles of good labeling practice, mandatory components of a label, and exempted products. CES 73 defines prepackaged food as "packaged or made up in advance ready for retail sale in a container." The required elements of a label include names of product and ingredients, ingredient statements including quantitative ingredient declarations where applicable, weight declarations, suppliers contact details, country of origin, storage instructions, date and batch coding, prohibitions on misleading information, allergen declarations, and instructions for use.

Required Labeling for Pre-packaged Foods:

In accordance with the Compulsory Ethiopian Standard (CES 73), the following information must be clearly and indelibly marked on the labels of prepackaged foods in either English or Amharic. Exporters should note that packaged foods with a surface area less than 10 cm² may be exempt from having to display some of these labeling elements. Labels found on U.S. food products are commonly accepted.

- Trade name of the food product.
- Common name of the food.
- Nutritional content.
- List of ingredients (except for single ingredient foods) in descending order of weight.
- Description of micronutrients used to enrich foods produced with fortification.
- Labeling, description, or ads of any food supplement must not represent to be used in disease prevention, treatment, or cure, or in any way characterize as a medicine.
- If the product contains any of the following food products or ingredients that may cause allergy, labeling must clearly describe its content:
 - o Breakfast cereals containing grain gluten such as wheat, rye, oats, barley, etc.
 - o Crustacean and their products.
 - o Eggs and by-products.
 - o Fish and fishery products.
 - o Peanuts, soybeans, and their products.
 - o Milk and dairy products, including lactose.
 - Nuts and derived products.
 - o Sulphites in concentration of 10 milligrams per Kg or higher.
- Net weight or volume of contents.
- Name and address of the manufacturer, packer, distributor, importer, exporter, or vendor.
- Country of origin.

- Production and expiration dates. (Note: Food products must have at least 50 percent of their shelf life remaining when they arrive at customs. Expired food cannot enter the country, nor can it be sold in the marketplace. Certain foods are exempt from carrying expiry dates, including fresh fruits and vegetables, wines, beverages with 10 percent alcoholic content by volume, vinegar, sugar, and candies and chewing gums having sugar contents above 35 percent).
- Product identification number/code identifying producing factory and lot.
- Instructions for use (if needed).

CES 197:2018 - General Standard for Labeling and Claims for Pre-Packaged Foods for Special Dietary Uses

This compulsory Ethiopian standard provides definition of foods for special dietary uses, mandatory components of a label for foods for special dietary uses, and specific prohibition on claims relating to special dietary use if the product concerned does not meet the criteria for these products. Furthermore, the standard has provisions on special requirements relating to retention of desirable properties by means of appropriate storage conditions, and exempted products.

Other Specific Labeling Requirements:

Labeling Requirements for Alcoholic Beverages

- For beverages containing more than 1.2 percent alcohol, the alcohol proof is required on the label.
- Alcoholic beverages having less than 10 percent of alcoholic content shall state product expiry date on its label.
- Alcoholic beverages are required to contain labels showing alcoholic volume and warning that alcohol consumption may cause health problems.
- The label should also contain a warning that women should not drink alcoholic beverages during pregnancy because of the risks of birth defects.

Labeling Requirements for Genetically Modified (GM) Foods

• GM foods must carry the label with the following statement: "genetically modified", "genetically modified organism" or other comparable description.

Labeling Requirements for Foods Treated with Ionizing Radiation

• Irradiated foods must contain the phrase "irradiated" or the internationally accepted food irradiation symbol indicating a food product has been irradiated with ionizing radiation may be placed besides the labeling.

Labeling Requirements for Baby Food Products

1) Labeling requirements of baby food shall be in accordance with the national compulsory General Standards for Pre-packaged Foods Labeling (CES 73).

- 2) Labels shall not discourage breast-feeding in any manner and shall be designed to provide the necessary information about the appropriate use of the product.
- 3) Any product shall not be described or presented on any label or in any labeling in a manner that is false, misleading, or discouraging breast-feeding or is likely to create an erroneous impression regarding its character in any respect.
- 4) Neither the container nor the label shall have pictures of the infants or other pictures or texts, which may idealize the use of the product.
- 5) The terms "humanized", "materialized" or other comparable terms may not be used.
- 6) The immediate container of the product shall be affixed or written on with a label bearing the following particulars in a clearly legible, conspicuous, and indelible manner at least in Amharic or English.
 - a) Name of the product and its identification as "infant formula," "complementary food," or "follow-up formula" or its equivalent.
 - b) The words "IMPORTANT NOTICE" in capital letters and indicated there under, the statement "breast-feeding is the normal and optimal way to feed infants and young children. Breast milk is important for the healthy growth and development of infants and young children. It protects against diarrhea and other illnesses" in characters "no less than one-third the size of the characters in the product name, and in no case less than 2 mm in height."
 - c) A statement of the superiority of breast milk using letters with more than 12 font size.
 - d) A statement that the product should be used only on the advice of a health professional as to the need for its use and the proper method of use.
 - e) Precautions and warnings, where necessary.
 - f) Appropriate instruction for use or preparation.
 - g) Name and full address of the manufacturer, including country of origin.
 - h) List of ingredients.
 - Nutritional information declaring in numerical form the amount of nutrients present in the product per portion of the product as recommended for daily consumption or amount per unit for single use.
 - i) Net content by weight for powdered products or volume for liquid.
 - k) Date of manufacture and expiry, which shall be indented and indicate at least the month and year, which the product is to be consumed, considering climatic and storage conditions.
 - 1) The storage condition, and where appropriate, shelf life of the product before and after opening and its reconstitution.
 - m) Batch or lot number.
 - n) Required professional advice, if necessary.
- 7) A statement "breast milk is the best food for your baby" or a comparable statement regarding the superiority of breast-feeding or breast milk shall be provided.
- 8) All ingredients on the label of the product shall be listed in accordance with the following subarticles:

- a) Source of protein in the product shall be identified and clearly shown on the label.
- b) Except for single ingredient products, a list of ingredients shall be declared on the label.
- c) If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used shall be declared.
- d) Additives such as fillers, artificial colors, sweeteners, flavors, or binders shall be listed by their specific names/ "E numbers" and qualified by words.
- e) "Natural" or "artificial" in descending order in weight or volume.

Labeling Requirements for Baby Food for Infants and Young Children

- 1) A manufacturer or distributor shall not offer for sale or sell baby food for infants and young children if the labeling includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.
- 2) A manufacturer or distributor shall not offer for sale or sell a baby food for infants and young children, unless the labeling indicates in a clear, conspicuous, and easily readable manner, in Amharic or English, the following particulars:
 - a) Instructions for appropriate preparation and use in words and in easily understood graphics.
 - b) The age in numeric figures after which the product is recommended.
 - c) A warning about the health risks of improper use, preparation, or storage and of introducing the product prior to the recommended age; "a minimum font of 3 mm tall letters based on the lower-case letter in bold red color on a white background for packages with less than 200 cm² of available label space and large font in proportion to the size of larger packages."
 - d) "No less than one-third the size of the characters in the product name, and in no case less than 3 mm in height in bold red letters on a white background."
 - e) The list of ingredients and the declaration of nutritional value in accordance with relevant national standards or, in the absence of such standard, with the relevant Codex Standard.
 - f) The required storage conditions both before and after opening, considering climatic conditions.
 - g) The product category (whether infant, follow-up, growing up, complimentary food with age group, etc.).
 - h) Contains the word, "WARNING" and indicated there under, the statement, "before deciding to supplement or replace breast-feeding with this product, seek the advice of a health professional. It is important for your baby's health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup" in characters no less than one-third the size of the characters in the product name, and in no case less than 3 mm in height and in bold red on a white background.
 - i) Preparation instructions for infant or follow-up formula in powdered form stating that:
 - I. Powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation.
 - II. It is necessary for formula to be prepared one feed at a time using water that has been boiled

(to 212 °F or 100 °C) and then added to the powdered infant formula immediately or when the water is at least 158 °F or 70°C, before feeding to the baby, cooled to body temperature. III. Any unused milk must be discarded immediately after every feed.

- i) Includes a feeding chart in the preparation instructions.
- k) In the case of follow-up formula, states that the product shall not be used for infants less than six months old or used as the sole source of nutrition for infants in characters "no less than one-third the size of the characters in the product name, and in no case less than 3mm in height."
- 1) A manufacturer or distributor shall not offer for sale or sell young children formula unless the container or label affixed thereto states that the product shall not be used to feed infants below 12 months or used as the sole source of nutrition for young children" in characters "no less than one-third the size of the characters in the product name, and in no case less than 3mm in height."
- 3) A manufacturer or distributor shall not offer for sale or sell a baby food for infants and young children:
 - o If the labeling contains any health or nutrition claim or any representation that states or suggests that a relationship exists between the product or constitute thereof and health, including the physiological role of a nutrient in growth, development, and normal functions of the body.

Labeling Requirements for Ready-to-Use Therapeutic and Complementary Foods

- Labeling requirements of ready-to-use therapeutic food and complimentary food products should be in accordance with the national compulsory standard CES 73 - General Standards for Prepackaged Foods Labeling. In addition, the following requirements mentioned in subsequent article should also be respected.
- 2) A manufacturer or distributor shall not offer for sale or sell a ready-to-feed therapeutic food or a complementary food product if the container or label affixed thereto contains:
 - a) Any text, image or other representation that suggests the suitability of the product for infants under six months including but not limited to references to development milestones clearly reached before six months, the use of pictures of infants appearing to be younger than six months.
 - b) Any text, image or other representation of the product or is likely to undermine or discourage breast-feeding or create a belief that the product is equivalent or superior to breast milk.
 - i. Any text, image or representation that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared complementary foods.
 - ii. Any recommendation to feed the product in a bottle or otherwise promote the use of bottle feeding.
 - iii. Any endorsement, or anything that may be conveyed or construed as an endorsement by a health professional, an association of health professional or other body; and

- iv. Any element that allows for cross-promotion of any other baby foods for infants and young children.
- 3) In addition to the requirements of sub-article (1), the label of a ready-to-feed therapeutic food or a complementary food product shall include:
 - a) A statement in characters "no less than one-third the size of the characters in the product name, and in no case less than 3 mm in height."
 - b) The importance of exclusive breast-feeding for the first six months and of continued breast-feeding up to two years or beyond.
 - c) The recommended age of introduction that is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
 - d) Instructions for preparation, storage, handling, and use.
 - e) A feeding chart showing the appropriate ration/serving size consistent with guiding principles issued by the World Health Organization (WHO).

Prohibitions Related to Labeling of Skimmed or Condensed Milk

- Labeling requirements for skimmed or condensed milk feeding should be in accordance to the national compulsory standard CES.
- A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless:
 - o The container or label affixed thereto contains the words, "this product should not be used to feed infants" in characters "no less than one-third the size of the characters in the product name, and in no case less than 3 mm in height."

Labeling Requirements for Low-Fat and Standard Milk

- Labeling requirements of law-fat and standard milk should be in accordance to the national compulsory standard CES 73 General Standards for Pre-packaged Foods Labeling.
- A manufacturer or distributor shall not offer for sale or sell low-fat or standard milk in powder or liquid form, unless:
 - o The container or label affixed thereto contains the words, "this product should not be used as an infant's sole source of nourishment" in characters "no less than one-third the size of the characters in the product name, and in no case less than 3 mm in height."

Labeling Requirements for Plant-Based Meat/Dairy Alternatives

The Ethiopian standard for plant-based meat or dairy alternatives has the same labeling requirements as any prepackaged foods. In addition to the general labeling requirements for prepackaged foods, the following specific labeling elements are required:

- For plant-based meat products such as texturized soy proteins (TSP) a clear statement "food for human" on the label.
- For dairy alternatives such as soymilk, the label shall have clear "instruction on disposal of used package."

Required Labeling Elements for Raw Materials for Food Products:

- Name of the raw material
- Ingredient list
- Net content
- Name and address of the producer and/or importer
- Country of origin
- Lot identification
- Expiry date or minimum useful life
- Conditions for product storage

Labeling Requirements for Animal and Animal Genetic Materials:

Ethiopia's labeling requirement for importation of animal genetic materials such as semen, ova and embryo must contain the information below:

- Breed name
- Donor number
- Date of production and batch number
- Additionally, transit package and/or letter must include country of origin, species, producer company, volume per package, storage temperature and means of transportation.

Importation of Animal and Animal Genetics Materials (AAGM) is allowed for specific purposes such as for commercial breeding and production, research and extension. The following conditions shall be met to import AAGM:

- Importations must fulfill the needs of the importer within the national interest.
- Must be certified free of GMOs or living modified organisms (LMOs).
- Labeling and contents of transit package/letters.

For importation of AAGMs, GOE regulatory authority requires that OIE guidelines be strictly adhered to. This includes from labeling, production and processing, health, manpower, transportation, and facility requirements.

Section III: Packaging and Container Regulations

In accordance with the Ethiopian Food and Drug Authority (EFDA) Proclamation No. 1112/2019, it is generally required that "packaging material shall be made out of substances, which are safe and suitable

for their intended use, and the product shall be packed in container which will safeguard its hygienic, safety, quality and food grade." Further, the Proclamation states "no packaging material shall be put into use unless it complies with the international and national safety and quality standards."

Any food product regulated under Proclamation No. 1112/2019 shall be appropriately packed and its packaging material shall not contaminate the product and comply with national standards. The primary packaging of a processed food shall have a label in Amharic or English language. The EFDA proclamation defines *primary packaging* as "the covering, wrapper, or container that has direct contact with the product intended for retail sale."

Individual product standards may also contain additional guidance and/or requirements as it relates to packaging and container requirements. As an example, the standard for canned peaches indicates packing requirements, including lacquer usage inside the can as well as can thickness. Packaging of infant and follow up formula must be made from a non-plastic material. In addition, for approval of packaging material, certification of analysis and specification (contact approval) is required.

Packaging Sustainability Measures:

The Ethiopian Standards Agency (ESA) embraces international standards related to packaging sustainability measures identical with the International Organization for Standardization (ISO). ESA has two specific standards applied to packaging and the environment. These are:

- 1) ES ISO 18606:2015 Packaging and the Environment (Organic Recycling)
- 2) ES ISO 18604:2014 Packaging and the Environment (Material Recycling)

ES ISO 18606:2015: This standard is applicable to organic recycling of used packaging but does not address regulations that exist regarding the recoverability of any residual packaged goods. The standard established the requirements for packaging suitable for organic recycling. The above standard defines organic recycling as the process "through microbial activity, the controlled biological treatment of the bio-degradable components of used packaging, which produces compost, in the case of anaerobic digestion, also methane." In addition, the standard does not consider landfilling and littering as organic recycling.

A packaging is considered as suitable for organic recycling if all the components are suitable for organic recycling. However, individual components of the packaging can be considered recoverable by organic recycling if they meet the requirements of this international standard. Furthermore, the suitability of packing components and packaging material is verified by test methods described in this standard. The standard provides normative descriptions of the maximum concentrations of regulated metals and other substances hazardous to the environment and determination of eco-toxic effects. The standard also contains recommended assessment checklist for meeting the requirements and provides examples of packaging suitable for organic recycling.

ES ISO 18604:2014: This standard specifies the requirements for packaging to be classified as recoverable in the form of material recycling while accommodating the continuing development of both packaging and recovery technologies. The standard also sets out procedures for assessment of meeting the requirements. The standard defines material recycling as "reprocessing, by means of a manufacturing process, of a used packaging material into products, a component incorporated into a product, or a secondary (recycled) raw material, excluding energy recovery and the use of the product as a fuel. The standard has established procedures and criteria for recyclable packaging in the product life cycle steps such as design, production, utilization, sorting by the end-user, and collection. For instance, if a plastic or PET bottle packaging complies with the standards or specifications, then the packaging is considered 100 percent recyclable.

Section IV: Food Additive Regulations

The Ethiopian Food and Drug Authority (EFDA) regulates the use of food additives, which must comply with both international and national food safety standards. Any food additive to be imported into Ethiopia shall be permitted by Codex Alimentarius or the country's standard concerning its use as an input for food processing with its due level.

The revised EFDA Proclamation No.1112/2019 defines "food additive" as any substance prepared in accordance with applicable requirements and added to food to give flavor, impart color, preserve, and enhance its appearance or other related functional purposes. Furthermore, Article 11 of the proclamation states that use of maximum level of a food additive shall be in accordance with the Ethiopian standard issued by the appropriate body.

Individual food and beverage standards, where applicable, reference both permitted and prohibited additives. Generally, food and beverage products covered under the Ethiopian Standards may contain only permitted additives in accordance with *Codex Stan 192*, General Standard for Food Additives. For example, in the case of natural wines, the Ethiopian Standard *ES: 315 2001* specifies list of permitted additives that may be added to fresh grapes, musts, and dry grapes during vinification. The standard also provides list of additives and treatments permitted during vinification and conservation of wines and sweat filtrates. In addition, it contains list of permitted substances and forbidden additives. For instance, tannin can be used for clarification purposes, but coloring substances are prohibited except for oenocyanin or caramel.

As stated on the labeling section, the packing-label of food additives shall contain at least the following particulars:

- 1) The term "food additive" expressed or printed on the label, and
- 2) Instruction about usage, handling, and precaution of the food.

Hard copies of the Ethiopian standards for food additives are available at ESA with payment of nominal administrative fees. Post can assist U.S. companies in obtaining copies of the standards on a case-by-case basis.

Section V: Pesticides and Other Contaminants

Ethiopia accepts the Codex General Standard for Pesticides and Contaminants. Food and Feed products regulated by the Ethiopian standards shall comply with the Codex General Standard for Contaminants and Toxins in Food and Feed (Codex Stan 193).

The revised EFDA Proclamation No.1112/2019, Article 5 stipulates that any food product may not have chemical residue including pesticide, fertilizer, animal medicine, food additive chemical, cleaning chemical, a radioactive substance, and other contaminants above the maximum level issued or adopted by the appropriate organ.

ESA has a general standard for contaminants and toxins in food and feed. This standard, which draws upon the corresponding Codex Standard (193-1995) lays out the 'principles and procedures' to manage and set acceptable tolerances for contaminants and toxins in food and feed. This standard, however, does not identify or list out contaminants and toxins of concern and their corresponding maximum levels. Instead, these are found in standards for individual commodities, where they exist. For instance, soymilk must comply with the maximum metal contaminants (lead and cadmium) and pesticide residue limits specified in Codex Stan 193.

In 2010, the Ethiopian government enacted the <u>Pesticide Registration and Control Proclamation</u>, No. 674/2010. The legislation establishes a mandatory registration system for pesticides, tailored to national needs. The registration process involves the risk-based evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment. The proclamation states, "no person shall import, manufacture or sell a pesticide, which has not been registered under this Act."

The Pesticide Registration and Control Proclamation mandates the Ministry of Agriculture (MoA) Plant Health Regulatory Directorate to:

- Regulate pesticide management, relating to importation, distribution, transportation, storage, retailing, and use.
- Adopt regulations.
- Promote the correct use of pesticides and search for alternatives to chemical pesticides.
- Raise awareness and provide technical support when the need arises, etc.

The Ministry of Agriculture (MoA) regulates and requires all pesticides to be registered prior to use. The registration process requires the applicant to provide efficacy, safety and quality data. Once registered,

the pesticide can be used for up to five years at which time the registration may be renewed. The list of registered pesticides can be found at the <u>Ministry of Agriculture</u> page.

In addition to registration, MoA also is responsible for establishing maximum residue limits (MRLs) and conducting pesticide residue analysis on primary agricultural products. Applicable MRLs as well as limits for other contaminants are listed in the individual product standards. For example, in the case of apples, there are 41 different MRLs, as well as limits for heavy metals (e.g., lead) and microbiological contaminants (e.g., coliform). Imported apples, as well as domestically produced apples, are expected to comply with these requirements. In the event where a national standard does not exist, the GOE will likely defer to the Codex recommendation.

The MoA's <u>Veterinary Drug and Animal Feed Administration and Control Authority</u> is responsible for setting standards related to animal feed and veterinary drugs, including maximum residue limits for veterinary drugs and other related compounds. Like pesticides, veterinary drugs must be tested for safety, efficacy, and quality and registered prior to use. The registration lasts for five years after which time the registration may be renewed. At present, Ethiopia is using Codex as its basis for veterinary drug MRLs.

Section VI: Other Requirements, Regulations, and Registration Measures

Facility Registration: The Ethiopian Food and Drug Authority (EFDA) requires pre-licensing formalities to issue a competency certificate to food manufacturers. According to the revised Food Manufacturing Factories Pre-Licensing Directive, the facility registration requirement applies to local food manufactures to ensure food safety and quality. EFDA classifies local food manufacturers into three different entities. This classification is based on expiry nature of the product, manufacturing process of the product, and end users of the product.

I. Manufacturers of Special Nutritional Purpose Foods:

- 1) Food supplement/dietary supplement/infant formula
- 2) Follow up formula
- 3) Complimentary foods for infants and young children
- 4) Ready to use supplementary foods (such as Plumpy Nut, Plumpy Sup, F-100 and F-75) for acute and moderate malnourished people.
- 5) Special nutritional purpose foods and
- 6) Other manufacturers producing foods of similar nature as above.

II. Manufacturers of High-Risk Food Products for General Purpose:

- 1) Processed animal product
- 2) Processed sea foods
- 3) Processed fruit and vegetable
- 4) Processed nuts

- 5) Therapeutic foods
- 6) Complementary foods (for children three years and older)
- 7) Fortified foods (iodized salt, edible oil, flour, etc.)

III. Manufacturers of Low-Risk Food Products:

- 1) Crackers, snack food and confectionery products
- 2) Edible oils and fats
- 3) Packed water
- 4) Soft drinks
- 5) Beers
- 6) Extruded products and noodles

The Ethiopian Food and Drug Authority (EFDA) also categorizes the following food products as *Notified food products*:

- 1) Hot sauce
- 2) Legume products
- 3) Packed rice products
- 4) Processed seed (corn, wheat, sorghum, barley, oat, etc.) products
- 5) Packed sugar
- 6) Bakery raw materials
- 7) Processed coffee and tea
- 8) Processed spices
- 9) Alcohol (more than 10%) and liquor products
- 10) Vinegars
- 11) Other related food products not mentioned in category I and II above
- 12) Imported food aid products donated by governmental or non-governmental organizations.
- 13) Raw materials used for food production.

Product Registration: EFDA has a mandatory list of food products that must be registered and approved prior to importation for the first time. Infant formula (milk) and food supplements are strictly prohibited from entering the market without prior registration and approval. Details are available in the Infant and Follow-up Formula Exporters Importers and Wholesalers Directive (2016) and Food Supplement Directive (2016).

In addition to infant formula and food supplements, EFDA requires registration for milk and milk products, meat and meat products, poultry products, sea foods, processed vegetables, sliced fruits, nuts and their products, therapeutic foods, cereal based complementary foods, confectioneries, fats and oils, processed fruits, packed water, soft drinks, beer, iodized salt, and noodles.

The required documentations for new registration of imported food products include:

- Application form for registration
- Agency agreement between manufacturer/exporter and local importer
- Certificate of Free Sale (or FDA's 'Certificate to a Foreign Government' for FDA-regulated products)
- Food manufacturing or products registration certificate or approval
- Authenticated copy of Good Manufacturing Practice (GMP), Hazard Analysis Critical Control Point (HACCP), or ISO 22000.2005 certificates. In appropriate circumstances, internationally accepted certification or certificate of quality management system may be accepted in lieu of GMP and HACCP.
- Certificate of lab analysis of sample product for registration from accredited lab
- Documents showing quality and safety of raw materials and food additives used in manufacturing.
- Study evidence for determining shelf life of the product.
- Veterinary certificate attesting free of diseases that can be transmitted from animals to human.
- Product sample
- Technical documents such as:
 - o Formulation, and manufacturing and packaging procedure
 - Data on method of analysis and specification of the finished product
 - o Stability study reports and shelf-life assignment
 - o Packaging and labeling requirements for finished product
 - Quality analysis result

• Other details of the product:

- o Trade name of the food product.
- o Common name of the food.
- Nutrition content.
- o List of ingredients (except for single ingredient foods) in descending order of weight.
- o Made-in country, name and address of the manufacturer or importer
- Production and expiration dates
- Product identification number
- Net weight or volume of contents
- o Description of micronutrients used to enrich foods produced with fortification
- o If the food product contains milk and milk products, fish and shellfish, wheat, barley, peanuts, soybeans, and other food allergenic, its labeling must clearly describe its content.
- o If the food is made of GM ingredients, a supporting information must be provided.
- o Irradiated foods must contain clear information showing that the food is irradiated.
- o Instructions for use (if needed).

Section VII: Other Specific Standards

The Ethiopian Standards Agency (ESA) <u>2021 Standards Catalogue</u> contains a list of voluntary and mandatory standards, ranging from food microbiology to food labeling and from beans to bananas. It is important to note that health, safety aspects, such as maximum residue limits for pesticides or other contaminants that are found in voluntary standards are, in fact, mandatory, and shipments must comply with these requirements. The voluntary aspect of these standards only refers to quality-related issues, such as the grade of the product.

ESA's <u>mandatory standards</u> 'have the force of law' and are 'enforced by laws and administrative regulations.' Food products subject to specific compulsory requirements are fresh and canned fruits and vegetables, coffee (export), alcoholic and non-alcoholic beverages, edible oil, oilseeds, food additives, as well as pre-packaged foods, including baby foods.

ESA has the goal to make the national standards available online. Presently, if you want a copy of a particular standard, you must go to the ESA library, submit a request, and pay a nominal fee to obtain the copy. Alternatively, importers should be able to provide U.S. suppliers with a copy of both the voluntary and compulsory standards. Post can assist U.S. companies in obtaining copies of standards on a case-by-case basis.

Section VIII: Trademarks, Brand Names and Intellectual Property Rights

The Ethiopian Intellectual Property Office (EIPO) oversees intellectual property rights (IPR) issues. Ethiopia is not yet a signatory to a number of major IPR treaties, such as the Paris Convention for the Protection of Industrial Property, the World Intellectual Property Organization (WIPO) Copyright Treaty, the Berne Convention for Literary and Artistic Works, the Madrid System for the International Registration of Marks, or the Patent Cooperation Treaty.

Please refer to recent publication of <u>Country Investment Climate Statement</u> section five on protection of property rights for a complete understanding of IPR situation in Ethiopia. In addition, Ethiopia's property rights laws, rules, regulations, and treaties are available at <u>WIPO</u>.

Section IX: Import Procedures

The following are the general steps for importing a product into the country.

- An importer must apply for an import permit and obtain a letter of credit from an Ethiopian bank for the total value of the imports before an order can be placed.
- Bank approves letter of credit and authorizes release of foreign exchange. (Note: Because of foreign exchange shortages, it can take several months for an importer to receive the requested L/C.)
- Importer pays foreign supplier for goods.
- Customs clearance and inspection by relevant government authority at Port of Djibouti or dry port in Ethiopia. (Note: Customs clearance and inspection can take several weeks.)

The certificates and documents listed below are generally required when shipping food and beverage products to Ethiopia.

- Registration certificate
- Agency agreement
- Original and copy of health certificates for food items excluding alcoholic drinks:
- o Phytosanitary Certificate, if the food item is an unprocessed vegetable, fruit, and cereal.
- o Veterinary Certificate if the food is unprocessed animal and animal product.
- Certificate of conformity, including laboratory analysis, for products with compulsory standards
- Certificate of Origin
- Free sale certificate (or FDA's 'Certificate to a Foreign Government' for FDA-regulated products)
- Packing list
- Customs declaration
- Bill of loading, airway bill or track bill
- Commercial invoice
- Certificate of irradiation, evidencing the amount of remaining in it is not harmful to human consumption if the food is irradiated.

Shipment of grains, oilseeds, fresh fruits, and vegetables require a phytosanitary certificate issued by a competent government authority. Similarly, livestock and livestock products require a veterinary certificate.

As noted in Section I, the Ministry of Trade and Industry has issued a standing notice to importers, informing them that all products must comply with national compulsory standards. Third-party certifiers can provide a written attestation that the shipment in question complies with the relevant Ethiopian standard(s), which will allow the cargo to enter the country without inspection at the point of entry. Uncertified cargoes will be subject to normal inspection procedures.

Please refer to recent edition of <u>Country Commercial Guide</u> for further details of Ethiopia's import procedures, regulations, and other relevant information.

Import of Compound Feed, Feed Ingredients and Additives: Ethiopia's Veterinary Drug and Animal Feed Administration and Control Authority (VDFACA) has a directive to control import of animal feed and related products. This directive is titled as "Feed Processor, Importer, Distributor and Exporter Registration and Certification Directive No. 03/2015." The directive is not available online. The directive requires the following documents to import compound feed, feed ingredients and additives:

- Registration Certificate
- Import Permit
- Sanitary or phytosanitary certificate
- Ingredient composition in order of largest to smallest

- Certificate of Batch Analysis
- Certificate of Good Manufacturing Practice (GMP)
- Certificate indicating that it is free from GMO
- Certificate of freedom from Protein of Ruminant origin

Section X: Trade Facilitation

The Government of Ethiopia with support from the World Bank recently launched an electronic single window platform that will help facilitate trade. This new initiative is part of the government's commitment to improve international trade and ease of doing business in the country. The new electronic single window (eSW) automates trade procedures and replaces the need for physical, manual, and duplicate processes. It also plays a key role in enhancing transparency for trade. The eSW system connects 16 major cross-border regulatory agencies. It enables traders to submit documentation and receive electronic permits relating to import and export through a single window submission, significantly reducing the time and cost to trade. The automated platform will create a paperless environment and eliminate multiple physical inspections and repetitive document submissions, it will reduce clearance time from 44 days to 13 days and eventually to 3 days.

Before launching the electronic single window service, Ethiopia had been using manual procedures that required frequent face-to-face interaction with regulatory agencies. This resulted in high trading costs and delays due to extensive documentary requirements, high levels of physical inspection of imports, and lack of coordination among border agencies.

The electronic single window platform has two major portals:

- 1) *Trader Portal*: The trader submits the trade documents required for customs and border clearance electronically, views the processing procedures and various statistical information, and provides the function to pay the taxes and fees electronically.
- 2) *CBRA Portal*: It provides the function that the person in charge of the authorities to process electronically the verification, inspection and approval of the documents received through the trader portal.

Please visit the <u>Ethiopian customs trade portal</u> for detailed information on taxes, tariffs, and other documentations related to import trade.

Summary of Key Proclamations, Regulations, Directives, and Guidelines

EFDA Food Control Proclamations and Regulation	Download Link
Revised Proclamation of Food, Medicine and Healthcare Administration and Control Authority, Proclamation No. 1112/2019.	Download
Regulation No. 299/2013 of Council of Ministers: Food, Medicine and Healthcare Administration and Control Authority.	<u>Download</u>
Ethiopian Food, Medicines and Health care Administration and Control Authority establishment Council of Ministers Regulation No. 189/2010.	<u>Download</u>
Proclamation No. 661/2009: Food, Medicine and Healthcare Administration and Control Authority.	<u>Download</u>
Pre-Shipment Inspection Scheme Establishment Proclamation (No. 173/1999)	<u>Download</u>
EFDA Food Directives and Guidelines	
Baby Food Control Directive, July 2018	Download
Infant and Follow up Formula Importers, Wholesalers and Exporters Directive, 2016	Download
Food Supplement Directive, March 2016	<u>Download</u>
Administrative Measures and Compliant Handling Directive, October 2012	<u>Download</u>
EFDA Service Fees and Charges, 2015	<u>Download</u>
Animal Health and Import-Export Related Regulations and Guidelines	
IGAD Regional Animal Health Certification Guidelines (ICPALD)	<u>Download</u>
Regulation No. 341/2015: Regulation to Provide for Live Animals Marketing	Download
Regulation No. 272/2012: Provide for the Establishment of Veterinary Drug and Feed Administration Control Authority (VDFACA)	Download
Animal Diseases Prevention and Control, Proclamation No. 267/2002:	<u>Download</u>
Live Animals Marketing, Proclamation No. 819/2014	Download
Plant Health and Related Regulations	
The Plant Quarantine Regulation No. 04/1992	<u>Download</u>
Pesticide Registration and Control, Proclamation No. 674/2010	<u>Download</u>
Guideline to Application for Registration of Plant Protection Products	<u>Download</u>
Ethiopia Biosafety Proclamation (Amendment), No. 896/2015	<u>Download</u>
Ethiopia National Biosafety Advisory Committee Establishment Regulation, No. 411/2017	Download

Attachments: Guidelines for Import & Export of Animal and Genetic Material.pdf

APPENDIX I: Government Regulatory Agency Contacts

Ministry of Trade and Industry (MoTI)

Email: moti@motin.gov.et Tel: +251 115 513 990 Addis Ababa, Ethiopia

Ministry of Agriculture (MoA)

Plant Health Regulatory Directorate

Email: gbekele3@gmail.com

Tel: +251 116 462 311

Livestock Import-Export Quarantine, Inspection, and Certification Directorate Email: wondimagegn.dejene@gmail.com

Tel: +251 116 462 301 Addis Ababa, Ethiopia

The Ethiopian Customs Commission (ECC)

Email: info@yoursite.com Tel: +251 118 505 251 Addis Ababa, Ethiopia

National Bank of Ethiopia (NBE)

Email: nbeinfo@nbe.gov.et Tel: +251 115 517 430 Addis Ababa, Ethiopia

Ethiopian Food and Drug Authority (EFDA)

Email: contactefda@efda.gov.et

Tel: +251 115 524 118 Addis Ababa, Ethiopia

Ethiopian Standards Agency (ESA)

Email: info@ethiostandards.org

Tel: +251 116 460 111 Addis Ababa, Ethiopia

Codex Contact Point for Ethiopia

Ethiopian Standard Agency (ESA) E-mail: codexeth@ethiostandards.org

Tel: + 251 116 460 525 Addis Ababa, Ethiopia

Ethiopian Conformity Assessment Enterprise (ECAE)

Email: info@ecae.com Tel: +251 116 460 569 Addis Ababa, Ethiopia

Ethiopia Environment, Forest, and Climate Change Commission (EFCCC)

Email: efcccethiopia@gmail.com

Tel: +251 111 704 038 Addis Ababa, Ethiopia

Ethiopian Intellectual Property Office (EIPO)

E-mail: info@eipo.gov.et Tel: + 251 115 528 000 Addis Ababa, Ethiopia

APENDIX II: Other Import Specialist Contacts

Third party inspection companies for food and agricultural products falling under the list of Mandatory Ethiopian Standards:

Control Union Certifications Ethiopia

Email: ethiopia@controlunion.com Tel: +251 +251 116 298 330 P.O. Box 7642 Addis Ababa, Ethiopia

SGS - Ethiopia POC
Tel: +251 116 670 477
Bole Sub City, Pecan Bld. 6th Floor,
Room No 602, Gurd Shola
P.O. Box 14498, Code 1000
Addis Ababa, Ethiopia

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